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VA RESEARCH AND NONPROFIT VA RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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VA RESEARCH AND NONPROFIT VA RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS

THURSDAY, SEPTEMBER 19, 2002

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC

The subcommittee met, pursuant to notice, at 11:05 a.m., in room 334, Cannon House Office Building, Hon. Steve Buyer (chairman of the subcommittee) presiding.

Present: Representatives Buyer, Boozman, and Udall.

OPENING STATEMENT OF CHAIRMAN BUYER

Mr. BUYER. The Subcommittee on Oversight and Investigations of the Committee on Veterans' Affairs will come to order.

This is a hearing on VA research dated September 19, 2002. Good morning.

Earlier this year, we held a joint hearing with the Health Subcommittee that revisited our 1999 hearing on the suspension of human subject medical research at the Greater L.A. VA medical facility, and also looked at the accountability of the VA research corporations.

Nothing is more important to the members of this committee than to ensure that our Nation's most vulnerable veterans are protected and not in any way abused by the very system whose mission is to safeguard their well-being.

It's important to know that the research violations uncovered at Los Angeles in 1999 have been fully addressed and corrected. We intend to make sure that such flagrant disregard of the laws and regulations governing "informed consent" never occurs again within the VA system.

I understand that Dr. Roswell, the Under Secretary for health, has requested that the Office of Research Compliance and Assurance provide him with an assessment of VA's human subject research protection accreditation program and the progress being made by the National Committee for Quality Assurance.

We welcome Dr. Mather, here to give us an update on his activities, and will await receipt of his final report before pursuing this issue in greater depth.

This morning's hearing will specifically address two areas of ongoing concern, which include the transfer of the intellectual property rights stemming from VA inventions and discoveries and the

need to strengthen reporting and accountability standards of the VA's 85 research and education foundations.

Today, we will hear from the VA about the establishment of its Technology Transfer Office. The Department of Commerce is here, as well, to comment on VA's efforts and to illustrate how they fit into the larger efforts of the Federal Government as a whole.

One question is, why hasn't the VA capitalized on its many discoveries by initiating its rightful share of patent ownerships? This is a question that I brought up at the last hearing and I look forward to exploring here today.

We need some answers, because the potential loss to the VA could be hundreds of millions of dollars in royalties, a figure that we tried to guesstimate, but hopefully you have something a little more concrete for us here today, not to mention the many millions of dollars in lost revenue that has already been experienced.

At our last hearing, we were told that the VA has become much more aggressive in seeking patent rights for its many medical discoveries, and I look forward to the testimony about your progress, and I thank you in this endeavor.

We also look forward to hearing from GAO and the IG, who will share their findings on the research corporations from field investigations conducted in Boston, San Francisco, Palo Alto, San Diego, Portland, Atlanta, and Indianapolis.

The IG will also comment on the revised responses to questions posed to the VA at the May hearing, which were inadequately answered and were explored even further by Dr. Snyder, of which still we're lacking answers.

Finally, we'll hear from the VA and NIH on the issues of indirect cost allocation with regards to NIH grant research carried out in VA facilities.

I look forward to hearing a lot of good ideas and believe this should be an informative hearing, and I will now yield to Mr. Udall for any opening statement he would like to make.

OPENING STATEMENT OF HON. TOM UDALL

Mr. UDALL. Thank you very much, Chairman Buyer.

I, too, want to thank all of our panel members and guests for their attendance at today's hearing. I personally thank you all, and I also want to thank you on behalf of our ranking member, Ms. Julia Carson, who unfortunately had to return to her home town yesterday because of a family emergency.

I'm sure that we all wish her and her family well, and Mr. Chairman, she asked that her written statement be included in the record.

Mr. BUYER. With no objection, it will be so entered.

[The statement of Hon. Julia Carson appears on p. 29.]

Mr. UDALL. My focus today will be on the indirect cost rate normally associated with some NIH grants but seemingly absent in NIH grants to the VA.

In this regard, we have some unfinished business from the last hearing on this subject held during May of this year. I have reviewed the record and reviewed the research by an independent contractor.

I understand that a meeting between the VA and NIH was promised for determining an appropriate level or level of compensation for indirect costs. I am interested in the progress in this area.

Mr. Chairman, I support your general focus on research corporation accountability. Government not correctly insists that private corporations be held accountable. I believe that even quasi-governmental organizations, such as the VA research corporations, must also be held accountable.

The devil is in the detail, and the question is, to what degree? What is an appropriate level of accountability and oversight for research corporations?

Human subject research, Mr. Chairman, is clearly a vital issue. We benefit when this research is successful, but we must guard against even the possibility of misinformation or reckless research. This is an issue that must always be a front-burner issue with the committee.

In the area of intellectual property rights for VA, there is a tremendous breadth and depth of VA research initiatives. Some initiatives have yielded innovations with profound impact on everyday health care and everyday life.

It is time VA takes the bows for their efforts, and at the same time, they must secure their intellectual property rights. This is especially important and would serve to buttress portions of the undernourished VA budget.

Again, welcome to all, and I look forward to this hearing, and yield back, Mr. Chairman.

Mr. BUYER. Thank you. Mr. Boozman.

Mr. BOOZMAN. I'd just like to thank you for calling the meeting, Mr. Chairman, and really look forward to the panel, and certainly this is a subject that we need to explore further, and again, I just appreciate that we're having the meeting.

Mr. BUYER. Thank you. I call to testify and recognize the first panel.

It is the Honorable Benjamin Wu, the Deputy Under Secretary for Technology at the Department of Commerce.

Also testifying on this panel will be the Honorable Robert Roswell, the Under Secretary for Health of the VA.

I'll ask my colleagues here, because Secretary Wu is under a tight time schedule—what I'd prefer to do here is, if you don't mind, Dr. Roswell, we take testimony from Mr. Wu, if any of my colleagues have any specific questions of you, we'll go ahead and break and do that real quick, and then we'll let you go and then proceed on.

Would that accommodate you?

Mr. WU. Thank you, Mr. Chairman. I appreciate that.

Mr. BUYER. All right. Thank you. You are now recognized for 5 minutes.

STATEMENTS OF HON. BENJAMIN H. WU, DEPUTY UNDER SECRETARY FOR TECHNOLOGY, TECHNOLOGY ADMINISTRATION, DEPARTMENT OF COMMERCE; AND HON. ROBERT H. ROSWELL, UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY: JAMES BURRIS, M.D., ACTING CHIEF RESEARCH AND DEVELOPMENT OFFICER, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; MINDY AISEN, M.D., DIRECTOR OF REHABILITATION RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; AND JOHN H. MATHER, M.D., CHIEF OFFICER, OFFICE OF RESEARCH COMPLIANCE AND ASSURANCE, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF HON. BENJAMIN H. WU

Mr. WU. Thank you. Good morning, Mr. Chairman, Mr. Udall, Mr. Boozman, and members of the subcommittee.

I appreciate the opportunity to appear before you to discuss the Federal Government's initiatives on government research and development and intellectual property rights, especially relating to transfer of government technology to the private sector for commercialization, which we commonly refer to technology transfer.

I commend you for your leadership on this issue and for holding this hearing.

The Department of Commerce, through our Technology Administration, has specific roles and responsibilities in the area of technology transfer. As the agency that represents industry, the department serves as the administration's main focal point for the discussion of technology transfer issues.

The Department of Commerce is pleased to play a significant role in the federal technology transfers, since it is particularly useful to get the full benefit for the public of the billions of dollars spent on research and development by the Federal Government.

By statute, the department coordinates federal technology transfer policies and makes recommendations for its effective implementation.

These coordination responsibilities are done primarily through the department's leadership of the Inter-agency Working Group on Technology Transfer, a group of technology transfer managers from all federal agencies, including the VA.

The Inter-agency Working Group discusses a wide range of agency initiatives and issues related to technology transfer, recommends policies, and also coordinates submission of congressional reports.

In our role as a coordinator and leader of the Inter-agency Working Group, we have crafted administration support for a number of technology transfer-related provisions and legislation, and as the administration considers ways to improve the efficiency and speed of the technology transfer efforts, the Inter-agency Working Group will continue to be a strong asset in organizing consultations with public and private technology transfer coordinators, identifying recommendations, and also prioritizing appropriate administrative or regulatory action.

The technology transfer authorities have been very useful in the science and technology enterprise of our Nation's federal research programs, including the Department of Veterans Affairs medical programs.

The VA deserves commendation for its current efforts and its desire to develop an active and a robust technology transfer program. In February 2000, VA appointed its first director of its technology transfer program and its first patent attorney last year.

Additionally, VA has entered into an arrangement with the National Technology Transfer Center at Wheeling Jesuit University in West Virginia, who we work closely with, also, to assist with its technology transfer program.

These developments, coupled with the April 2001 announcement by Secretary Principi that the VA should also take the lead in aggressively disseminating new discoveries and inventions made at the VA medical research facilities, indicate a new and growing recollection of the importance of technology transfer to the vitality of the department's research activities, so it can be expected that the number of VA inventions, patents, and licenses will substantially increase over time.

This is an obviously positive development, because, as you know from the previous hearings, the landscape of federal research and development is changing. Federal Government funding for R&D, while still very important, is no longer the driver of United States science and technology investment.

The primary drivers of technology investment now increasingly reside in the private sector, and also in the universities, and accordingly, there needs to be greater collaboration between government, industry, and universities for research that will ultimately lead to collaboration, for it is when innovation is commercialized and put into the marketplace that the American public gets the greatest gain for its federally funded research through jobs, through taxes, through royalties, and also in enhanced international competition.

A technology transfer tool, such as cooperative research and development agreements and patent licensing are ways for federally funded innovations to be developed into commercially useful products and processes, and Congress has been a real leader in these efforts.

Congress has helped to lead the way, with the passage of the two most seminal technology transfer laws, in 1980, and that was the Stevenson-Wydler Innovation Act and also the Bayh-Dole Act.

The manner in which the Federal Government works with the private sector in developing and distributing technologies changed in fundamental ways with the passage of these two seminal pieces of legislation.

Mr. Chairman, in my previous life here in the House, I had the pleasure of working for Congresswoman Connie Morella from Maryland, who was a sponsor of the two most recent congressionally enacted technology transfer laws that significantly amended the laws affecting CRADAs, federal patents, and technology licensing.

As a result of these technology transfer laws, the government began to find ways to partner with industry and universities in de-

velopment of technologies that both furthered agency missions and also advanced our Nation's competitiveness and the overall strength of our economy, and as a result, federal technology transfer has helped to develop everyday products such as the global positioning system, the HIV home test kit, stronger and lighter materials for fuel-efficient cars, corn that's more resistant to drought and disease.

These are just a few of the hundreds of examples of technologies that the Federal Government originally held intellectual property to and either licensed out the technology or have collaborated with industry to commercialize.

Through the years, Congress, based on input solicited from industry, attempted to improve and then streamline these technology transfer processes, and for effective commercialization of new innovation or technology, our partners must be given adequate incentives to bring the products to the marketplace for commercialization.

To be appropriately incentivized, industry needs to have sufficient intellectual property rights in a procedure that is as streamlined and impediment-free as possible.

In the limited time that I have remaining, let me take, for example, the Bayh-Dole Act, which has been a subject of discussion within the VA.

The Bayh-Dole Act allows federal agencies to license government-owned, patented, scientific inventions non-exclusively, partially exclusively, or exclusively, depending on which license is determined to be the most effective means for achieving commercialization, and with the success of licensing federal inventions, the Bayh-Dole Act is widely viewed as an effective framework for federal technology transfer.

As a matter of fact, the Association of University Managers, Technology Managers, for fiscal year 2000, indicated that universities earned $1.26 billion in royalties, licenses, introduced at least 347 new commercial products, and 454 new companies were created as a result of this procedure.

The Bayh bill, and all of the technology transfer litigation, has been very effective and utilized in its review by the Department of Veterans Affairs, and there are a few issues in which the Interagency Working Group is looking at in conjunction with the VA and the other agencies relating to employees without compensation, the WOC, the inter-institutional agreements such as the CTAA, which the VA is looking at, as well as dual employees with joint appointments.

So we look forward to working closely with the VA and all the other agencies that make up the Inter-agency Working Group on these and other issues, because, given the importance and benefits of technology transfer, we understand, through the department and within the administration, that the ability of the United States to compete has been strengthened by new paradigms which are being created and fostered under these technology transfer laws in bringing together the universities, government, and the industry, all the three entities that perform research and development in this Nation, and by doing so, we can further our scientific enterprise and make our Nation stronger.

Thank you very much for your time, Mr. Chairman.

[The prepared statement of Mr. Wu appears on p. 30.]

Mr. BUYER. Mr. Wu, I've only been here 10 years, but I voted on a lot of different bills that send a lot of money out there for research, whether it's from agri-science, food safety, just name it, even in the health fields and through NIH. I will continue to be an advocate here for the funding streams to our colleges and universities; I don't have a problem with that.

What's starting to bother me are these major universities and colleges getting this exclusivity with regard to their patent rights and nothing coming back to the VA. I just told Mr. Udall, I haven't seen tuition go down at all.

So what you have are major colleges and universities, they get all excited, too, and they start building buildings and they start doing other things, and this is all pushing the bounds and all, but I want to know this specifically.

What is the Department of Commerce's position on the VA asserting its intellectual property rights to discoveries that it's involved with?

Mr. WU. Well, we believe that the federal agencies should assert their intellectual property rights as they see fit.

However, we need to keep in mind the principles of technology transfer and the need to bring in collaborative partnerships between the three entities if we're, in fact, going to have a new paradigm for effective research and development and scientific discovery in this country.

One of the keys, though, for innovation is making sure that the American public is able to reap the benefits from it, and it can only do so through commercialization.

Commercialization allows for companies to be created, allows for jobs to be created, and allows for new innovations and new discoveries to be put onto the marketplace for distribution, and commercialization is really the goal of technology transfer.

If we allow the Federal Government to hold title, and only the Federal Government, the Federal Government has not had a strong track record, actually it does very poorly, in commercialization. Essentially, these products will then sit on a shelf

Every day in our Nation's 700 federal laboratories we have new innovations, new discoveries being created, and these discoveries are being done to further the agency mission.

For example, DOE does energy work. DOD labs do defense mission-related work. But in these laboratories, we also see great commercial applications that may be directly resulted or a spinoff, and for the Federal Government to just hold title to these inventions, then we're never going to get these products out into the marketplace.

We have companies who are interested in partnering with federal laboratories. We have universities who are able to bring in their breadth of experience, the graduate students who do the work, the research, and also their background.

Mr. BUYER. Mr. Wu, time out. The Federal Government is not interested here in making a cornerstone on the marketplace.

If we're going to be partnering with major universities and corporations for research to help our veterans, we want that to be out in the marketplace. Okay?

Mr. Udall, do you have any questions?

Mr. UDALL. I just want to thank Dr. Wu for his testimony, and I also recognize what a benefit technology transfer is to the private sector in job growth.

I have a national laboratory, and we try to encourage that technology transfer in New Mexico, and it's resulted in many companies starting and building the job base around the lab and in the local community.

So thank you very much for your testimony. I don't have any questions, Mr. Chairman.

Mr. BUYER. I just want to thank you for coming today, and I think the support of the Department of Commerce in the VA's efforts to enforce its patent rights.

Mr. WU. Certainly, Mr. Chairman. Thank you very much for looking at this issue and we, as part of the Inter-agency Working Group, look forward to working with the VA.

They should be commended for recognizing the importance of technology transfer. There are some issues that we want to work with the VA to create harmonization on certain of the agreements and certain policies, but the VA has come out very strong and aggressively, and I think it's sending a message to those who want to work with the VA, and we look forward to working with them.

Mr. BUYER. Dr. Roswell, do you have any comments on Mr. Wu's testimony?

Dr. ROSWELL. No. I'd just like to thank you for being here, and we appreciate your testimony.

Mr. WU. Aren't you nice?

(Laughter.)

Mr. BUYER. Thank you, Dr. Roswell. Thank you, Mr. Secretary.

Mr. WU. Thank you, Mr. Chairman.

Mr. BUYER. Dr. Roswell, you're now recognized for 5 minutes.

STATEMENT OF HON. ROBERT H. ROSWELL

Dr. ROSWELL. Chairman Buyer, Mr. Udall, and members of the committee, thank you for the opportunity to appear before you to discuss various research and development issues today.

The history of VA research is a history of discoveries that have benefited all American citizens for many years.

VA did not claim the ownership rights to new technologies that its research developed, and as a result, VA facilities and laboratories lost the opportunity to benefit financially from those discoveries.

Today, VA does take credit for the work of its researchers. VA's technology transfer program requires that VA assert an ownership interest where appropriate so that VA can build upon its discoveries. Any resulting financial gain is then used on behalf of our veterans.

VA recognizes that its university research affiliates often have an interest in an invention made at a VA facility. Although VA can assert an ownership right in inventions made by its employees, it cannot do so to the exclusion of our university partners.

VA also understands that the Bayh-Dole Act has imposed certain requirements and responsibilities on university research affiliates. VA believes that its own rights, responsibilities, and interests are in no way in conflict with the provisions of Bayh-Dole.

To enhance cooperation between VA and its research affiliates, VA developed a cooperative technology administration agreement. Over 50 percent of our major university partners have executed such an agreement with the VA.

With these agreements, affiliated universities generally take the lead in patenting and commercializing jointly-owned inventions and the revenues of that commercialization are then shared by the university and VA.

In 1988, Congress authorized the creation of VA non-profit research corporations. Public Law 106–117 expanded this authority to allow VA non-profit corporations to support either or both research and education.

VA currently has 85 active non-profit research corporations and educational foundations. They enable VA to optimally spend the funds received from non-VA sources. They are also not subject to VA federal employment regulations or ceilings.

In 2001, non-profits received almost $180 million in donations, grants, and interest for research and education activities. They supported almost 4,700 VA-approved projects, many providing direct benefits to our VA patients.

Non-profits also provide salary support for clinical research personnel who monitor veteran patients enrolled in clinical trials..

Because non-profits have managed funds very efficiently, 90 percent of all non-profit expenditures in 2001 directly supported approved research and education.

Local facility leadership has primary oversight responsibility for the non-profits. The facility director approves all board members and serves on the board, as do other facility officials.

A certified public accountant and an external auditor assists each board of directors in their oversight functions.

We are currently reviewing suggestions that we've found very helpful from VA's own Office of the Inspector General as well as the Government Accounting Office. These recommendations will improve the reporting the oversight activities of non-profits.

At this time, I'm very close to making a decision to create a program office within our research and development office that would provide greater oversight of non-profit corporations, request the use of accrual-based accounting techniques as suggested by our inspector general, and solicit each year the management letters as part of the evaluation done by our auditors of the individual research corporations.

VA is fully committed to protecting participants in clinical trials and other research projects.

During the past 3 years, VA facilities received more than $85 million to support research administrative functions. This year, VA is providing over $30 million per year in administrative support funding and will make up to an additional $10 million in non-recurring funds available over 2 years for Institutional Review Board or IRB-related proposals.

Participants in clinical trials will also benefit from several other initiatives, which I have discussed in my formal statement.

I will mention at this time, however, that the Handbook on Human Subjects Protection is now awaiting final review. It combines the efforts of VA and non-VA experts and has been available on VA's web site throughout its development.

Many of its new requirements are good clinical practices that the field has already begun to adopt.

At the May hearing, I discussed accreditation of VA's human research protection program through the National Committee on Quality Assurance, or NCQA.

To date, 15 facilities have been accredited with conditions, two have received a final result of "not accredited," and two have received preliminary results of "not accredited." Four sites still await final reports.

I have also noted that this first of its kind program had temporarily suspended accreditation reviews in order to conduct quality improvement activities. VA and NCQA both agreed that the standards needed modification to streamline the review process and clarify selected requirements.

NCQA has now released revised standards for public comment on September 5th. The revised standards reflect the Institute of Medicine's recommendations encouraging institutions to involve participants in human research programs.

For the program's second year, NCQA and VA have agreed to coordinate oversight requirements for VA medical centers that use institutional review boards of affiliated academic institutions that may be accredited by another agency, the Association for Accreditation of Human Research Protection Programs, or AAHRPP.

These sites will receive a more limited NCQA survey, and NCQA will use an accreditation decision that combines the results of both the NCQA and AAHRPP surveys.

Mr. Chairman, this concludes my statement. My colleagues at the table, Dr. Mindy Aisen, Dr. James Burris, and Dr. John Mather, will be happy to answer any questions you or members of the subcommittee may have.

[The prepared statement Dr. Roswell appears on p. 40.]

Mr. BUYER. We have a 15-minute and a 5-minute vote, so we'll try to get some of the questions in. We're going to have to come back. I apologize.

In the last 10 years, what would you say are the greatest accomplishments of VA research? What do you think are the top one, two, three?

Dr. ROSWELL. The accomplishments are significant, but going back to the concept of the radioimmunoassay, which is now a routine use in all clinical medicine, a development that received the Nobel Prize——

Mr. BUYER. Which we have no royalties for, right?

Dr. ROSWELL. Excuse me?

Mr. BUYER. Which we have no royalties for?

Dr. ROSWELL. You're correct, Mr. Chairman.

Mr. BUYER. Okay. Give me number two.

Dr. ROSWELL. The Seattle foot is another example, a prosthetic device that allows enhanced mobility of lower extremity amputees.

Magnetic resonance imaging is another example. Cardiac——

Mr. BUYER. On your second one, do we have any royalties?

Dr. ROSWELL. No.

Mr. BUYER. Okay. On your third?

Dr. ROSWELL. No.

Mr. BUYER. What is your third again?

Dr. ROSWELL. I believe I mentioned MRI technology, magnetic resonance imaging.

Mr. BUYER. That's used a lot, isn't it?

Dr. ROSWELL. It is.

Mr. BUYER. Yeah. All right, we don't have that one, either. What's your fourth? Don't hold your head low. That's fine. I won't beat up on you. I think you got the point.

Dr. ROSWELL. The point is well made.

Mr. BUYER. The point is well made.

Since the VA has now begun attaining intellectual property rights, is there any revenue stream as of yet?

Dr. ROSWELL. I'd be happy to get back with you, and Dr. Burris may know that.

I can tell you this, that the commercialization of new intellectual properties is difficult——

Mr. BUYER. Dr. Burris, do you know?

Dr. BURRIS. There has been revenue from one invention at the University of Oklahoma and a second now from Stanford University; so there is a small revenue stream that has commenced.

But, as I'm sure you know, it usually takes 8 to 10 years to really develop a sufficient portfolio of intellectual properties to develop a significant revenue stream.

Mr. BUYER. Okay. I want to ask this question. Because I also sit on the Health Subcommittee of Commerce.

In NIH, you know, they don't like to talk about their research and where they're going and their funding streams, and there's a reason we try to keep that sort of distant from Congress.

Since heart disease is the leading cause of premature permanent disability among Americans, about one in four stroke survivors is permanently disabled, what are VA's research priorities on both heart disease and stroke rehabilitation research?

Dr. ROSWELL. Well, they're significant. Virtually all of VA's research portfolio is directed towards diseases that have a high prevalence or a special predilection for veterans in what we call designated research areas.

In addition to directing our research portfolio to ischemic heart disease or heart attack, stroke, and the rehabilitation, we also have quality enhancement research initiatives (QUERI) which actually focus on how we translate the outcomes of research into improved clinical practice.

These QUERI (Quality Enhancement Research Initiative) processes are part of our health services research component and have been very successful in taking those technologies and addressing them specifically.

We do have a QUERI on ischemic heart disease and a stroke QUERI is planned to begin next year.

Mr. BUYER. In your testimony, you state that over 50 percent of your major university partners have signed cooperative agreements

with the VA. I think that's great progress, but I understand there are some major institutions that are still holding out.

Would you please name the major colleges and universities or institutions that are holding out or not cooperating with the VA?

Dr. ROSWELL. If I may preface that answer by stating that VA has and will continue to assert its intellectual property rights even absent a cooperative technology administration agreement (CTAA).

Mr. BUYER. I'd like you to do this. Would you provide, as of today, the list of major colleges and universities and institutions that have not signed these agreements?

Dr. ROSWELL. Yes, we will. We would be happy to do that.

Mr. BUYER. Thank you. We're going to take a break right now, and we'll go vote, and we'll return.

[Recess.]

Mr. BUYER. The hearing will come back to order.

Where we left off, Dr. Roswell, was the discussion about some major institutions that are still sort of holding out.

I don't know what, necessarily, I mean by holding out. There might be current discussions with some. Some might be somewhat recalcitrant. I don't know.

Will you articulate a little bit better for me and name some of the major universities whom we've had long-standing relationships with, who may not be so interested in these partnering arrangements?

Dr. ROSWELL. Mr. Chairman, we'll provide you after the hearing a complete list, but several of the universities where we have not yet been able to establish a CTAA and would like to because of the size and magnitude of the affiliation would include such notable universities as Yale, Duke, Emory, and the University of Michigan.

Mr. BUYER. When you provide that information, if you could provide to this subcommittee what the funding stream is, what it presently is and what it has been over the last 10 years.

I want to know how much money is going to these universities and why they're not cooperating with us.

(See pp. 93 and 97.)

Dr. ROSWELL. Yes, sir.

Mr. BUYER. Okay? One thing Congress knows how to do is to get attention, and we're going to do that.

At this point, let me yield to Mr. Udall for any questions he may have.

Mr. UDALL. Dr. Roswell, before we discuss research, could we take a moment to discuss the state of VA health care today?

Some 300,000 veterans are currently waiting to receive medical care from the VA. Other veterans are waiting just to enroll.

Do you agree that the VA does not have sufficient resources at this time to provide timely quality health care?

Dr. ROSWELL. Well, certainly with the current open enrollment process, Mr. Udall, we have had a recent demand for care that has exceeded our capacity.

Mr. UDALL. Turning now to research, generally, a wide variety of research projects are conducted at VA facilities.

Does the research also include research programs for, let us say, cancer studies or research on substance abuse?

Dr. ROSWELL. Yes, they do.

Mr. UDALL. Now, I'd like to address at this point the issue of costs associated with research conducted at VA facilities.

Can you briefly explain the various ways research at the VA is funded, beginning with VA-funded research and then including outside funding resources?

Dr. ROSWELL. There are a variety of mechanisms to fund VA research.

Our own VA research appropriation is an intramural program that provides over $370 million a year, the majority of which is directed to VA-sponsored and funded research.

But that only accounts for roughly a third of the total portfolio of research done in VA.

Almost an equal amount of research, close to $400 million a year, is funded through grants from the National Institutes of Health.

In addition to NIH money that's received through VA investigators, there are a variety of other sources, including pharmaceutical companies who are interested in developing new products to market, and we're involved with a variety of private endowments, a variety of other sources of funds that create a total research portfolio in excess of $1 billion a year.

Mr. UDALL. And what percentage is the NIH of that?

Dr. ROSWELL. It's roughly a third of the total portfolio.

Mr. UDALL. Of the 1 billion. Let's talk about outside funding sources.

Research at VA facilities may incur direct expenses associated with a particular research project; is that correct?

Dr. ROSWELL. That is correct.

Mr. UDALL. And direct costs are usually covered by the grant or the contract provisions; is that correct?

Dr. ROSWELL. In a non-VA institution, direct costs would typically be recovered by the institution. In the VA, we actually use dollars to cover those direct costs, which are predominantly faculty salary or staff salary.

Mr. UDALL. Now, there are also indirect costs associated with the project. Our witness on Panel 3, Mr. Kirschenman, is an expert in that area.

Can we assume the VA contracted with him to determine indirect costs VA-wide because the VA was in some way interested in those costs?

Dr. ROSWELL. Absolutely. We're very concerned about the indirect costs associated with research, our indirect costs, if you will, the facilities and administration costs, or F&A costs associated with the VA research.

According to the report you cite, it was slightly over 23 percent of the total cost of the research grant.

Mr. UDALL. And could you tell me why you're so interested in those, the research costs?

Dr. ROSWELL. Well, I think it's important to understand the cost of the research, but as this committee has discussed before, we're also interested, where appropriate, in recovering the indirect costs associated with research.

Mr. UDALL. And those costs also impact your other programs that you're running, don't they?

Dr. ROSWELL. They clearly do. The indirect costs are borne on our medical care appropriation, and to the extent that those indirect costs increase with an increasing research portfolio, it does place a burden on the total budget authority the department has.

Mr. UDALL. Dr. Roswell, are you aware that Public Law 90–30, Section 507, dated June 24, 1967, once required that appropriations to the public health service available for research, training, or demonstration project grants pursuant to the Public Health Service Act shall be available on the same terms and conditions as apply to non-federal institutions for grants to the same purpose federal agencies, including the Veterans Administration?

Dr. ROSWELL. I have read that previously, yes.

Mr. UDALL. The way I read that is, if a grant is good for a non-federal institution, it's also good for a federal institution. Is that the way you read it?

Dr. ROSWELL. I'm not an attorney, but that was my understanding of the law as it was written in 1967.

Mr. UDALL. Did you ever get—are you aware of any attorneys' advice within the department as to that particular issue? Is your understanding from talking with your attorneys?

Dr. ROSWELL. Our General Counsel has advised that there is no legal barrier currently to preclude us to recover indirect costs.

Mr. UDALL. With regard to the language I just mentioned in Public Law 9031, similar language exists today in Title XLII, USC Chapter 60(a), Subchapter 1, Part (b), Section 238, titled "The Availability of Appropriations for Grants to Federal Institution."

It specifies that for some specific research projects, like substance abuse, the public health service shall assure that the same terms and conditions as apply to non-federal institutions also apply to federal institutions.

It also stipulates that grants to federal institutions may be funded at 100 percent of the cost.

Now, since 1989, has NIH provided indirect costs to the VA for NIH research grants?

Dr. ROSWELL. No, they have not.

Mr. UDALL. Do you know if NIH provides indirect costs to any non-federal institution?

Dr. ROSWELL. Well, certainly my assumption is that they do.

Mr. UDALL. Do you know any of those?

Dr. ROSWELL. Non-federal institutions?

Mr. UDALL. Yeah.

Dr. ROSWELL. Well, they're routinely provided to most, or to academic institutions.

Mr. UDALL. And as you've said, it's on a routine basis, so they do this all the time?

Dr. ROSWELL. That's my understanding, yes.

Mr. UDALL. What is the VA doing at this point to try to move this process along in terms of recovering indirect costs?

Dr. ROSWELL. Following the previous hearing before this committee, we actually have had discussions with NIH. We agreed to put together a group and negotiate indirect costs. However, that effort, to date, has not been successful.

We do have a meeting tentatively scheduled for next month to again renew discussions about what mechanism or term might be used to calculate an equitable indirect cost rate for the VA.

Mr. UDALL. Coming to an indirect cost rate isn't that hard, is it, based on this Kirschenman Study and others? I mean, it would be something pretty easy to do, don't you think?

Dr. ROSWELL. Certainly, he's an expert in the field, but he was able to provide us very precise data on indirect costs.

Mr. UDALL. So what's the problem you're running into with the NIH?

Dr. ROSWELL. Well, the position of NIH—and I certainly won't presume to speak for NIH, who I believe will testify later in this hearing.

But their position, as I understand it and based on my discussions with them, is that they don't believe it would be appropriate to fund VA for its full indirect costs, as is provided to other institutions, because VA has an appropriation which, in fact, could bear some of the costs or does bear some of the indirect costs currently associated with VA research.

So what they're asked us for is a mechanism to look at only the incremental costs associated with administering a specific NIH grant.

That type of incremental or marginal cost basis involves accounting principles that we don't routinely employ, and it's created a very onerous challenge for us to try to come up with the kind of accounting methodology that would satisfy their request.

Mr. UDALL. They don't require that of universities, though, do they?

Dr. ROSWELL. I don't believe so.

Mr. UDALL. Okay. Thank you very much, Mr. Chairman.

Mr. BUYER. Thank you.

Dr. Mather, could you give us an assessment on the improvements and corrections of human subject protection of the most vulnerable patients that have been made by the VA?

Mr. MATHER. Mr. Chairman, in the last hearing, I think there was a long iteration of a number of those, but from the standpoint of my office, ORCA, and the Office of Research and Development, there has been a lot of work that has been accomplished.

In Dr. Roswell's testimony, there was allusion to a number of items that the Office of Research and Development has done.

Mr. BUYER. Bring us up to date from the last hearing forward.

Dr. MATHER. Since the last hearing, in my immediate office we have completed what we've characterized as Senior Executive Seminar, so that all VISNs have had these sessions, of a couple of days, where the senior management have been brought up to speed on all of the aspects of those regulations and guidances that protect human subjects.

We have continued to track the results of the NCQA-sponsored accreditation process. We have continued to track those sites which were found to be not-accreditable at this point in time, and tracking on the various recommendations we have made.

We received information on an additional site that was not accredited by NCQA last week, and yesterday, we had at that particular VA medical center, staff from my office checking to make

sure that there was no medical hurt to the subjects enrolled in the research there or no apparent egregious violations of the regulations. We found, indeed and in truth, that there were no serious violations in this regard.

This particular facility intends appealing its Non-Accredited status, and that's due around the 10th of October. The following week, we will be in there with a full team doing what we call a Systematic Post-Accreditation Review.

Mr. BUYER. Which facility was not accredited?

Mr. MATHER. This was the Northampton VA medical center in Massachusetts.

Mr. BUYER. All right.

Dr. MATHER. We also have continued, though, with one particular effort, and that is to try and pull together what we're calling a Quality Assurance/Quality Improvement Tool-kit.

One of the key standards in the NCQA accreditation is for individual VA medical centers to put together a first-rate QA/QI program for its human research activities.

We anticipate that with all of the releases of copyrights and so on that we have received, that that particular Tool-kit will be available by the end of this month in a CD ROM format. This we have done for various of our other particular products that have gone out, and we think that this kind of activity is very, very important.

We continue to use our web site to great effect in keeping it up to date, and with the various information letters and alerts.

So I think that gives you sort of a sense, sir, about what we're continuing to do in ORCA.

Mr. BUYER. Thank you. Dr. Aisen, I have attempted not to equivocate where I stand on the issue of the VA enforcing their intellectual property rights.

Do you have any comment on the testimony and questions or answers you've heard here today, since you're heading up this technology transfer?

Dr. AISEN. Well, I think that Dr. Roswell and Dr. Burris have given you pretty complete information.

We have added four more university partners. That includes "fair" Harvard—I think that that helped us get a few more cooperative technology administration agreements.

I agree completely with the list of uncooperative universities, as mentioned by Dr. Roswell.

Also, we do have some progress, in terms of commercializing, beyond what Dr. Burris mentioned, including our first two licenses. One has already got under way, and the other will be signed within a month. These will be the first VA exclusively funded, nurtured, patented, and marketed.

I guess I am a little disappointed in what I heard from Commerce today. I thought that we would hear something about the dual appointment personnel issue.

Indeed, there is a need for the country as a whole, for the academic community as a whole, to understand that there are people who have dual appointments and that there is compatibility between Bayh-Dole and the Executive Order. And that we do have to work together to share ownership.

We (in VA Technology Transfer) never forget who we work for. We work for the veterans. We only want to support (dissemination of) quality research. Money is not irrelevant, but it's hardly the only thing.

So we're not interested in duplicating the universities' efforts and we're not interested in taking what doesn't belong to us. We just want to be included in the process.

And I think that there really is a need for Commerce to officially recognize that there is a need for them to operationalize the compatibility of Bayh-Dole and the Executive Order ownership—coexisting in one inventor, in some cases.

Mr. BUYER. Dr. Aisen, candor is a bad term in this town, and I appreciate your stepping forward with your candor and giving your testimony. I appreciate it.

I also would appreciate it if you would make an appointment with my office, and come by, so we can talk.

Dr. AISEN. Okay.

Mr. BUYER. All right. This concludes Panel 1.

On Panel 2, we have Mr. Michael Slachta, the Assistant Inspector General for audit, Department of Veterans Affairs. Also testifying will be Ms. Cynthia Bascetta, Director of Veterans' Health and Benefits Issues, United States General Accounting Office.

Mr. Slachta, you are now recognized for 5 minutes.

STATEMENTS OF MICHAEL SLACHTA, JR., ASSISTANT INSPECTOR GENERAL FOR AUDITING, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY JOHN BILOBRAN, DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITING, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS; AND CYNTHIA A. BASCETTA, DIRECTOR, VETERANS' HEALTH AND BENEFITS ISSUES, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY MICHAEL T. BLAIR, JR., ASSISTANT DIRECTOR OF HEALTH CARE, GENERAL ACCOUNTING OFFICE

STATEMENT OF MICHAEL SLACHTA, JR.

Mr. SLACHTA. Mr. Chairman, I am accompanied by Mr. John Bilobran, deputy assistant inspector general for auditing.

We're here today to report back to the committee on the results of our work on reviewing the comments to the department's updated response to the subcommittee's questions and to summarize our fiscal year 2002 results of our on-site reviews at two VA nonprofit research and education corporations.

The department's updated submission to the subcommittee's questions is more responsive than the first.

Some questions were not answered because the information was not available to the department. For those questions, the department has offered to compile national data on corporate expenditures and fund use.

Compiling data nationally will improve visibility over corporate operations and the business relationship these corporations have with VA.

It will also improve the ability of the department to oversee corporate activities and ensure research funds are used only to benefit

VA research. Aggregation of revenues and expenditures nationally will also enhance congressional visibility over corporate activities.

Examples of the types of information the department should compile include:

"Other donations" corporations make, such as those made to the General Post Fund;

Reimbursements made from nonprofit research corporations to the medical care appropriation;

Medical centers that were reimbursed and the amount of each reimbursement;

Research projects terminated and the reasons for their termination; and

Research projects that were completed, and for those that were completed that had funds remaining, the amount of remaining or unused funds.

The department in its comments also stated that it, "will instruct its facilities to determine how much of VA-approved research funds were administered by VA research corporations."

We support that direction and believe the department should also ensure that work performed by corporations is consistent with national departmental goals.

In fiscal year 2002, we reviewed the operations at two nonprofit research corporations. Overall, we concluded that the corporations benefitted VA by making available corporate funds to renovate department research facilities, obtain state-of-the-art research equipment, and administer research projects.

Nothing came to our attention indicating that controls over expenditures and fund usage at these facilities were inadequate.

However, we believe there are opportunities to further improve oversight and accountability of research and education corporations without losing the flexibilities intended by the Congress when it authorized the establishment of these corporations.

In particular, we believe oversight would benefit by:

Requiring the corporations to adopt accrual basis accounting;

Standardizing financial reporting;

Establishing a department office to oversee corporate annual reporting;

Improving departmental guidance defining research expenditures; and

Looking at the feasibility of consolidating research corporations, particularly in locations where VA facilities have integrated or merged operations.

Our reviews found that:

Standardizing financial reporting will enhance the corporation's ability to identify, charge, and recover appropriate overhead costs for the services provided.

The independent annual certified financial reports that corporations submit in support of congressional reporting requirements are not designed to provide the level of detail needed to verify the need and justification of the expenditures.

Standardized financial reporting, beginning with a standardized chart of accounts , would enhance visibility over corporate financial activities;

Departmental responsibility for collection and summarization of the annual financial and performance information is currently rotated among VHA research staff, and the information is forwarded without substantive review.

We believe the consistency and accuracy of reporting would be improved by assigning responsibility to a VA program office that would review the information and take appropriate followup actions to ensure annual reports are accurate, reliable, and complete;

The department should look for opportunities to consolidate the number of research corporations, to avoid unnecessary administrative costs, reduce unnecessary infrastructure , and facilitate oversight by reducing the number of corporate entities.

The department has integrated and consolidated many of its health care facility operations. However, similar actions to merge VA research and education corporations have not followed.

We feel the VA could benefit by initiating a study to assess the feasibility of consolidating the number of entities.

VA research and education corporations provide significant benefits to VA, but improved financial and administrative control can improve oversight and accountability.

I will be pleased to answer any questions the committee may have.

[The prepared statement of Mr. Slachta appears on p. 47.]

Mr. BUYER. Ms. Bascetta.

STATEMENT OF CYNTHIA A. BASCETTA

Ms. BASCETTA. Mr. Chairman and Mr. Udall, I'm pleased to be here today to discuss nonprofit research corporations, a growing component of VA research. With me today is Michael Blair, the assistant director who led the review.

As we've discussed, VA research contributes to the discovery of new treatments for diseases and disabilities that affect veterans, and the Nation's population as a whole. Funding from the nonprofits increased almost 140 percent between 1996 and the year 2000, and totaled almost $175 million in fiscal year 2000.

In 1994, the inspector general conducted a major review of nonprofits and raised concerns about the adequacy of VA's policies and guidance relating to budgeting, accounting, and oversight of these corporations.

After your hearing this May, you asked the IG and us to provide more current information on VA's nonprofit corporations. Today, I'd like to focus on the processes VA has in place to detect conflicts of interest in research supported by the nonprofits and VA's monitoring and oversight of their activities.

First, though, I'd like to tell you about what we found about the benefits of corporations.

As a flexible funding mechanism, they have, indeed, enhanced VA research, infrastructure, and environment. For example, the indirect funds that we've talked about this morning that have been collected by the nonprofits have been used to renovate laboratory space, purchase equipment, maintain VA research libraries, and cover travel expenses to conferences. In turn, the research environment has been better able to attract highly qualified physicians who often provide patient care, as well. Researchers also told us

that funding flexibility enables the nonprofits to respond to their individual project needs. For example, two nonprofits were able to quickly purchase specialized equipment that would have taken months if they had had to go through VA's normal contracting process.

So clearly, flexibility can yield benefits, but it also carries risk. You specifically asked us to look at the processes in place to detect potential conflicts of interest that could arise. We found that investigators on research projects administered by the nonprofits must follow federal statutes and regulations applicable to federal employees concerning both conduct and conflict of interest. NIH and FDA impose additional requirements for financial disclosure on principal investigators. We also found that investigators at three of the five nonprofits we visited were required to disclose their financial interests for each project that they conducted.

The Secretary of VA has delegated responsibility for overseeing its nonprofit corporations to the local medical center directors, who are also nonprofit board members. They, as well as the chief of staffs, are required to file financial disclosure forms. However, headquarters does not review these forms and compare them to ongoing research at the medical facilities. Similarly, although each nonprofit submits its financial statements and management letters to headquarters, headquarters relies on local oversight to assure that any deficiencies noted by independent auditors are corrected. In this regard, we were very glad to hear this morning Dr. Roswell's statement in his oral testimony that he intends to deal with these kinds of weaknesses.

Beyond annual audits, officials at the five nonprofits we reviewed told us that they had not been the subject of systematic substantive review. Without routine national oversight, such as through VA's Office of Research and Development, it would be difficult to ensure that areas for improvement are identified and that the nonprofit corporations correct any problems noted by the independent auditors. VA also has not evaluated, in a broader sense, the nonprofit corporations to measure their effectiveness or to compare their operations to see if they can achieve even more of these valuable benefits.

In conclusion, VA is placing increasing reliance on the nonprofit research corporations as they become an integral component of the research program. Indeed, because of the large amount of funding that now flows through the nonprofits, the absence of VA oversight is not inconsequential. While medical center directors provide an essential oversight function locally, they are not at arm's length from the nonprofits. As a result, VA headquarters could consider national oversight to better ensure that the benefits of the nonprofit corporations are maximized and achieved in ways that safeguard VA's interests. Such high-level oversight of both financial activities and program effectiveness would be critical elements of continued success.

I'd be happy to answer any questions that you might have.

[The prepared statement of Ms. Bascetta appears on p. 50.]

Mr. BUYER. I'd like to thank both of you. It's unfortunate that you had to take a re-look at an issue that should have been accomplished the first time.

Mr. Slachta, you're very kind in saying that some of the information may not have been completely available.

But I want to thank you for going back, and I appreciate your testimony. I had a chance to review it.

I will have some questions that I will submit for the record for you. At this time, I yield to Mr. Udall for any questions he may have.

Mr. UDALL. Thank you, Mr. Chairman.

Mr. Slachta, what is the likelihood there is a commingling of VA funds dedicated for research and VA funds dedicated for health care at the indirect cost level?

Mr. SLACHTA. It's happening. There's no question, there is a commingling.

Mr. UDALL. Could you explain a little bit how that happens?

Mr. SLACHTA. Well, VA doesn't attempt to separate the funds, doesn't attempt to separate the costs.

For example, everything from management, the R&D committees, their salaries and their support efforts are paid out of the medical care appropriation.

Environmental sciences, building maintenance, those are coming out of medical care appropriation.

Those are just some examples. I mean, there are many, many examples.

Mr. UDALL. And here's another example. Let's say for fire coverage, if you had an on-campus nursing home and an on-campus research facility, and you're dealing with the fire coverage. The facility hosts VA and NIH-sponsored research.

So effectively, the VA is providing free fire coverage for the NIH researchers? Is that——

Mr. SLACHTA. Yes, that's correct.

Mr. UDALL. So that kind of thing is being repeated frequently in the VA?

Mr. SLACHTA. In every VA facility.

Mr. UDALL. Yeah. Okay.

I would ask the GAO the same question.

Ms. BASCETTA. We didn't do the intensive type of review that the IG conducted, but we did note that, certainly these kinds of situations that you're describing are commonplace.

Mr. UDALL. Thank you. Mr. Chairman, I yield back. Thank you.

Mr. BUYER. Thank you for your testimony. This concludes the second panel.

For that third panel, the committee recognizes Mr. Antonio Laracuente, chairman of the National Association of Veterans' Research and Education Foundations; Dr. Wendy Baldwin, Deputy Director for Extramural Research at the National Institutes of Health; Mr. John Bradley, Director of Finance at the Office of Research and Development at the Department of Veterans Affairs; and Mr. Henry Kirschenman.

Go ahead.

STATEMENTS OF ANTONIO LARACUENTE, EXECUTIVE DIRECTOR, ATLANTA RESEARCH AND EDUCATION FOUNDATION (AREF) AND CHAIRMAN, NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION FOUNDATIONS (NAVREF); HENRY G. KIRSCHENMAN, JR., CPA; JOHN A. BRADLEY, DIRECTOR OF FINANCE, OFFICE OF RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; AND WENDY BALDWIN, M.D., DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ANTONIO LARACUENTE

Mr. LARACUENTE. I guess I'll go first.

Good afternoon, Mr. Chairman, and members of the subcommittee. I am Antonio Laracuente, executive director of the VA affiliated nonprofit in Atlanta and chairman of NAVREF.

As you are aware, investigators from the General Accounting Office spent the summer conducting in-depth site visits of five foundations. My spoken testimony focuses on my own experience with the GAO auditors and pending legislation that would improve nonprofit accountability.

My foundation was the first one the GAO visited. After a quick review of the IG and GAO testimonies, it appears that several major themes were adequately addressed by the nonprofits, including why does the VA need nonprofits and what rules and regulations apply to the nonprofits?

However, we would like to verbally respond to the recommendation on the number of nonprofits and address the other issues in a written response, specifically the standardization of accounting practices and the chart of accounts.

Does the VA need 86 nonprofits?

Again and again, the GAO site visitors asked, does each VAMC need its own nonprofit?

My unequivocal answer was yes. The many advantages of a one-on-one relationship between a VAMC and a nonprofit include:

Local oversight by a board that holds VA interests paramount;

Management that is invested in the success of the medical center's research program;

Responsiveness to facility and individual investigator needs;

On-site services resulting in convenience for investigators; and

Quick turnaround on procurement and hiring.

Regarding increased accountability, NAVREF has given serious consideration to concerns about accountability expressed by the members of the Health and Oversight Subcommittees during the May 16th hearing.

In our view, two relevant items are pending.

First, NAVREF has concerns about the content of H.R. 3645, Section 7, "Improved Accountability of Research Corporations."

We strongly recommend that this section should be amended to:

First, impose on all of the corporations a requirement that within 3 years of enactment, their annual audits should be performed in accordance with generally accepted government accounting standards;

Second, each year require the inspector general of the Department of Veterans Affairs to review the most recent audit of at least 10 percent of the corporations.

These two items would address the primary concerns expressed by the members of the subcommittee during the May 16th hearing.

As detailed in Attachment A of our written testimony, the other overly burdensome and costly requirements specified in Section 7 should be eliminated.

NAVREF has no objection to increased accountability, but feels the requirements put in place to achieve this objective should be reasonable and purposeful.

The second pending item focuses on contracts between VA medical centers and nonprofits.

As you may be aware, the corporations have been seeking an approved means of better serving the VA research and education missions through use of VA's contracting authorities. Allowing VAMCs to contract with the nonprofits to support VA-funded programs subject to a VA-approved contract would greatly increase accountability.

A reimbursement authority has been suggested. However, we feel that this would provide less accountability than using VA's existing contracting authorities, which have a full body of implementing regulations to ensure adequate controls.

Again, we strongly encourage the House to approve contracting between VAMCs and nonprofits.

Thank you for your consideration of our views. I'd be pleased to answer any questions.

[The prepared statement of Mr. Laracuente, with attachment, appears on p. 64.]

Mr. BUYER. Mr. Kirschenman.

STATEMENT OF HENRY G. KIRSCHENMAN, JR.

Mr. KIRSCHENMAN. Mr. Chairman and members of the subcommittee, I was engaged by the Veterans Health Administration to identify the indirect costs associated with its research function and to calculate the indirect cost rates that would apply to its research grants.

More specifically, I calculated the indirect costs associated with the National Institutes of Health grants. The indirect cost rate for those grants is 23. Five percent of total direct costs.

I submitted my calculations in May of 2002. I am here to respond to questions which you may have about the rationale behind the rates or the calculation itself.

In identifying the research costs and calculating the rates, I followed the costing concepts and guidance contained in the Cost Accounting Handbook of the Department of Veterans Affairs and the several documents issued by the Office of Management and Budget, specifically:

Statement Number 4, Managerial Cost Accounting Concepts and Standards for the Federal Government, issued by the Federal Financial Accounting Advisory Board;

The Circulars A–21, A–122, and A–87; and

The Federal Acquisition Regulations (FAR).

The three circulars govern the costing and other federally supported programs at universities, other nonprofit institutions, and state and local governments, respectively.

The Federal Acquisition Regulations govern the costing of federally supported projects conducted by commercial organizations.

The guidance contained in these publications reference and conform with generally accepted accounting principles and are consistent with each other. In my opinion, application of the guidance contained in those documents results in indirect costs rates that reasonably reflect the costs of performing research.

I also consulted OMB Circular A–25, which establishes federal policy regarding user charges to be assessed by government agencies for the use or sale of their services or goods.

The guidance for determining the cost of such services and goods is consistent with the guidance in the documents I just cited. Again, the rates I calculated conform with the costing and charging concepts contained in that circular.

The critical concept contained in all of these documents is of benefit. That is, an activity must provide benefit to a project for its associated costs to be recognized as a charge against it. All the costs included in my rate calculations meet that criterion.

The methodology I followed in identifying the indirect costs related to the research conducted by the Veterans Health Administration and to calculate the rates conform with the costing concepts contained in these cited document, with two exceptions.

The rates I have calculated do not include amounts for depreciation or a use allowance for VHA buildings and equipment used in the conduct of the research as provided for in all the cited documents, or a rate of return factor on these assets as provided for in the FAR and recommended in Circular A–25.

Additionally, there are other costs which might be argued to benefit the research that the Veterans Health Administration opted not to include in the interest of conservatism. Thus, it is my opinion that the calculated rates themselves are conservative.

[The prepared statement of Mr. Kirschenman appears on p. 84.]

Mr. BUYER. I yield to Mr. Udall for any questions.

Mr. UDALL. Thank you.

Mr. Bradley, you heard the testimony of the assistant inspector general and the GAO in the commingling. Do you believe at the indirect costs level funds, between the research functions and the health care functions sometimes commingle?

Mr. BRADLEY. Yes, I do.

Mr. UDALL. If this is true, then a non-reimbursed indirect costs must be paid from some VA source, and the health care side of VHA would be sheltering some of the indirect cost burden; is that correct?

Mr. BRADLEY. I believe that is correct.

Mr. UDALL. The VA currently covers these indirect costs associated with NIH grants. Could this have an unwanted impact of any degree on veterans' health care?

Mr. BRADLEY. Well, I think that's, it's hard to prove with numbers, because of the commingling you reference, Mr. Udall.

However, I think intuitively, if you look at the number, the dollar number of grants that are now being conducted at VA facilities,

which in 2001 actually exceeded the amount of VA grants being conducted in VA facilities, that that conclusion is somewhat inescapable.

Mr. UDALL. During the hearing on this topic in May, Ms. Baldwin indicated that she would be happy to sit down with the VA to establish what would be an appropriate level of compensation for additional cost.

Did this meeting occur, and what level of agreement was reached?

Mr. BRADLEY. We did schedule a meeting in September for what I thought was going to be a meeting to establish a rate.

Because of the proceedings in the previous hearing, I thought we were at a point where we agreed that, some kind of indirect rate would be appropriate for VA, and it was just a matter of determining what that rate should be.

Unfortunately, we weren't able to reach an agreement. NIH doesn't believe that an indirect rate for VA is appropriate, and so they did not want to discuss at that particular time an indirect rate for the VA.

Mr. UDALL. So basically, the position is they're taking a hard line with regard to any indirect reimbursement?

Mr. BRADLEY. Well, I think some of this is somewhat semantical. They refused to discuss an indirect rate, but they are willing to pursue discussions about incremental cost reimbursement.

Some of this I think, in my opinion, is somewhat semantical, but you can ask Dr. Baldwin further about that.

Mr. UDALL. Could you explain a little further "somewhat semantical"?

I mean, I think we heard earlier that there's a big difference between incremental and indirect, that incremental is something very hard to find, I believe.

Mr. BRADLEY. Yes. We did not know, going into this meeting, that VA was going to be held to a standard different than, say, universities who are negotiating an indirect cost rate.

That's why we asked Mr. Kirschenman to help us, because that was a process he's familiar with, and it's one that the VA is not familiar with, since giving up the indirect costs rates it had in the late 1980s.

Mr. UDALL. Thank you, Mr. Bradley.

Mr. Kirschenman, to your knowledge, does NIH recognize and pay indirect costs on its contracts awarded to federal agencies?

Mr. KIRSCHENMAN. Yes, I believe it does.

Mr. UDALL. And from your knowledge, does NIH pay indirect costs to universities, nonprofit entities, state and local governments, and commercial organizations which conduct research under NIH grants?

Mr. KIRSCHENMAN. Yes, if they're calculated in accordance with the circulars I mentioned, yes.

Mr. UDALL. And in your opinion, are the so-called indirect costs incurred by the VHA and other research-performing entities and reflected in their indirect cost rates real and necessary costs as opposed to profit, for example?

Mr. KIRSCHENMAN. Yes. The idea of indirect costs being a form of profit I think was discredited many, many years ago, and it's

universally accepted that they are real costs and necessary for the effective performance of research grants and contracts.

Mr. UDALL. In your opinion, is there any fundamental conceptual difference in determining the costs associated with grants as opposed to contracts?

Mr. KIRSCHENMAN. No, there isn't, and the indirect cost rates that are calculated for other institutions under the circulars I mentioned are commonly applied to contracts, as well as grants.

Mr. UDALL. And would an indirect cost rate calculated under the documents you cited apply to contracts as well as grants?

Mr. KIRSCHENMAN. Yes, it would.

Mr. UDALL. Thank you, Dr. Kirschenman.

Dr. Baldwin, again, thank you for appearing today.

In May, you stated that you have an indirect cost rate with some institutions of 8 percent. Are there any other rates?

Dr. BALDWIN. There are indirect cost rates, for universities, for companies, and for other entities with which we do business.

Indirect cost rates are negotiated with entities where we do business, such as universities or small businesses.

The circulars that Mr. Kirschenman referred to really don't apply to federal agencies: It would be quite unusual to calculate a full indirect cost rate for another federal agency.

Mr. UDALL. What are the other rates in addition to this 8 percent?

Dr. BALDWIN. They're very variable. The administrative——

Mr. UDALL. What's the range?

Dr. BALDWIN. The range is probably from 25 to 30 percent, up to 100 percent.

Mr. UDALL. And you didn't have an indirect cost rate for foreign institutions, if I read your testimony correctly from May?

Dr. BALDWIN. Yes. That's new.

Mr. UDALL. Mr. Chairman, my overall concern is that this may be having an indirect and unwanted impact on our veterans and I'm sure I have many follow-up questions concerning this undesirable impact, but at this point, I would yield back to you and I have several closing comments, but I'll certainly defer to you on any closing.

Mr. BUYER. The subcommittee will be submitting written questions to all those who testified today, Mr. Udall, so you're more than welcome to submit written questions and follow up.

I do have one.

Mr. Laracuente, concerning the recent move to allow the nonprofit corporations to contract services to the VA, why do you believe it's necessary to codify this into law, considering that both the GAO and the IG have said that the nonprofit research corporations already have the power to donate services to the VA as an in-kind expense?

Mr. LARACUENTE. The main reason is, in 1999, the general counsel determined that a transfer of funds from VA appropriated dollars could not occur under a contractual arrangement.

Our feeling is that the nonprofit can provide services to the VA and have the appropriate grant pay for, or the appropriate award pay for those services that would be at cost.

So, for example, you have a core facility that is supported by a VA nonprofit corporation to the tune of several hundred thousand dollars per year. They have to receive compensation to cover the cost for any reagents or any personnel that are involved, contracts for the equipment, and so forth.

So we believe that those costs which are associated with running this facility can be placed into many of the grants that are administered by the nonprofit corporations, such as NIH grants or such as private donated grants, but they should also come from every single source, so there's continuity and there's consistency in the recovery of these costs associated with running the facility.

Mr. BUYER. Could we reasonably expect that the nonprofits would continue to donate these services to the VA if they could sell them to the facility under a contract?

Mr. LARACUENTE. The nonprofit would provide the services to the VA and the VA would sell them to another entity? I don't believe that could happen under what we propose.

Mr. BUYER. Can we reasonably expect that the nonprofits would continue to donate these services to the VA if they could sell them to the facility under a contract?

Mr. LARACUENTE. Yes, sir.

Mr. BUYER. I don't know. My instincts aren't with you. I don't know. I hear your testimony. I give great deference to the GAO and IG's testimony. I'm just letting you know what my instincts are telling me. All right? I'll be a good listener.

Let me yield to Mr. Udall for any closing comments he'll make.

Mr. UDALL. Thank you, Mr. Chairman.

Dr. Baldwin, and if you're still in the room, Dr. Roswell, you may wish to consider this today.

We have heard today that the VA has long waiting lines for health care, due to a shortage of resources.

We have also heard, from an expert who has testified, that the VA clearly has indirect costs; that VA's covering of indirect costs associated with NIH grants may have an unwanted impact on the accessibility of veterans' health care; that NIH provides indirect cost fees to non-federal institutions, including foreign institutions, and that for some specific types of grants, Title XLII addresses the issue of the same terms and conditions for grants to federal and non-federal institutions.

Why can and why should NIH exclude VA from indirect costs? I would ask you to consider the law and consider the need for our veterans.

I think with that, Mr. Chairman, I would yield back to you and thank this third and final panel for their participation and attendance today.

Mr. BUYER. Thank you, Mr. Udall. I want to thank all the panels for testifying today.

I think the VA has made good progress in the area of securing a fair share of intellectual property rights. As we heard today, there is still plenty of work to do.

I am most interested, again, Dr. Roswell, in seeing a list of major institutions who are not cooperating, and I also want to see that revenue stream.

We will continue to monitor the VA efforts to ensure human research subject protections to the maximum extent possible.

I thank all of you for your attention and testimony.

This concludes the hearing.

[Whereupon, at 1 p.m., the subcommittee was adjourned.]

APPENDIX

OPENING STATEMENT FOR CONGRESSWOMAN JULIA CARSON

RANKING DEMOCRATIC MEMBER, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION

In May of this year, we had a joint hearing with the Health Care Subcommittee on issues remarkably similar today's hearing issues on Department of Veterans Affairs (VA) medical- and health-related research.

At the May hearing, the Subcommittee heard testimony in four specific areas regarding VA research activities. We focused on the accountability of VA Research Corporations and we reviewed the VA's once relaxed approach to securing intellectual property rights and patents for VA discoveries and inventions. We also reviewed VA's research program and associated protocols and safeguards for the conduct of human subject research. Additionally, we explored the general fairness of a possible add-on for indirect costs associated with research conducted under grants from the National Institutes of Health.

In May, I established one goal to guide the review process for this series of Subcommittee hearings. Our goal must be to assure the effective and safe conduct of research to better healthcare and to improve the general health of veterans and of other Americans.

Issues remain in all four issue areas. For example, as long as VA conducts human studies research, this Committee will provide aggressive oversight. When we heard testimony about human subject research in May, the human subjects program was not problem free, but it generally appeared to be responsibly conducted with an adequate level VA oversight. The Committee will visit this area as necessary to assure safe and responsible human subject research.

Two other issues remain from our previous research hearing that should be brought to some level of closure. Each issue has an impact on VA funding of research and may ultimately influence the quality and accessibility of the healthcare available to our veterans.

I must ask the question, if VA were to receive additional funds springing from control of intellectual property rights or in the form of a reasonable add on for indirect costs on NIH sponsored grants, would the general availability and quality of healthcare VA-wide improve? If the answer is yes in any meaningful degree, should we not explore the potential?

Conversely, is veterans' healthcare suffering, in any way, by VA's historical reluctance to pursue patents and by its willingness since 1989 to cover indirect costs for medical and health research associated with NIH grants conducted at VA facilities? If this is true, what recourse is appropriate?

We have been told about of the outstanding and wonderful discoveries and inventions VA research has yielded. VA should fully earn the rights to its intellectual progeny—and put those proceeds to use for more robust research programs and better and more accessible healthcare for our veterans.

At the hearing in May, I asked a senior representative from National Institutes of Health who serves as the Director of the Extramural Grant Program if she would discuss the appropriate level of an "add-on" for indirect costs associated with grants to the VA. Dr. Baldwin testified that she, ". . . would be happy to sit down with the VA to establish what would be an appropriate level of compensation for additional costs." I look forward to hearing about that meeting's success in determining the sufficiency of that level. The bottom line is, if those fair and reasonable costs lighten the burden on VA's infrastructure, and that in turn—directly or indirectly—strengthens the healthcare our veterans receive, I would deem that a worthy goal.

Statement of
Benjamin H. Wu
Deputy Under Secretary for Technology

Technology Administration
U.S. Department of Commerce

Before the

Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs

U.S. House of Representatives
107th Congress, 2nd Session

Hearing on the Department of Veterans Affairs Medical Research Programs

September 19, 2002

TESTIMONY OF
BENJAMIN H. WU
DEPUTY UNDER SECRETARY FOR TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE COMMITTEE ON VETERANS' AFFAIRS
SEPTEMBER 19, 2002

Good morning, Chairman Buyer, Ranking Member Carson, and Members of the Subcommittee. I am Ben Wu, Deputy Under Secretary for Technology at the Department of Commerce. I have been asked to participate at today's hearing on the Department of Veterans Affairs (VA) research activities and to comment on the VA's technology transfer efforts. In addition, I will broadly review the Federal technology transfer enterprise of transferring government technology to the private sector for commercialization.

The Department of Veterans Affairs deserves commendation for its efforts in developing an active technology transfer program. In February 2000, VA appointed the first director of its technology transfer program and its first patent attorney last year. Additionally, VA has entered into an arrangement with the National Technology Transfer Center at Wheeling Jesuit University in West Virginia to assist it with its technology transfer program.

These developments, coupled with the April 2001 announcement by Secretary Anthony Principi that the VA would take the lead in aggressively disseminating new discoveries and inventions made by VA researchers, indicate a new and growing recognition of the importance of technology transfer to the vitality of the Department's research activities. Thus, it is expected that the number of VA inventions, patents, and licenses will substantially increase over time.

The Department of Commerce is pleased to play a significant role in Federal technology transfer because of the benefits received by the public from the billions of dollars spent on research and development by the Federal government. By statute, Commerce coordinates Federal technology transfer policies.

In my testimony, I will review the Department of Commerce coordination leadership roles and responsibilities in technology transfer, the importance of intellectual property rights in creating greater innovation partnerships with the Federal government, provide a statutory review of Congressionally enacted technology transfer laws, and offer some thoughts regarding VA and its technology transfer efforts.

The Department of Commerce Roles and Responsibilities in Technology Transfer

The Department of Commerce, through our Technology Administration (TA), has specific roles and responsibilities in the area of technology transfer – particularly through our Office of Technology Policy and the National Institute of Standards and Technology. These functions are detailed below.

Technology Administration, Office of Technology Policy (OTP)

The Office of Technology Policy plays a significant role in the development, implementation, and analysis of technology transfer policies and practices, in close consultation with Congress and other agencies. As the Administration's focal point for discussion of technology transfer issues, OTP also coordinates and works closely with the Inter-Agency Working Group on Technology Transfer (IWG). The IWG discusses a wide range of agency activities and issues relating to technology transfer, recommends policies for technology transfer, and coordinates the submission by agencies of data on inventions and technology transfer for congressional reports.

OTP's statutory responsibilities include:

- Assisting agencies in the implementation of relevant laws, including the Bayh-Dole Act and the Stevenson-Wydler Act;
- Developing policies and issuing regulations governing the ownership of patents arising from Federally funded research and the licensing of Federally owned inventions (see implementing arrangements in 37 CFR Parts 401 and 404); and
- Compiling and analyzing information and reporting on agency implementation of technology transfer mechanisms such as Cooperative Research and Development Agreements (CRADA) and patent licenses.

Through FY 2000, the Office of Technology Policy was responsible for producing a biennial report to Congress on the technology transfer activities of all Federal agencies. Requirements in the Technology Transfer Commercialization Act of 2000 (TTCA) shifted this reporting responsibility to an annual basis. Beginning in the current fiscal year, the TTCA requires each agency with a Federal laboratory to produce with its budget submission, an annual report on its technology transfer activities and outcomes. In addition, the Secretary of Commerce is required to prepare a government-wide summary report based on these submissions. The Office of Technology Policy is responsible for coordinating agency submissions and producing the Secretary's summary report.

In the role of coordinator and leader of the IWG, OTP has crafted administration support for a number of technology transfer–related provisions and legislation, including the recently passed Technology Transfer Commercialization Act of 2000. As the Administration considers ways to improve the efficiency and speed of technology transfer, it is important to

consult the technology transfer practitioners throughout the government, as well as their counterparts in industry and universities.

The Department of Commerce's experience and relationship with the IWG has been, and will no doubt continue to be, a strong asset in organizing such consultations, identifying recommendations, and prioritizing appropriate administrative or regulatory action.

Technology Administration, NIST

NIST's mission is to develop and promote measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life. The NIST laboratories develop and disseminate measurement techniques, reference data, test methods, standards, and other infrastructural technologies and service that support U.S. industry, scientific research, and the activities of many Federal agencies. NIST works directly with industry partners (and consortia), universities, associations, and other government agencies, and utilizes diverse mechanisms to transfer the knowledge and technologies that result from its laboratory research.

In keeping with its mission, NIST's technology transfer activities are focused on pursuing the most efficient and effective path to utilization and commercialization, which often necessitates the broad dissemination of research results, rather than the creation of intellectual property and associated licenses.

Activities carried out by NIST related to technology transfer include:

- NIST's Office of Technology Partnerships manages NIST's formal technology transfer activities, such as CRADA participation and the protection and licensing of intellectual property.

- Pursuant to the Technology Transfer Commercialization Act of 2000, NIST has reported on its technology transfer activities annually to the Technology Administration's Office of Technology Policy. This information will be incorporated into a report submitted with the Department's annual budget documents.

- NIST works closely with the Office of Technology Policy on other technology transfer-related issues, through participation in the IWG, the Federal Laboratory Consortium for Technology Transfer (FLC), and informal consultation.

Technology transfer tools such as Cooperative Research and Development Agreements (CRADA) and patent licensing are relatively simple ways for U.S. businesses to develop Federally funded innovations into commercially useful products and processes. Congress created these tools in the 1980s at a time of unprecedented technological challenge to U.S. industry, but they are useful even in today's dynamic technology markets.

The manner in which the Federal government works with the private sector in developing and diffusing technologies changed fundamentally with the passage of the Bayh-Dole, Stevenson-Wydler, and Federal Technology Transfer Acts. The agencies and the private sector began to find ways to partner in the development of technologies that both furthered agency missions and advanced the competitiveness of industry and the strength of our economy.

Federal technology transfer has helped develop everyday products such as stronger and lighter materials for more fuel efficient cars, the Global Positioning System (GPS) that offers pinpoint precise locations for navigation on the seas or on the highways, and the HIV home kit that allows people to collect samples in the privacy of their own home and send them to a laboratory for analysis. These are just a few of the many hundreds of examples of technologies to which the Federal government originally held intellectual property title, and either licensed the technology or collaborated with industry to commercialize. These examples demonstrate the extent to which effective Federal technology transfer serves to stimulate the economy.

Successful technology transfer is a constantly evolving effort. In its biennial technology transfer report entitled *Tech Transfer 2000,* the Department of Commerce's Office of Technology Policy found the following:

- Managing intellectual property must become more of an agency priority;
- More help is needed to make it easier for industry partners to find the right laboratory;
- A CRADA can be used effectively in many different circumstances and is an extremely flexible instrument; and
- Measures of success in technology transfer must be developed by agencies in partnership with the business community.

Recent Technology Transfer Laws and Intellectual Property Rights Distribution

Congress has a rich and long history of promoting technology transfer. Federal technology transfer began with the Stevenson-Wydler Technology Innovation Act in 1980 (P.L. 96-480). The Stevenson-Wydler Act required Federal laboratories to take an active role in partnering with industry and established technology transfer offices at all major Federal laboratories.

That landmark legislation was expanded considerably with the Federal Technology Transfer Act of 1986 (P.L. 99-502) and the National Competitiveness Technology Transfer Act of 1989 (P.L. 101-189). The Federal Technology Transfer Act of 1986

allowed a government-owned, government-operated laboratory, which we know as a GOGO, to enter into a CRADA with industry, universities, and others. A CRADA allows a laboratory and an industrial partner to negotiate patent rights and royalties before they conduct joint research. This gives the company patent protection for any inventions and products that result from the collaboration. This patent protection provides an incentive for the companies to invest in turning laboratory ideas into commercial products.

A CRADA also provides a Federal laboratory, in fulfilling its mission, with valuable insights into the needs and priorities of industry, and with the expertise available only in industry. The National Competitiveness Technology Transfer Act of 1989 extended the CRADA authority to a government-owned, contractor-operated (GOCO) laboratory such as the Department of Energy labs. It also protected information and innovations, brought into and created through a CRADA, from disclosure.

Since 1986, thousands of CRADA's have been signed, resulting in the transfer of technology, knowledge, and expertise back and forth between our Federal laboratories and the private sector. Under current law, the work done under a CRADA must not detract from the mission responsibilities of a Federal laboratory.

Yet despite the success of the CRADA legislation, there were existing impediments for companies that Congress felt needed to be addressed. The law was originally designed to provide a great deal of flexibility in the negotiation of intellectual property rights to both the private sector partner and the Federal laboratory. However, it provided little guidance to either party on the adequacy of the rights that a private sector partner should receive in a CRADA.

Agencies were given broad discretion in the determination of intellectual property rights under CRADA legislation. This often resulted in laborious negotiations of patent rights for certain laboratories and their partners each time they discussed a new CRADA. With options ranging from assigning the company full patent title to providing the company with only a nonexclusive license for a narrow field of use, both sides had to undergo this negotiation on the range of intellectual property rights for each CRADA.

This uncertainty of intellectual property rights coupled with the time and effort required in negotiation, hindered collaboration by the private sector with Federal laboratories. Some agencies have found that companies are reluctant to enter into CRADAs, or equally important, to commit substantial investments to commercialize CRADA inventions, unless they have some assurance they will control important intellectual property rights.

The enactment of the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) enhanced the possibility of commercialization of technology and industrial innovation, by providing assurances that sufficient rights to intellectual property will be granted to the private sector partner with a Federal laboratory. The Act

guarantees to the private sector partner the option, at minimum, of selecting an exclusive license in a field of use for a new invention created in a CRADA. The company would then have the right to use the new invention in exchange for reasonable compensation to the laboratory.

In addition, the Act addresses concerns about government rights to an invention created in a CRADA. It provides that the Federal government will retain minimum statutory rights to use the technology for its own purposes.

Another one of the most successful legislative frameworks for advancing Federal technology transfer has been the Bayh-Dole Act of 1980 (P.L. 96-517, Patent and Trademark Act Amendments of 1980). The Bayh-Dole Act permits universities, not-for-profit organizations, and small businesses to obtain title to inventions developed with Federal support. The Bayh-Dole Act also allows Federal agencies to license Government-owned patented scientific inventions nonexclusively, partially exclusively, or exclusively, depending upon which license is determined to be the most effective means for achieving commercialization.

Critical pressures originally prompted the passage of the Bayh-Dole Act. Prior to its enactment, many discoveries resulting from Federally funded scientific research were not commercialized for the benefit of the public. Since the Federal Government lacked the resources to market new inventions, and private industry was reluctant to make high-risk investments without the protection of patent rights, many valuable innovations were left unused on the shelf of Federal laboratories.

With its success in licensing Federally funded inventions, the Bayh-Dole Act is widely viewed as an effective framework for Federal technology transfer. For example, the Association of University Technology Managers (AUTM) conducted a study on the effect of the Bayh-Dole Act. AUTM said that the Bayh-Dole Act not only encourages the commercialization of inventions by universities that would otherwise gather dust on the shelf, but it also brings in revenues to the Federal Government through licensing fees on Government-owned patents. The private sector has already demonstrated a strong interest in the strategic advantages of partnering with a Federal laboratory through a CRADA or through the licensing of Government-owned technology.

Nevertheless, both past and prospective private industry partners voiced their concerns regarding the Federal technology licensing process. Companies were deterred by the delays and uncertainty often associated with the lengthy Federal technology transfer process. These procedural barriers and delays could increase transaction costs and are often incompatible with the private sector's need for a swift commercialization calendar. The regulations governing Federal technology transfer also made it difficult for a Government-owned, Government-operated laboratory (GOGO) to bring existing scientific inventions into a CRADA even when its inclusion would create a more complete technology package.

A GOGO did not have the flexibility that small business and non-profits had in

managing their inventions under the Bayh-Dole Act. Also, a GOGO, unlike a GOCO, faced statutory notification provisions when granting exclusive licenses, and more importantly, it could not include existing inventions in a CRADA.

By reducing the delay and uncertainty created by existing procedural barriers, and by lowering the transactional costs associated with licensing Federal technologies from the Government, Congress believed it could greatly increase participation by the private sector in its technology transfer programs. This approach would expedite the commercialization of Government-owned inventions, and through royalties, could reduce the cost to the American taxpayer for the production of new technology-based products created in our Nation's Federal laboratories.

As a result, the Technology Transfer Commercialization Act of 2000 (P.L. 106-404) was enacted. The law sought to remove the procedural obstacles and, to the greatest extent possible, the uncertainty involved in the licensing of Federally patented inventions created in a Government-owned, Government-operated (GOGO) laboratory. This was achieved by applying the successful Bayh-Dole Act provisions to a GOGO. With the enactment of this law, the ability of the United States to compete has been strengthened and a new paradigm for greater collaboration among the scientific enterprises that conduct our nation's research and development – Government, industry, and universities – has been created.

Implementation of the Technology Transfer Laws by the VA

According to the May 17, 2001 Department of Veterans Affairs Intellectual Property Handbook, retention of ownership and protection of intellectual property developed by VA investigators are key issues. It is also important to acknowledge cases where co-ownership issues exist with VA academic affiliates. To address this issue, a model inter-institutional agreement (IIA) was developed by the VA. This legal agreement outlines relevant definitions, terms, and conditions for handling intellectual property between both organizations.

The VA believes that using the IIA allows VA a co-ownership interest while providing the academic affiliate unimpeded access and authority to patent and market the intellectual property in question. This makes the invention attractive to manufacturers to ensure that if they develop the product for the marketplace, they will have exclusive rights to produce and market the invention. Additionally, the VA believes that the overall benefit to the Federal government and the taxpayers is that a patent will protect an invention resulting from Federally-funded research.

Successful patents licensed to manufacturers would provide a royalty stream. As a result, VA inventors would benefit from royalties for their personal use, as well as a return of royalties to their research laboratories and facility. The taxpayer gains by the return of funds to the laboratories to further medical research. The VA believes that using IIAs provides a win-win situation for the VA and academic affiliates, while maintaining, strengthening, and/or expanding existing partnerships to the mutual benefit

of both organizations. Consequently, these agreements are used with academic affiliates whenever possible.

Regarding patents, the VA patent process begins when intellectual property has been disclosed and reviewed by the VA General Counsel and a determination has been made to retain ownership of an invention. An invention owned by the Federal government needs to be protected by an application for a domestic patent.

The VA may elect to use outside counsel if it is determined appropriate. All VA-owned inventions not covered by IIAs will receive centralized patenting support. This support includes handling patent applications, provisional patents, patent filings, follow-up requests for information concerning pending patent applications, international filings where applicable and other necessary actions.

Regarding a CRADA, in exchange for what VA receives from a collaborating party, the VA may provide personnel, services, facilities, equipment, or other resources, but not funding toward the conduct of specific research and development efforts which are consistent with VA's mission. The laboratory director may grant licenses or, in exceptional circumstances, assignments or options thereto, for reasonable compensation when appropriate, to collaborating parties for any inventions made by a Federal employee under such agreements. However, a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world, by or on behalf of the Government, must be retained. In such cases where it is determined to grant any of the rights in advance, they shall be granted directly to the collaborating party. The VA prefers to use a CRADA only when no other appropriate option is available.

VA Technology Transfer Issues

Although VA does not have an external research program, it has significant interaction with universities because many of the researchers also hold appointments at universities. For those receiving money from their universities under grants and contracts from other agencies, the Bayh-Dole Act may determine the rights to their inventions.

The facts surrounding the making of those inventions determine what type of recognition and return is appropriate. For example, under Bayh-Dole, the inventing university must acknowledge the rights of the Federal government in the patent with the name of the funding agency. The university is required to share royalties with the inventors but not with the funding agency although the university must use the remainder of the royalties for education or scientific purposes.

With the VA's new emphasis on technology transfer over the past two years, the agency has entered into more than 40 Cooperative Technology Administration Agreements (CTAA) with universities. These agreements usually cover the patenting and licensing of inventions made by individuals who have joint appointments at the VA

and a university. By clarifying the rights and responsibilities of the parties, these agreements are intended to facilitate the commercialization of joint inventions.

The issues associated with joint appointments in R&D collaborations, however, are not limited to the VA and so we believe should be addressed more broadly. This VA issue was recently discussed in the IWG on technology transfer and it was discovered that VA is not the only agency that has joint appointments. In addition, the treatment of inventions by university employees who work in Federal laboratories as visiting scientists seems to vary among the agencies. Accordingly, the Department of Commerce is planning to continue the discussion with the interagency group to develop some uniform principles in dealing with inventions by university visiting scientists and "joint" employees without impacting negatively the very successful technology transfer programs at universities under the Bayh-Dole Act. We are planning to ask the IWG to assist in developing a model agreement to cover the administration of such inventions and intend to use VA's CTAA as a point of departure.

Thank you, Mr. Chairman. I appreciate the opportunity to present the views of the Department of Commerce today on intellectual property rights from a technology transfer viewpoint. I will be pleased to answer any questions that you and the other members of the Committee may have.

Statement of
The Honorable Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
On Various Research Issues
before the
Subcommittee on Oversight and Investigations
of the
Committee on Veterans' Affairs
U.S. House of Representatives

September 19, 2002

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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to appear before you to discuss various research and development issues that we understand you are interested in. Specifically, my testimony focuses on the Department of Veterans Affairs (VA) technology transfer program, non-profit research corporations and educational foundations, and human subject protections. With me today are Dr. James F. Burris, Chief Research and Development Officer; Dr. John H. Mather, Chief Officer, Office of Research Compliance and Assurance; Dr. Mindy L. Aisen, Director, Rehabilitation Research and Development Service; and Mr. John A. Bradley, Director of Finance, Office of Research and Development.

1. VA Technology Transfer Program (TTP)

The history of the VA research program is a history of discoveries that have benefited not only veterans but also all American citizens. VA researchers have played key roles in developing the cardiac pacemaker, the CAT Scanner, the Seattle Foot, magnetic resonance imaging, and the nicotine patch. The first liver transplant in the United States was performed at a VA medical facility, and VA researchers pioneered the first successful drug treatments for high blood pressure and schizophrenia.

For many years, VA did not claim ownership rights to the new technologies its researchers developed. As a result, VA facilities and laboratories lost the opportunity to benefit financially from the discoveries they brought to life. Some important VA discoveries that did not capture the interest of private industry were never offered to the general public, despite their benefits to veterans and others. Today, VA takes credit for both the past and the future work of its researchers. If that work results in financial gain, VA uses that gain on behalf of veterans.

To facilitate this vision, the TTP requires that VA assert an ownership interest whenever appropriate, so that VA can build upon its discoveries and ensure access to technologies by veterans. The TTP is committed to supporting the highest quality intramural research program. This means not only moving discovery from the laboratory to clinical practice in a timely manner, but also

assuring that inventors and their host VA medical centers (VAMC) receive optimal advice and support so that they may realize equitable compensation and recognition.

VA operates a substantial research program in connection with the research programs at many of the medical institutions with whom it is affiliated. As a result, many VA researchers also hold academic appointments with VA affiliates. Some of VA's best and most beneficial inventions have come out of this setting, and VA continues to promote this research relationship, as it benefits our veterans and the public generally.

Although VA can assert an ownership right in inventions made by its employees under Executive Order 10096, it cannot, and does not, do so to the exclusion of our university partners or the inventors. Since many of VA's researchers hold dual appointments with VA and a university, VA recognizes that, in such cases, the universities often have an interest in an invention made at a VA facility, leading to joint ownership.

To further enhance cooperation between VA and its research affiliates, and to facilitate the technology transfer process, VA's TTP developed a Cooperative Technology Administration Agreement (CTAA). The first such agreement, developed in collaboration with the University of California, was signed in May 2000 and included all 10 campuses of the University system. This CTAA served as the template for future agreements with other affiliates, but has evolved with input from other research partners. To date, over 50 percent of our major university partners have executed a CTAA with VA. In the absence of a CTAA, VA and an affiliated university would have to negotiate jointly developed technology on a case-by-case basis, a time consuming and expensive process. With a CTAA, an affiliated university will generally take the lead on patenting and commercializing jointly owned inventions.

VA understands that the Bayh-Dole Act has imposed certain requirements and responsibilities on its university research affiliates. VA believes that its own rights, responsibilities, and interests in the operation of a research program are not in conflict with those requirements.

VA has been meeting with members of the Association of American Medical Colleges and the Council on Governmental Relations to discuss VA technology transfer issues. Both organizations expressed general support of the use of the CTAA but also requested that VA consider authorizing variations from the model CTAA as circumstances at individual research universities dictate. VA has provided an updated model CTAA on the Research web site that allows potential partners to select specific language that best suits their particular needs for certain sections of the CTAA. Feedback on this has been very positive. The

website also contains other information to assist partners in understanding this program.

When VA is the sole owner, or the only joint owner with a university partner that does not wish to take the lead in developing an invention, VA may choose to patent and commercialize the intellectual property. In the last two years, nine patent applications have been submitted to the US Patent and Trademark Office (USPTO) for action. An additional five applications are in preparation with contract patent counsel for submission to USPTO. VA has recently concluded its first commercial licensing agreement and will finalize a second agreement this autumn.

VA's intellectual property portfolio has grown steadily from FY 1999 to date, as shown below.

- In FY 1999, VA received 48 invention disclosures and asserted ownership rights on 20. Of those 20 inventions, 12 involved joint ownership where the affiliate assumed the lead. In the remaining eight, VA obtained sole ownership or assumed responsibility as the lead agency. VA retained a government use license in 13 inventions.
- In FY 2000, VA received 85 invention disclosures and VA asserted ownership rights on 51. Thirty-nine (39) involved joint ownership where the affiliate assumed the lead. VA obtained sole ownership or assumed responsibility as the lead agency in the remaining 12. VA retained a government use license in 18 inventions.
- In FY 2001, VA received 132 invention disclosures and asserted ownership rights on 91. Sixty-eight involved joint ownership where the affiliate assumed the lead. In 20, VA obtained sole ownership or assumed responsibility as the lead agency. Three are being handled under public domain processing. VA retained a government use license in 15 inventions.
- In FY 2002 to date, VA has received 115 invention disclosures. VA has asserted ownership rights on 62, 55 of which involved joint ownership where the affiliate assumed the lead. VA obtained sole ownership or assumed responsibility as the lead agency in 7, and none were handled under public domain processing. VA retained a government use license in 7 inventions.

2. Non-profit Research Corporations and Educational Foundations

In 1988, Congress authorized the creation of non-profit research corporations at VAMCs to support the VA research mission. Public Law 106-117 (1999), the Veterans Millennium Health Care and Benefits Act, expanded the authority to create new VA non-profit corporations to support research or education or both. It also authorized existing VA non-profit corporations to expand their mission to include support of education activities as well as

research. Education activities supported by the non-profits may be directed at patients or employees. Such activities include broad instructional learning experiences for veterans and their families that focus on improving and maintaining patient health as well as work-related instruction and training for VA staff.

There are 85 active VA non-profit research corporations and educational foundations (non-profits). These non-profits enable the Department to spend optimally the funds it receives from non-VA sources. The non-profits are not subject to Federal employment regulations or ceilings.

In 2001, non-profits received $179.5 million in donations, grants, and interest for both research and education activities. Non-profits supported almost 4,700 VA-approved projects. Many are medical research clinical trials that focus on conditions prevalent in the veteran population and thus provide a direct benefit to VA patients. Non-profits also provide salary support for clinical research personnel to monitor veteran patients enrolled in clinical trials. These services enable the research participants to receive additional care and attention. In addition, the general public benefits from approval of new treatments that are developed through this research.

Non-profits also enable many facilities to fund essential services. For example, some non-profits, such as the McGuire Research Institute in Richmond, Virginia, are helping facilities meet increasingly complex and stringent human research requirements by hiring research compliance and institutional review board (IRB) staff. Others, such as the Atlanta Research and Education Foundation, have paid for numerous renovation and repair projects, which include the design and remodeling of laboratories. The Indiana Institute for Medical Research has purchased confocal microscopes and other equipment for the Indianapolis VAMC.

In 2001, non-profits managed funds very efficiently, as evidenced by a low administrative overhead rate whose mean and median equaled 11 percent. As a result, 90 percent of all non-profit expenditures directly supported approved research and education. This reflects the sound oversight and management of each board of directors and the dedicated efforts of the non-profit staffs.

VA assigns primary oversight of non-profits to the local facility leadership. The facility director approves all board members and, as required by statute, serves on the board with the facility chief of staff and the associate chief of staff for research/education. A certified public accountant and an external auditor assist each corporation board of directors in their oversight function. In addition, facility directors have at their disposal the same measures to prevent waste, fraud, and abuse in the operations of the VA non-profits as they do for other organizations within their purview. This would include, for example, a request

that the Chief Financial Officer at the facility review certain corporation documents or investigations conducted by the Office of the Inspector General. Non-profits also are subject to audit and inspection by the Internal Revenue Service. They also receive periodic scrutiny by state, city, and other local government agencies.

3. Human Subject Protections

VA is fully committed to protecting those who participate in clinical trials and other research projects. At the previous hearing, I described many of the initiatives that VA has undertaken to ensure that its scientists and research staff fully understand and comply with the stringent ethical principles and rigorous regulatory requirements of our human research protection program. The role of the Office of Research Compliance and Assurance (ORCA) was discussed at the previous hearing. In this statement I will update information previously provided and focus more on the activities of VA's Office of Research and Development (ORD).

During the past three years VA facilities received more than $85 million to support research administrative functions including human subject protections. This funding has permitted facilities to increase staffing, education, resources (such as computers and computer software to allow better tracking and more complete record keeping), and networking among facilities to disseminate best practices and model documents.

This year, ORD is providing over $30 million per year in administrative support funding, and it will make up to an additional $10 million in non-recurring funds available over two years for Institutional Review Board-related proposals.

An important educational tool is the Research and Development Accreditation Consultation Team, or ReDACT. ReDACT offers consultation, coaching and counseling for local IRBs and research personnel. The team consists of experts in human subjects protection and National Committee on Quality Assurance (NCQA) standards, and we expect it to be a key part of VA's effort to protect research participants.

Participants in clinical trials will also benefit from several other initiatives. ORD has collaborated with veterans service organizations to convene focus groups that review informed consent documents and procedures to make the process more understandable and meaningful to potential research participants. Trial investigators must receive formal training in human research protections before submitting research proposals to their IRB for review and approval. In addition, investigators in our Cooperative Studies Program, a program that conducts very large multi-site studies, must attend training in Good Clinical Practices, the international "gold standard" for conducting clinical trials. A Site Monitoring and Review Team (SMART) provides site monitoring and Good

Clinical Practices reviews in an effort to improve the conduct of clinical trials. SMART conducts approximately 125 random and requested site visits per year. VA also ensures that the activities of research personnel comply with applicable medical privacy rules mandated by the Health Insurance Portability and Accountability Act of 1996.

The Handbook on Human Subjects Protection is awaiting final review before being disseminated to the field. The handbook combines the concerted effort of both VA and non-VA experts in the field of human subjects protection to enhance VA policies. Facilities will need virtually no additional time and effort to implement the handbook. The draft handbook has been available on VA's web site throughout its development and many of the new requirements are good clinical practices that the field has begun to adopt. ORD is also developing a Web-based instruction/guidance document on writing informed consent documents. Educational efforts will also be provided through national and regional conferences, programs in conjunction with the ReDACT effort, and national conference calls.

Indicative of the success of these efforts is a recent quality improvement survey that ORD conducted. Ninety-seven percent of responding research subjects agreed with the statement "The Informed Consent process including discussion with study staff gave me the information needed to make an informed decision about whether or not to participate in the study."

At the previous hearing, I discussed at length VA's efforts to accredit its human research protection programs through the National Committee on Quality Assurance (NCQA). As of September 18, 2002, eight additional final reports have been issued, with seven facilities being "Accredited with Conditions," and one site receiving "Not Accredited" status. Cumulatively, 15 facilities have been "Accredited with Conditions," two have received a final result of "Not Accredited," two have received a preliminary result of "Not Accredited," and four sites still await final reports. ORCA is continuing to conduct reviews at these sites.

I also noted that this first-of-its-kind program had temporarily suspended accreditation reviews in order to conduct quality improvement activities, based on the experiences of the first 23 inspections. VA and NCQA have both agreed that the standards needed modification to help streamline the review process and to clarify selected requirements. As a result, NCQA released revised standards for public comment on September 5.

The revised standards reflect Institute of Medicine recommendations encouraging institutions to involve participants in human research programs. NCQA has proposed broadening standards requiring research centers to conduct surveys of participants and potential participants and to use their input to help improve their research and their human subject protection programs. The

standards also promote self-evaluation, through which VA medical centers can analyze and rate their own performance, and continuously improve their research programs.

For the program's second year, NCQA and VA have agreed on an approach to coordinate oversight requirements for VAMCs that use the IRBs of affiliated academic institutions. Under this process, sites that use the IRBs of an academic affiliate accredited by another IRB accounting body, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), will be permitted to undergo a more limited NCQA survey. Upon completion of the survey, NCQA will issue an accreditation decision that combines the results of the NCQA and AAHRPP surveys. NCQA, AAHRPP, and VA will be developing detailed plans to implement the new process in the coming weeks.

Mr. Chairman, this concludes my statement. My colleagues and I will now be happy to answer any questions that you and other members of the Subcommittee might have.

STATEMENT OF
MICHAEL SLACHTA, JR.

ASSISTANT INSPECTOR GENERAL FOR AUDITING
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS

DEPARTMENT OF VETERANS AFFAIRS MEDICAL RESEARCH PROGRAMS

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS

September 19, 2002

Mr. Chairman and Members of the Subcommittee:

I am here today to discuss the results of our work related to nonprofit research and education corporations affiliated with the Veterans Health Administration facilities. Specifically, I will provide:

- Our comments to the Department's updated response to your questionnaire on nonprofit research and education corporations, and
- Summarize our Fiscal Year (FY) 2002 results of onsite reviews we performed at two VA affiliated nonprofit research and education corporations.

The Department's updated submission to the Subcommittee's questions is more responsive. The Department has offered to compile national data on corporate expenditures and fund use. Compiling data nationally will improve visibility over corporate operations and the business relationship these corporations have with VA. It will also improve the ability of the Department to oversee corporate activities and ensure research funds are used only to benefit VA research. Aggregation of revenues and expenditures nationally will also enhance Congressional visibility over corporate activities. The Department should compile:

- "Other donations" such as those made to the General Post Fund,
- Reimbursements made from nonprofit research corporations to the medical care appropriation,
- Medical Centers that were reimbursed and the amount of each reimbursement,
- Research projects terminated in the last five fiscal years, and the reasons for their termination,

- Research projects that were completed in the last five years, and for those completed that had funds remaining, the amount of remaining or unused funds.

The Department also stated that it ... "will instruct its facilities to determine how much of VA approved research funds were administered by VA research corporations". We support that direction and believe the Department should also ensure that work performed by corporations is consistent with national Departmental goals.

In FY 2002, we reviewed operations at two nonprofit research and education corporations. Overall, we concluded that the corporations benefited VA by making available corporate funds to renovate Department research facilities, obtain state-of-the art research equipment, and administer research projects. Nothing came to our attention indicating that controls over expenditure and fund usage at these facilities were inadequate.

However, we believe there are opportunities to further improve oversight and accountability of research and education corporations without losing the flexibilities intended by the Congress when it authorized the establishment of these corporations. In particular, we believe oversight would benefit by:

- Requiring corporations to adopt accrual basis accounting.
- Standardizing financial reporting.
- Establishing a Department office to oversee corporate annual reporting.
- Improving Departmental guidance defining research expenditures.
- Consolidating research corporations, particularly in locations where VA facilities have integrated or merged operations.

Our reviews found that:

- Some corporations use cash-basis or modified cash-basis accounting while others use accrual based accounting. Cash-basis accounting and modified cash-basis accounting are referred to as a comprehensive basis of accounting other than Generally Accepted Accounting Principles (GAAP). We recommend that corporations comply with GAAP accounting and reporting practices to ensure consistent financial reporting to the Congress.
- Standardizing financial reporting will enhance the corporation's ability to identify, charge and recover appropriate overhead costs for the services provided. The independent annual certified financial reports that corporations submit in support of Congressional reporting requirements are not designed to provide the level of detail needed to verify the need and justification of the expenditure.

Standardized financial reporting, beginning with a standardized chart of accounts, would enhance visibility over corporate financial activities.

- Departmental responsibility for collection and summarization of the annual financial and performance information is rotated among VHA research staff, and the information is forwarded without substantive review. We believe the consistency and accuracy of reporting would be improved by assigning responsibility to a VA program office that would review of the information and take appropriate follow-up action to ensure annual reports are accurate, reliable, and complete.

- The Department should look for opportunities to consolidate the number of research corporations, to avoid unnecessary administrative costs, reduce unnecessary infrastructure, and facilitate oversight by reducing the number of corporate entities. The Department has integrated and consolidated many of its health care facility operations, however, similar actions to merge VA research and education corporations have not followed. We feel VA could benefit by initiating a study to assess the feasibility of consolidating the current number of VA entities.

VA research and education corporations provide significant benefits to VA, but improved financial and administrative control can improve oversight and accountability. I will be pleased to answer any questions the committee may have.

United States General Accounting Office

GAO

Testimony

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

For Release on Delivery
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VA HEALTH CARE

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

Statement of Cynthia A. Bascetta
Director, Health Care—Veterans' Health and Benefits Issues

GAO-02-1103T

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

[1]Pub. 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.*

[2]Three 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

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

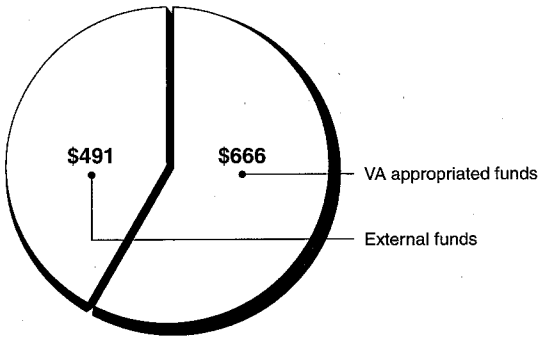
[4]For the past 50 years, many VA medical centers have been affiliated with medical schools for patient care, medical education, research, and sharing of staff and other resources.

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.

[5]Research 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

[6]The 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.

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.

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**

[a]These 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.

[b]These funds are for intergovernmental personnel agreements, which allow temporary reassignment of employees between VA and the nonprofit corporations.

[c]Includes initiatives such as VA/DOD research on post traumatic stress disorder.

[d]This 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

[7]One 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.

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 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 Service[10] regulations, and investigators conducting pharmaceutical

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

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

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

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 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

[11]IRBs 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.

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.

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 statements[12] and management letters[13] 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.

[12]By 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.

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

[14]The 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.

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-122[15] 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.

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

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

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.

NAVREF
National Association of Veterans' Research and Education Foundations
5018 Sangamore Road, Suite 300 Bethesda, MD 20816
301.229.1048 Email: navref@navref.org
FAX: 301.229.0442 Web:www.navref.org

Testimony

Before the

Subcommittee on Oversight and Investigations

Of the

Committee on Veterans Affairs

Regarding the

VA-Affiliated Nonprofit Research and

Education Corporations

September 19, 2002

Presented by

Antonio Laracuente

Chairman

National Association of Veterans'

Research and Education Foundations (NAVREF)

Good morning, Mr. Chairman and members of the Subcommittee on Oversight and Investigations of the Committee on Veterans Affairs. Thank you for the opportunity to present testimony on improving accountability of the VA-affiliated nonprofit research and education corporations. 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-six active VA-affiliated nonprofits.

As you are aware, investigators from the General Accounting Office (GAO) spent the summer conducting in-depth site visits of the foundations in Atlanta, Portland, San Diego, Boston and Indianapolis, and the IG visited two foundations, San Francisco and Palo Alto. Because their findings were not made public in time for me to comment on them before the deadline for written testimony, my statement focuses on my own experience with the GAO auditors and pending legislation that would improve nonprofit accountability: Section 7 of H.R. 3645, and provisions regarding contracting and Federal Tort Claims Act coverage originally contained in S. 2132 that are now in the Senate-passed version of H.R. 3253.

GAO and IG Site Visits

My foundation was the first one the GAO investigators visited. Foundation and medical center staff spent more than 20 hours in focused discussions with the GAO team responding to questions. We arranged briefings with medical center staff including principal investigators, the medical center director, chief of staff and the ACOS R&D, and provided full access to our files. Since ours was the first site, the team began with no prior knowledge of the VA-affiliated nonprofits and being unique, the foundations did not fit into any pre-existing frame of reference. Throughout the visit, we found the auditors to be astute questioners. Ultimately, four themes developed during questioning by the GAO site visitors that I will address in this statement:

1. **Why does VA need the nonprofits?** When I cited the many ways AREF supports the VA research program in Atlanta, the GAO auditors questioned why a nonprofit was needed, maintaining that federal means to accomplish the objective exist. I would be the first to acknowledge that in a

perfect world, there would be no need for the foundations. However, two realities make the foundations necessary:

First, VA funding is inadequate to meet the increasingly complex needs of supporting a research program of the caliber our veterans deserve.

- You heard in testimony in May that the Richmond nonprofit underwrites the entire cost of that medical center's institutional review board to the tune of $600,000 annually.
- As discussed in my April 24 testimony on research facilities, there is no designated VA funding stream to meet the increasingly urgent need for research facility maintenance and improvements. Repeatedly, the foundations are called upon to cover the cost of moving walls, upgrading electrical supply and improving ventilation.
- Appropriated funding to support research related travel simply is not available and last year the foundations expended more than $4 million in travel and related costs so VA investigators could disseminate important research findings, keep current in their fields and interact with their peers.
- Although VA facilities house a significant number of projects administered by affiliated universities, the universities rarely provide support for the VA research infrastructure.

Second, time constraints on research grants require quick turnaround on procurement and flexibility in hiring that cannot be accommodated using federal mechanisms such as the General Post Funds (GPF). Despite changes in the GPF authority that made them more flexible, VA's General Post Funds remain an inadequate, cumbersome and inflexible mechanism to manage private sector and non-VA federal research funds. It is far more efficient and cost effective for a foundation to hire research employees and donate their services to VA, or when appropriate, enter into Intergovernmental Personnel Act assignments. The same goes for procurement. Using private sector funds and non-VA federal grants, nonprofits can purchase goods and services quickly and then can donate them to VA. If Congress eliminated the nonprofits and the funds were managed through the GPF, I can assure you that efficiencies would be lost and ultimately, the funds the nonprofits currently administer would return to universities and the benefits would accrue to the universities, not to the VA research program.

I could give you many more examples, but they would only serve to illustrate my first point: in 1988, Congress recognized the need for a flexible funding mechanism to manage non-VA research funds and the nonprofits have been highly successful in meeting that need.

2. **What rules and regulations apply to the nonprofits?** Accustomed to auditing federal agencies and expenditures of federal funds by other organizations, the GAO site visitors appeared at times uncertain about applicable statutes and regulations for organizations that in most cases administer a mix of non-VA federal and private sector funding. We had some lively discussions when it became apparent that the site visitors were inclined to impose on AREF expenditures the requirements relevant to procurement for federal agencies, hiring federal employees and federal employees' travel. Rather, we must - and do - comply with the regulations that are specific to nonprofits that expend federal funds, OMB Circulars A-133, A-122 and A-110. Also, in the case of expenditures of private sector funds, IRS regulations apply. Nonprofits are **not** required to spend down all the private sector funds they take in, and indeed sound nonprofit management entails maintaining an operating reserve equivalent to at least three months expenses.

   Along the same lines, a nonprofit should not be viewed as deficient if the site visitors conclude that VA's own regulations on conflict of interest disclosure and outside employment are less rigorous than the standards required of GAO investigators. As discussed in my May 16 testimony, the nonprofits are required to follow federal regulations applicable generally to nonprofits as well as a broad array of federal, state and local regulations. At most, nonprofit employees should be held to standards set by VA regarding conflicts of interest.

3. **Are the nonprofits private or federal entities?** NAVREF has long maintained that the nonprofits are private organizations, albeit subject to federal oversight and regulation. The NAVREF view is based on three items:

   - The opening clause of the statute that authorizes the nonprofits clearly states that " . . . any such corporation, and its directors and employees, shall be required to comply only with those Federal laws, regulations and executive orders and directives which apply generally to private nonprofit corporations."
   - Other clauses in the authorizing statute [7366(a)(1)(A) and (B)] assign to the Inspector General responsibilities regarding the nonprofits and specify that nonprofit records shall be made

available to the General Accounting Office. If the nonprofits were federal agencies, there would be no need for the statute to make these points.

- Further, House Report 100-373 which accompanied H.R. 3449, the original nonprofit legislation, states, "These corporations would not be considered for any purposes as corporations owned or controlled by the United States, except for limitations made applicable to these corporations by this Act."

Also, in a letter dated July 17, 2002, VA General Counsel ". . . concluded that it is unclear whether the Economy Act, which our predecessors had relied upon as authorizing OGC to bill the corporations for its legal services, is sound authority for that purpose." As you may be aware, the Economy Act allows one federal agency, or a major organizational unit within an agency, to place an order with and to make a payment to another agency or organizational unit. It is our understanding that GC determined that the nonprofits are not sufficiently federal to allow use of the Economy Act as the basis for billing between VA and the nonprofits. (Note: NAVREF does not object to such billing and urges VA to determine the appropriate mechanism so billing can resume.)

4. **Does VA need 86 nonprofits?** Again and again the GAO site visitors questioned why each VAMC needs its own nonprofit. I am uncertain whether this question was motivated by a desire to have fewer nonprofits to oversee or to engender cost efficiencies. Regardless, my unequivocal answer was "yes." The nonprofit has tremendous value for the research program at each facility. The many advantages of a one-to-one relationship between a VAMC and a nonprofit include:

- Local oversight by the board
- Management that is invested in the success of the medical center's research program
- Responsiveness to facility and individual investigator needs
- On site services resulting in convenience for investigators and quick turnaround on procurement and hiring
- Direct access to the VA personnel and committees who conduct research administered by the nonprofit

The only advantage of consolidating nonprofits that we can envision would be a cost saving on accounting, insurance and some administrative functions, although we are not sure that these would

provide long-term, tangible savings. However, these costs are already minimal and in our view the benefits of the current one-on-one relationship far outweigh the value of the possible savings.

Recommendations Regarding Increased Accountability

NAVREF has given consideration to concerns about accountability expressed by members of the Health and Oversight Subcommittees during the May 16 hearing. I wish to remind the Subcommittee that even though the IG has not been routinely auditing the foundations, the foundations have been subject to many other types of ongoing oversight and review since their inception. As provided in the authorizing statute, our records are open to the IG and GAO at any time. A great deal of information is already provided to VA in the nonprofits' annual reports which include the audit and IRS nonprofit informational return, Form 990. Each board of directors provides continuous, local oversight. And each nonprofit has an independent accountant and auditor. Depending on the nonprofit's revenues and activities, an audit is required every one to three years and the level of scrutiny for those administering federal funds is very high.

That said, the May 16 hearing clarified the Subcommittee's key concerns: 1) No one in VA is responsible for a critical review of the information provided in the annual reports; and 2) The IG has not been conducting routine reviews of the nonprofits. In our view, two pieces of relevant legislation are pending.

1. HR 3645, the *Veterans **Health Care and Procurement** Improvement Act of 2002*, Section 7, ***Improved Accountability of Research Corporations Established at Department of Veterans Affairs Medical Centers.***

   NAVREF has serious concerns about the content of this bill. As passed by the House on July 22, it imposes on the nonprofits numerous burdensome requirements, some of which provide no discernible improvement in accountability. We are dismayed that NAVREF was not made aware that the Chairman planned to introduce legislation affecting the corporations prior to receipt of the GAO report on the corporations and this follow up hearing. We would have been pleased to participate in the development of the original bill, H.R. 5084, and to comment on drafts.

Our detailed comments on the bill passed as section 7 of H.R. 3645 are provided as Attachment A. On July 24, NAVREF representatives met with Subcommittee staff to discuss our concerns. However, because we do not know what changes are under consideration or what may be added as a result of this hearing, our comments in Attachment A are based on Section 7 of H.R. 3645 as passed by the House on July 22.

To summarize our comments, we strongly recommend that at a minimum, H.R. 3645, Section 7 should be amended to accomplish the following:

- Impose on **all** of the VA-affiliated nonprofit research and education corporations a requirement that within three years of enactment, the annual audit conducted in accordance with 38 USC §7366 (b) shall be performed in accordance with generally accepted government auditing standards.
- Require that the Inspector General of the Department of Veterans Affairs shall each year review the most recent audit under 38 USC §7366 (b) of at least 10 percent of the corporations
- Impose on VA a requirement to respond to congressional requests for information about one nonprofit within 30 days and within 90 days for requests requiring compilation of information from all the nonprofits.
- Set a June 1 deadline for the nonprofits' annual reports to VA and an October 1 deadline for the VA report to Congress.

These four items would address the primary concerns expressed by members of the Subcommittee during the May 16 hearing regarding oversight of the corporations. As detailed in Attachment A, the other overly burdensome and costly requirements specified in Section 7 should be eliminated. NAVREF has no objection to increased accountability, but feels the requirements put in place to achieve this objective should be reasonable and purposeful.

2. **H.R. 3253 Department of Veterans Affairs Emergency Preparedness Act of 2002 (Engrossed Amendment as Agreed to by Senate), Sections 401-403 regarding the Research Corporations**

As you may be aware, the Senate-passed version of H.R. 3253 contains three provisions regarding the VA nonprofits that are not contained in the House version. We strongly urge your support for all three, but one in particular, Section 401, greatly increases accountability of transactions between VAMCs and the nonprofits.

Section 401. Modification of Certain Authorities on Research Corporations. Our objective in this item is to once again allow VA medical centers and VA nonprofits to contract with each other just as they would with any other service provider, subject to VA's existing contracting authorities. Such contracts were allowed—and supported by two Office of General Counsel opinions—until December 2001 when General Counsel imposed a blanket prohibition on any contracts between VAMCs and the nonprofits. In Section 401, we are seeking a legislative remedy. As detailed in NAVREF's July 17 letter to you, this provision:

- Clarifies that VA medical centers and NPCs may use VA's existing contracting authorities to acquire research or education services.
- Raises the level of scrutiny of transactions between VAMCs and NPCs.
- Maximizes the benefits of the VAMC/NPC partnership.

We strongly disagree with VA's views on this provision as expressed in General Counsel Tim McClain's written statement before the Senate Committee on Veterans Affairs on May 2.

- A payment pursuant to a VA-approved contract is **not** a "transfer; " it is a fee for a service.
- Contracts executed between VA and a corporation would **not** be "outside the scope of Federal procurement law." Rather, they would be subject to applicable laws, regulations and VA Handbooks, including those pertinent to affiliated institutions under VA's enhanced sharing authority (§8153).
- The nonprofits' primary focus would **not** change - they would remain flexible funding mechanisms to support research and education. Until GC imposed a prohibition on all contracts in December 2001, contracts enhanced the nonprofits' ability to support VA research.

- Because all research projects and education activities supported by the nonprofits must be approved by VA, and contracts under this authority would have to be approved by VA contracting officials, VA would **not** cede control to the nonprofits.

Further, NAVREF has been assured by field contracting officials and VA attorneys that both VA and other federal contracting statutes and regulations are sufficient to manage potential conflicts of interest.

Fees charged by nonprofits under the authority provided in Section 402 are likely to reflect only the foundation's cost of providing the service and would largely be reimbursement. Nonprofits that make a "profit" on an activity are at risk of incurring unrelated business income tax and jeopardizing their tax-exempt status. Therefore, we anticipate that services provided by foundations in support of VA-approved research and education would be both efficient and cost-effective for VA with the added accountability provided by review and approval by VA contracting officials.

A "reimbursement authority" has been suggested in lieu of using VA's existing contracting authorities. However, we feel this would provide less accountability than using VA's existing contracting authorities which have a full body of implementing regulations to ensure adequate controls. Again, we strongly encourage the House to accept the Senate provision regarding contracting between VAMCs and the nonprofits.

Section 402. Coverage of Research Corporation Personnel Under Federal Tort Claims Act and Other Tort Claims Laws. The objective of this provision is to clarify that foundation employees are covered under the Federal Tort Claims Act (FTCA) if they have departmental without compensation (WOC) appointments, work under the supervision of VA employees and perform VA-approved work, subject to certification by the Attorney General.

As you may be aware, in March 2000, the Department of Justice determined that corporation employees are not covered by the FTCA by virtue of their WOC appointments. VA General Counsel strongly disagrees with the Justice position and submitted a formal appeal in October 2001. However, it may take as much as four years to receive a response, and such a response may be negative.

Consequently, NAVREF is seeking a legislative solution and VA supports this remedy. As the Justice letter points out, Congress has extended FTCA coverage to the employees and contractors of a number of organizations that perform government functions or implement government objectives. Since 1989, both VA and the NPCs have been led to believe that NPC employees with WOC appointments working on VA-approved research under the supervision of VA employees would be covered by the FTCA. As a result, an explicit statement to that effect by Congress would impose no new burden on VA or the Department of Justice. Because the VA-affiliated nonprofit research and education corporations exist solely to support the VA research and education missions, in our view it is appropriate to be explicit in providing FTCA coverage to NPC employees engaged in activities that further VA's research and education missions.

Section 403. Permanent Authority for Research Corporations. This provision repeals the sunset clause that prohibits the establishment of new VA-affiliated nonprofits after December 31, 2003. In NAVREF's view, the nonprofits have proven their value to VA and the sunset clause should be eliminated entirely. However, a new expiration date of December 31, 2006 is an acceptable alternative.

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

Attachment A

Summary of NAVREF Comments on Section 7 of H.R. 3645
Discussion of Each Item by Section is Provided on the Following Pages

NAVREF strongly supports:

1. A **phased in** requirement that the annual audit conducted under 38 USC §7366 (b) must be performed in accordance with generally accepted government auditing standards (GAS).
2. A requirement that the Inspector General of the Department of Veterans Affairs shall each year review the most recent audit of at least 10 percent of the corporations.
3. A requirement that VA must respond to congressional requests for information about one nonprofit within 30 days and within 90 days for requests requiring compilation of information from all the nonprofits.
4. A June 1 deadline for the nonprofits' annual reports to VA and an October 1 deadline for the VA report to Congress.

NAVREF strongly opposes:

1. A requirement that compels all of the corporations to establish the calendar year as their business year. *NAVREF supports discretionary business years to allow compliance with multiple federal (not just VA), state and private sector reporting deadlines.*
2. A March 1 deadline for submission of the annual reports to VA. *NAVREF supports a statutory deadline of June 1 consistent with the current VA requirement.*
3. Imposition of an audit on all corporations in accordance with Office of Management and Budget Circular A-133. *NAVREF supports such an audit for the corporations in accordance with the Single Audit Act statutory threshold of $300,000 in federal expenditures for the business year.*
4. Imposition of an annual audit on all corporations with a bank balance of $300,000 at any time during the business year. *NAVREF supports an annual audit for corporations with **revenues** over $300,000 and once every three years for those with **revenues** between $10,000 and $300,000.*

With modifications, NAVREF could support:

1. Submission of a detailed **summary** statement of the operations, activities and accomplishments of the previous business year. NAVREF would be pleased to develop a template.
2. Submission of a description of each **major education** activity supported during the year, provided that an "activity" is defined as a specific education or training action or pursuit costing an aggregate of more than $1,000 during the business year.
3. A requirement that each corporation must report the recipient, amount, and purpose of any **direct** payment made to, or travel support provided for, a member of the board of directors. This should not be in the audit, but could perhaps be reported under 38 USC §7366 (d).

NAVREF supports elimination of the following requirements as duplicative of reporting already available to VA and Congress or as being burdensome without providing useful information:

1. **A statement of the amount of funds controlled as of the first and last day of the year.** This information is provided for the business year in IRS Form 990, Part IV, Line 74, Columns (A) and (B) [Lines 19 and 21 of IRS Form 990 EZ]. *NAVREF recommends adding this item to §7366(d).*
2. **A statement of every source and amount of funds received during the year.** Each corporation reports the contributor and amount of each contribution over $5,000 in Schedule B, *Schedule of Contributors*, of IRS Form 990. Also, a similar requirement is already provided in §7366(d).
3. **An itemized accounting of all disbursements made during the year.** This information is reported by both program and functional category in both the audit and in Part II of IRS Form 990. An itemized list would be hundreds or even thousands of pages long for each corporation.
4. **A description of each research project including the title and purpose.** The corporations already report this information to VA, and it is readily available from VA's RDIS database. A printout would amount to about 4,600 pages.

Detailed NAVREF Comments on Section 7 of H.R. 3645
Approved by the House on July 22

1. SEC. 7 IMPROVED ACCOUNTABILITY OF RESEARCH CORPORATIONS ESTABLISHED AT DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTERS.

Recommendation: Clarify that the requirements apply to both research and education corporations by adding "and education" to the title: **IMPROVED ACCOUNTABILITY OF RESEARCH AND EDUCATION CORPORATIONS ESTABLISHED AT DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTERS.**

2. Provision (a) Audits and Improved Annual Report `(b)(1) ***Not later than March 1 each year,*** **each such corporation shall submit to the secretary a report concerning the preceding calendar year.**

Most of the corporations could not report complete and audited information on a calendar year basis by March 1. While many of the corporations use the calendar year as their business year, they need at least 5 months to clear and reconcile all transactions and for their auditors to perform their work prior to completing IRS Form 990 which is due on the 15th day of the 5th month after the close of the business year. Both the audit and the IRS Form 990 are prerequisites for completing the annual report to VA. Only the eight corporations with business year start dates ranging from April 1 through September 1 could accommodate a March 1 annual report deadline.

Recommendation: Establish a June 1 deadline for the corporations' annual reports to VA, consistent with current VA policy. *"Not later than June 1 each year, each such corporation shall submit to the Secretary a report concerning the corporation's own most recently completed business year."*

3. Provision (a) `(b)(1) Not later than March 1 each year, each such corporation shall submit to the secretary ***a report concerning the preceding calendar year.***

Only 46 NAVREF members use the calendar year as their business year and therefore 38 would be unable to comply with this and other requirements in the bill that are based on the calendar year. Using the discretion allowed by the IRS and to the best of our knowledge, all other federal and state reporting agencies, each corporation has established a business year that meets its individual needs. These include permitting sufficient time after the end of the business year to meet the June 1 annual deadline that has been in effect since the corporations' inception and to meet their accountants' requirements. Business years are also established to accommodate other reporting deadlines – VA, IRS, HHS, state, local, etc., and to avoid conflicts with competing demands on management time.

Some of the corporations that use the calendar year as their business year have had difficulty with the June 1 deadline due to auditor delays and have been advised to consider changing to a July 1 or October 1 business year to allow more time to complete their annual report to VA. At least two of these are in the midst of such a change right now. Congress should be aware that if an organization has changed its business year previously, it must provide substantial justification to the IRS for a second change. Also, when changing business years, a nonprofit incurs the significant expense of performing two audits and completing two IRS Forms 990 in one year as well as making the necessary adjustments in their accounting systems. Regardless of what business year start date a nonprofit uses, it reflects twelve

months of activity. This is a sufficient degree of consistency for every other agency and organization to which the VA nonprofits must report.

Recommendation: Delete all references to "calendar year" and replace them with "business year."

4. Provision `(A) A detailed statement of the corporation's operations, activities, and accomplishments during the preceding calendar year.

This requirement is already contained in §7366(b) of the current statute.

Recommendation: If the corporations' response has been inadequate to date, it may be useful to modify this to state, "A detailed summary of the corporation's operations, activities, and accomplishments during the preceding business year." NAVREF would be pleased to work with Congress to develop a template that meets its needs.

5. Provision `(B) *A description of each research project* or activity for which funds were provided by the corporation during that year or for which funds were provided by the corporation during a preceding year and that is ongoing during the year covered by the report, including, for each such project or activity, *the title of the project* or activity and *a description of the purpose of the project* or activity.

The corporations already provide this information to VA, and it is readily available to Congress from VA's RDIS database. A total printout would amount to approximately 4,600 pages.

Recommendation: If Congress is interested in obtaining this, we recommend adding it to the list of reporting items that VA is required to submit rather than imposing a duplicative burden on the corporations. Note: A list of projects by name and funding source is already required in §7366(d).

5. Provision `(B) A description of each research project or *activity* for which funds were provided by the corporation during that year or for which funds were provided by the corporation during a preceding year and that is ongoing during the year covered by the report, including, for each such project or *activity*, the title of the project or *activity* and a description of the purpose of the project or *activity*.

Clarification of what constitutes an "activity" is needed. The corporations' only "activities" are research and education or training. To date, corporations have reported only research *projects* and education *activities*.

Recommendation: Apply this requirement to major education activities to make it parallel to the research project reporting requirement. "Activity" should be defined as a specific education or training action or pursuit costing an aggregate of more than $1,000 during the business year.

6. Provision `(C) *A statement of the amount of funds controlled by the corporation as of the first day, and as of the last day, of the year covered by the report* and a statement of the amount of funds received, shown by source, during the year.

This information is provided in Part IV of IRS Form 990, Part IV, Lines 74, Columns (A) and (B).

Recommendation: Add this item to the list of reporting requirements in §7366 (d).

7. Provision `(C) A statement of the amount of funds controlled by the corporation as of the first day, and as of the last day, of the year covered by the report and *a statement of the amount of funds received, shown by source, during the year.*

Every nonprofit reports the name of each contributor of over $5,000 during the business year, and the amount contributed, in Schedule B, Schedule of Contributors, of IRS Form 990.

Please note that section §7366 (d) (2) (B)-(D) in the existing statute already requires information about nongovernmental contributions by source and amount, exceeding a $25,000 threshold. In our view, it would make sense to consolidate these requirements.

Recommendation: Congress should accept the IRS threshold and definition of "source" as "contributors." This item should be deleted from the bill because the information is already reported in the IRS Form 990 that is a component of the corporations' annual reports to VA.

8. Provision `(D) An itemized accounting of all disbursements made during the year.

An itemized accounting of all disbursements made during the year would amount to hundreds, or even thousands, of pages of relatively meaningless and repetitive information for each corporation that would be cumbersome if not impossible to search for specific information. The same information is reported in summary form by program and functional category in both the audit and in Part II of IRS Form 990. If the IG or Congress wanted an itemized accounting of a specific disbursement, or a single category of disbursement, it could be provided by the corporation on request. However, Congress should be aware that even the most sophisticated accounting systems provide space for just a few key words to identify disbursements. Please note that the NPCs already report the payee and amount of payments over $35,000 in §7366(d).

Recommendation: Delete this item entirely.

9. Provision `(2) A corporation with a balance of funds under its control in excess of $300,000 at any time during a calendar year shall obtain an audit of the corporation for that year.

This represents a significant change from the current requirement for an audit on the basis of **revenues** as reported on Line 12 of IRS Form 990 [see §7366(b)]. NAVREF anticipates that this change would require annual audits for twelve corporations that currently obtain one every three years. This represents a significant unanticipated and unbudgeted expense for these small corporations, with little net gain in increased oversight.

Recommendation: Preserve the current annual audit threshold of $300,000 in revenues.

10. Provision "(2) . . . The report on any such audit shall specifically state whether the corporation audited made any payment, or provided any travel, during the period covered by the audit to a member of the board of directors of the corporation and, if so, the amount and recipient of any such payment or travel.

A report of payments made to individual board members is not an appropriate item for an audit and is not included in any of the audit SOPs we reviewed. Nonprofits already report payments for

"compensation," "expenses" and "allowances" for services as board members in Part V of IRS Form 990.

Recommendation: If Congress wants additional information about payments made to board members, we feel this would be best accomplished as a new reporting item under 7366(d) and described as a requirement that each corporation must report the recipient, amount, and purpose of any **direct** payment made to, or travel support provided for, a member of the board of directors. This should not be in the audit, but could perhaps be reported under 38 USC §7366 (d). If necessary, the IG could be tasked with reviewing this information outside the audit.

11. Provision `(3) *Any audit under paragraph (2) shall be performed by an independent auditor and shall be performed in accordance with generally accepted Government auditing standards* and in accordance with Office of Management and Budget Circular A-133.

NAVREF supports imposing on all of the corporations the requirement that their audits must be conducted in accordance with generally accepted government auditing standards (GAS or GAGAS) provided that the requirement is phased in over three years. This type of audit has the particular advantage of testing the organization's internal controls, but requires an auditor who specializes in nonprofit auditing and has specific training in GAS audit requirements. As a result, those corporations that have not yet been required to have GAS audits may have to terminate their engagements with their current auditors and conduct a search for a new auditor with specialized skill sets. Also, they would need time to ensure that they have the systems in place required to meet the GAS criteria. Finally, we anticipate that depending on locality and volume of transactions, this type of audit will cost $1,000-5,000 more than a standard nonprofit audit so the corporations would need time to budget for the additional expense.

Recommendation: Provide a three-year phase in period for GAS audits.

12. Provision `(3) Any audit under paragraph (2) shall be performed by an independent auditor and shall be performed in accordance with generally accepted Government auditing standards and in *accordance with Office of Management and Budget Circular A-133.*

NAVREF opposes any requirement that appears to impose an A-133 audit on all of the corporations for the following reasons:

1. By statute (The Single Audit Act), an A-133 audit is required only of nonprofits that expend at least $300,000 in federal funds during the year. This provision would create a statutory conflict.
2. This threshold was raised in 1997 specifically because agencies recognized that it was not cost effective to impose an A-133 audit on nonprofits with lower levels of federal expenditures.
3. Some corporations receive and expend no federal funds. The A-133 audit requirements are designed to test compliance with the cost principles of the granting agency and applicable regulations. When there is no cognizant agency, there are no applicable cost principles or regulations to test.

Approximately twenty-five of the corporations already undergo annual A-133 audits. For the others, a sufficiently raised degree of scrutiny is provided by imposing a GAS audit on all of the corporations, a move NAVREF supports.

If NAVREF has misunderstood provision (3) and the Committee simply wishes to reiterate the OMB requirement for nonprofits with more than $300,000 in federal expenditures, NAVREF still recommends deleting *"and in accordance with Office of Management and Budget Circular A-133"* as superfluous.

Recommendation: Delete *"and in accordance with Office of Management and Budget Circular A-133."*

13. Provision `(4) The Inspector General of the Department shall each year review the most recent audit under paragraph (2) of not less than 10 percent of the corporations described in the first sentence of paragraph (2) and not less than 10 percent of the corporations described in the second sentence of that paragraph. As part of such review, the Inspector General shall determine whether the audit was carried out in accordance with generally accepted Government auditing standards, as required by paragraph (3).".

Recommendation: NAVREF supports this requirement, but recommends that the basis for the two categories should be $300,000 in revenues as discussed above.

14. Provision (b) Annual Report of Secretary (B)(ii) by inserting after the first sentence the following new sentence: "Each such report shall be based on the annual reports submitted by the corporations to the Secretary under section §7366(b) of this title and shall be submitted not later than *May 1* of the year following the year covered by such reports.'; and

Given that it is possible for only a few corporations to comply with a March 1 deadline, VA could not meet a May 1 deadline. VA can best speak for itself as to what would be a reasonable deadline. However, the VA report to Congress requires careful compilation of a great deal of information. We anticipate that an October 1 deadline would be more reasonable.

Recommendation: Consult with VA to determine a mutually agreeable deadline.

Please note:

Some of the new items that corporations would be required to report to VA have not been incorporated in the VA's report to the Committees nor has anyone at VA been tasked with reviewing them. See attached table. If that was the Committee's intent, we question the purpose and value of the new reporting requirements. Finally, some of the new requirements described as "statements" may be more efficiently provided as items in §7366 (d).

Additional comments:

1. The Inspector General citation in §7366(a)(1)(B) appears to be out of date and should be updated.

2. NAVREF recommends adding to §7366 a new requirement that VA must respond to congressional requests for information about one nonprofit within 30 days and within 90 days for requests requiring compilation of information from all the nonprofits.

3. On previous occasions, NAVREF has brought to the attention of Congress that §7366 (c)(2) could be misinterpreted to impose on the corporation executive director the impossible burden of certifying that every director, employee and VA employee associated with the corporation is in compliance with federal statutes and regulations pertaining to conflicts of interest. As far as we

have been able to determine, no federal agency expects one employee to certify another's compliance with federal ethics regulations, and nor should corporation employees. We feel the executive director should be responsible for ensuring that corporation employees are trained in federal ethics regulations and should respond appropriately upon identifying violations. However, he/she cannot certify an employee's across-the-board compliance.

When this provision was last revised in 1996, the objective was to have the executive director **verify** that each employee, etc., has certified that he or she is aware of and in compliance with such federal statutes and regulations. This was designed to allow the executive director to sign just one verification, eliminating the need for the executive director to forward to VA annually each employee's ethics certification statement.

Current Statute:

§7366 (c) Each member of the board of directors of a corporation established under this subchapter, each employee of such a corporation, and each employee of the department who is involved in the functions of the corporation during any year

(1) shall be subject to federal laws and regulations applicable to Federal Employees with respect to conflicts of interest in the performance of official functions and

(2) shall submit to the Secretary a statement *signed by the executive director of the corporation certifying that each director and employee is aware of and has complied with such laws and regulations in the same manner as Federal employees are required to.*

Clarifying Revision:

§7366 (c) Each member of the board of directors of a corporation established under this subchapter, each employee of such a corporation, and each employee of the department who is involved in the functions of the corporation during any year shall be subject to federal laws and regulations applicable to Federal Employees with respect to conflicts of interest in the performance of official functions. *Annually, each corporation shall submit to the Secretary a statement signed by the executive director of the corporation verifying that each director and employee has certified awareness of and compliance with such laws and regulations in the same manner as Federal employees are required to.*

Existing Statute Source or Other Source Document	Current NPC Reporting Requirements		Proposed Statute Section 7 of HR 3645	Proposed NPC Reporting Requirement (Sec. 7, HR 3645)	Submitted to VA	Designated reviewer	Submit. to Congress by VA	NAVREF Recommendations
§7366 (b)	Detailed statement of corporations operations, activities and accomplishments during that year	*	§7366 (b) 1A	Detailed statement of corporation's operations, activities, and accomplishments during preceding calendar year	yes		no	Detailed **summary** of the corporation's operations, activities, and accomplishments during the year - NAVREF would be pleased to develop a template.
§7366 (c) 2	Each member of the board of directors of the corporation established under this subchapter, each employee of such a corporation, and each employee of the department who is involved in the functions of the corporation during any year 1) shall be subject to federal laws and regulations applicable to Federal Employees with respect to conflicts of interest in the performance of official functions and 2) shall submit to the Secretary a statement signed by the executive director of the corporation certifying that each director and employee is aware of and has complied with such laws and regulations in the same manner as Federal employees are required to.	*	§7366 (c) 2	Same	yes		no	Each member of the board of directors of a corporation established under this subchapter, each employee of such corporation, and each employee of the department who is involved in the functions of the corporation during any year 1) shall be subject to federal laws and regulations applicable to Federal Employees with respect to conflicts of interest in the performance of official functions and 2) **shall annually submit to the Secretary a statement signed by the executive director of the corporation verifying that each director and employee has certified awareness of and compliance with such laws and regulations in the same manner as Federal Employees are required to.**
VHA Handbook 1200.17	By policy, annual reports due June 1 to VA Office of Research and Development and Office of Academic Affairs concerning preceding fiscal year	*	§7366 (b) 1	Annual Report due March 1 to Secretary concerning the preceding calendar year	yes		yes	1) Annual Report due June 1 to Secretary. 2) NAVREF supports discretionary business years to allow compliance with multiple federal (not just VA), state and private sector reporting deadlines.
VHA Handbook 1200.17	A list of the research projects supported by the NPC is submitted in the annual report	*	§7366 (b) 1B	Description of each research project, title and purpose	yes		no	Delete - information readily available from VA's RDIS database. A total printout would amount to approximately 4,600 pages. Note: A list of projects by name and funding source is already required in §7366 (d) of existing statute
VHA Handbook 1200.17	A list of education activities supported by the NPC is submitted in the annual report		§7366 (b) 1B	Description of each activity, title and purpose	yes		no	Keep proposed change provided that "activity" is applied to **major** education activities and "activity" is defined as a specific education or training action or pursuit, costing an aggregate of more than $1,000 during the fiscal year.
IRS Form 990	Listed on IRS Form 990, Part IV, Lines 45-74 columns A and B	*	§7366 (b) 1C	Statement of amount of funds controlled by corporation on 1st and last day of the year	yes		no	Move to §7366 (d) of existing statute - Note: NPCs report this information on IRS Form 990 or 990 EZ
IRS Form 990 and VHA Handbook 1200.17	NPCs report contributors of $5,000 or more, by source, on IRS Form 990, Schedule B, Contributors of $25,000 or more (§7366 (d)2D), by source, in annual report to VA	*	§7366 (b) 1C	Statement of amount of funds received, shown by source	yes		yes	Delete. Each NPC reports the amount and name of each contributor over $5,000 during the fiscal year in Schedule B, *Schedule of Contributors*, of IRS Form 990. Note: proposed requirement conflicts with similar requirement provided in §7366 (d)2D.
IRS Form 990 and VHA Handbook 1200.17	Expenses reported by function and program in audit and IRS Form 990, Part II. Disbursements of $35,000 or more, by payee, in annual report to VA (§7366 (d))	*	§7366 (b) 1D	Itemized accounting of all disbursements	yes		no	Delete. Itemized accounting of all disbursements would amount to hundreds/thousands of pages of documentation per NPC. Information is already reported by both program and functional category in both the audit and in Part II of IRS Form 990. Note: NPCs report payee and amount of payments over $35,000 in §7366 (d) of existing statute.
§7366 (b)	Most recent audit included in corporation's annual report to the Secretary	*	§7366 (b) 1E	Most recent audit included in corporation's annual report to the Secretary	yes		no	Concur
			§7366 (b) 1F	Other information as may be necessary to enable the Secretary to prepare the annual report to congressional committees	yes		no	Concur

* Identical or similar information provided in current annual reports submitted to VA or in IRS Form 990

9/12/02

Existing Statute Section or Other Source Document	Current NPC Reporting Requirements		Proposed Statute Section 7 of HR 3645	Proposed NPC Reporting Requirement (Sec. 7, HR 3645)	Submitted to VA	Designated reviewer	Submit. to Congress by VA	NAVREF Recommendations
§7366 (b)	Annual audit for corporations with revenues greater than $300,000; at least every 3 years for corporation with revenues between $10,000 and $300,000		§7366 (b) 2	Annual audit for corporations with a balance of funds in excess of $300,000 during the calendar year; at least every 3 years for any other corporation	yes		no	Keep current criteria - NAVREF supports an annual audit for NPCs with **revenues** over $300,000 and once every three years for those with lower **revenues.**
IRS Form 990	Payments made to board members reported on IRS Form 990, Part V	*	§7366 (b) 2	Identify board members who received payments or travel support: provide name and amounts	yes		no	Report amount and payee of compensation and reimbursements paid directly to board members. Move to §7366 (d) of existing statute.
			§7366 (b) 3	Audit in accordance with generally accepted Government auditing standards			N/A	Annual audit performed in accordance with generally accepted Government auditing standards required **with a phase in period of three years.**
Single Audit Act of 1999 Public Law 104-156	Corporations with less than $300,000 in Federal expenditures are exempt from audits under A-133. Corporations with $300,000 or more in Federal expenditures conduct audits accordingly		§7366 (b) 3	Audit in accordance with Office of Management and Budget Circular A-133			N/A	Delete. NAVREF supports an A-133 audit for NPCs in accordance with OMB threshold of $300,000 in federal expenditures for the year.
			§7366 (b) 4	IG review of 10% of audits of NPCs with balance of funds in excess of $300,000 during the calendar year and 10% of audits of NPCs with balance of funds less than $300,000 during the calendar year		VA IG	no	IG review audits of 10% NPCs with $300,000 in **revenues** during the preceding fiscal year and 10% of NPCs with less than $300,000 in **revenues** during the preceding fiscal year.
			§7366 (b) 4	IG determination of whether the audit was carried out in accordance with generally accepted Government auditing standards		VA IG	no	Concur
§7366 (d) 1	Location of each corporation	*	§7367 (a) 1	Same	yes		yes	None
§7366 (d) 2A	Total amount received by corporation	*	§7367 (a) 2A	Same	yes		yes	None
§7366 (d) 2B	Total amount received from governmental entities for research	*	§7367 (a) 2B	Same	yes		yes	None
§7366 (d) 2B	Total amount received from governmental entities for education	*	§7367 (a) 2B	Same	yes		yes	None
§7366 (d) 2C	Total amount received from all other sources for research	*	§7367 (a) 2C	Same	yes		yes	None
§7366 (d) 2C	Total amount received from all other sources for education	*	§7367 (a) 2C	Same	yes		yes	None
§7366 (d) 2D	Source of funds, if amount received from a non-governmental entities exceeded $25,000	*	§7367 (a) 2D	Same	yes		yes	None
§7366 (d) 3	Total amount expended by each corporation	*	§7367 (a) 3	Same	yes		yes	None
§7366 (d) 3A	Total amount expended for salary for research staff	*	§7367 (a) 3A	Same	yes		yes	None
§7366 (d) 3A	Total amount expended for salary for education staff	*	§7367 (a) 3A	Same	yes		yes	None
§7366 (d) 3A	Total amount expended for salary for support staff	*	§7367 (a) 3A	Same	yes		yes	None
§7366 (d) 3B	Total amount expended for direct support of research	*	§7367 (a) 3B	Same	yes		yes	None
§7366 (d) 3B	Total amount expended for direct support of education	*	§7367 (a) 3B	Same	yes		yes	None
§7366 (d) 3C	Name of payee if amount expended exceeded $35,000.	*	§7367 (a) 3C	Same	yes		yes	None
§7366 (d) 4	Total amount expended by each corporation for travel conducted in conjunction with research	*	§7367 (a) 4	Same	yes		yes	None
§7366 (d) 4	Total amount expended by each corporation for travel conducted in conjunction with education	*	§7367 (a) 4	Same	yes		yes	None

* Identical or similar information provided in current annual reports submitted to VA or in IRS Form 990

9/12/02

Statement of Henry G. Kirschenmann, Jr.
Before the Subcommittee on Oversight and Investigations
Committee on Veterans Affairs
U.S. House of Representatives
September 19, 2002

I was engaged by the Veterans Health Administration to identify the indirect costs associated with its research function and to calculate the indirect cost rates that would apply to its research grants. More specifically, I calculated indirect costs especially associated with National Institutes of Health (NIH) grants, and determined that the average indirect cost rate for those grants is 23.52%. I submitted my calculations in May 2002. I am here to respond to questions which you my have about the rationale behind the rates or the calculation itself.

In identifying the research costs and calculating the rates, I followed the costing concepts and guidance contained in the Cost Accounting Handbook of the Department of Veterans Affairs and the several documents issued by the Office of Management and Budget, specifically, a) Statement Number 4, Managerial Cost Accounting Concepts and Standards for the Federal Government, issued by the Federal Financial Accounting Standards Board, b) the Circulars A-21, A-122, A-87, and c) The Federal Acquisition Regulations (FAR). The Circulars govern the costing of research and other Federally supported programs at universities, other non-profit institutions, and state and local governments, respectively. The Federal Acquisition Regulations govern the costing of federally supported projects conducted by commercial organizations. The guidance contained in these publications conforms to Generally Accepted Accounting Principles and are consistent with each other. In my opinion application of the guidance contained in those documents results in indirect cost rates that reasonably reflect the costs of performing research. I also consulted OMB Circular A-25, which establishes Federal policy regarding user charges to be assessed by Government agencies for the use or sale of their services or goods. The guidance for determining the costs of such services and goods is consistent with the guidance in the documents I have just cited. Again, the rates I calculated conform to the costing and charging concepts contained in that Circular.

The critical concept contained in all of these documents is that of benefit. That is, an activity must provide benefit to a project for its associated costs to be recognized as a charge against it. All the costs included in my rate calculations meet those criteria.

The methodology I followed in identifying the indirect costs related to the research conducted by the Veterans Health Administration and to calculate the rates conform to the costing concepts contained in these cited documents with two exceptions. The rates I have calculated do not include amounts for the depreciation or a use allowance for VHA buildings and equipment used in the conduct of the research as provided for in all the cited documents or a rate of return factor on these assets as provided for in the FAR and recommended in Circular A-25. Additionally, There were other costs, which might be argued to benefit the research that the Veterans Health Administration opted not to include in the interest of conservatism. Thus, it is my opinion that the calculated rates themselves are conservative.

VETERANS HEALTH ADMINISTRATION
Indirect Cost Rate Calculation & Rates
Applicable to Research Projects
Based on Fiscal Year 2000 Costs

INTRODUCTION

The Veterans Health Administration (VHA), a major component of the Department of Veterans Affairs, performs research at more than eighty-five medical centers throughout the nation. This research is funded through separate annual Congressional appropriations for Medical Care and for Research, from grants and other awards from Federal agencies, principally the National Institutes of Health and the Department of Defense, and from other sources.

Indirect cost rates are calculated herein for each Medical Center, for each Veterans Integrated Services Network (VISN), and for the VHA as an entity.

There is scant Government-wide guidance on the costing of research or other programs performed by Federal agencies. There is guidance for the costing of research and other functions conducted by state and local governments, colleges and universities, other nonprofit organizations and commercial organizations. That guidance is found in the Federal cost principals issued by the Office of Management and Budget and the Federal Acquisition Regulations (FAR) issued by the General Services Administration - Circulars A-87, A-2I, A-110, and FAR Part 31, respectively. There is also guidance in the VA Cost Accounting Handbook and the guidelines contained in Provision 6.d.1 of OMB Circular A-25 (Revised) concerning fees assessed for Government services or use of Government goods or resources. The methodology used to calculate the rates contained herein conforms with the costing concepts contained in these documents. There is one exception: the calculation does not include depreciation/use allowances on buildings and equipment used in the performance of the research as permitted in all of the Circulars and in the FAR nor a rate of return on these assets as recognized in the FAR and recommended under Circular A-25. The critical concept contained in all of these documents is that of benefit; a cost must benefit a project for it to be recognized as a charge against it. All the costs included in the rate calculations meet those criteria.

THE RATE CALCULATION

On-site and off-site indirect cost rates have been calculated for each Medical Center, for each Veterans Integrated Services Network (VISN), and for the VHA as an entity. Rates have also been calculated for NIH sponsored projects conducted on site but largely administered by universities affiliated with the medical centers. The rates are calculated as a percentage of the total direct costs applicable to the research activities.

The on-site NIH rates are a recognition that certain projects, while conducted at VA facilities, are largely under the administrative direction of the affiliated universities and hence benefit from a lesser amount of medical center administrative costs reflected in Schedule II.

The medical center administrative support costs are apportioned based on total direct costs, the facilities costs are apportioned based on space usage.

Total direct research costs are those costs directly associated with research projects and funded thru the Research appropriation plus 20% of the salaries of the Medical Care professional Staff. The 20% factor reflects the research related salaries of medical professionals who are paid through the Medical Care appropriation.

SCHEDULE I

VETERANS HEALTH ADMINISTRATION
Indirect Cost Rates Calculation
VISN/Medical Centers
Fiscal Year 2000

VISN/Med Ctrs	VA Hdqtrs	VHA Central Office	VISN	Medical Center Administrative	Medical Center NIH	Medical Center Facilities	Total (1)	Direct Costs	IDC Rates Full On-Site	IDC Rates NIH On-Site
Total	14,470,911	15,456,613	5,678,591	113,295,640	33,537,776	78,570,905	227,472,660	623,680,771	36.47%	23.68%
VISN 1	1,123,200	1,199,708	630,337	9,176,410	2,806,150	4,171,045	18,300,699	48,408,704	33.87%	20.51%
405 White River Junction, V	98,921	105,659	55,514	882,492	222,502	532,951	1,675,538	4,263,399	39.30%	23.82%
518 Bedford, MA	147,860	157,932	82,979	1,184,085	486,636	348,147	1,921,003	6,372,620	30.14%	19.20%
523 Boston, MA	418,821	447,349	235,041	3,294,364	1,007,678	1,169,809	5,565,384	18,050,722	30.83%	18.16%
608 Manchester, NH	33,896	36,205	19,022	185,822	83,479	94,903	369,848	1,460,882	25.32%	18.31%
650 Providence, RI	65,067	69,499	36,515	593,786	129,371	411,204	1,176,072	2,804,319	41.94%	25.38%
689 West Haven, CT	358,634	383,063	201,265	3,035,861	876,484	1,614,031	5,592,855	15,456,761	36.18%	22.21%
VISN 2	303,792	324,485	169,608	2,097,055	568,800	1,488,733	4,383,673	13,093,099	33.48%	21.81%
500 Albany, NY	100,776	107,641	56,264	685,621	250,674	616,457	1,566,759	4,343,354	36.07%	26.06%
528 Buffalo, NY	107,152	114,451	59,824	813,497	159,687	531,723	1,626,647	4,618,142	35.22%	21.07%
670 Syracuse, NY	95,863	102,393	53,521	597,937	158,439	340,553	1,190,267	4,131,603	28.81%	18.17%
VISN 3	713,684	762,298	762,294	5,329,499	1,508,459	7,689,007	15,256,782	30,759,029	49.60%	37.18%
526 Bronx, NY	121,499	129,775	129,775	930,947	336,846	2,296,544	3,608,540	5,236,489	68.91%	57.57%
561 East Orange, NJ	169,673	181,231	181,230	1,429,001	244,011	1,972,778	3,933,913	7,312,734	53.80%	37.59%
630 New York, NY	311,809	333,048	333,046	2,135,781	681,281	2,831,158	5,944,842	13,438,628	44.24%	33.41%
632 Northport, NY	110,703	118,244	118,243	833,770	246,321	588,527	1,769,487	4,771,178	37.09%	24.77%
VISN 4	514,835	549,903	257,192	3,127,734	1,156,041	1,855,099	6,304,763	22,188,818	28.41%	19.53%
542 Coatesville, PA	34,498	36,847	17,234	324,590	81,249	693,364	1,106,533	1,486,810	74.42%	58.06%
642 Philadelphia, PA	213,167	227,687	106,490	1,339,282	493,485	547,780	2,434,407	9,187,271	26.50%	17.29%
646 Pittsburg, PA	267,170	285,368	133,468	1,463,862	581,307	613,955	2,763,824	11,514,737	24.00%	16.34%
VISN 5	515,690	550,817	89,960	3,342,494	807,714	1,404,979	5,903,941	22,225,702	26.56%	15.61%
512 Baltimore, MD	303,170	323,821	52,887	2,243,378	451,099	540,830	3,464,087	13,066,321	26.51%	12.79%
688 Washington, DC	212,520	226,996	37,073	1,099,116	456,615	864,149	2,439,854	9,159,381	26.64%	19.62%
VISN 6	537,176	573,766	122,858	4,833,993	1,293,258	1,837,024	7,904,618	23,151,707	34.14%	18.85%
558 Durham, NC	323,536	345,574	73,876	3,461,126	835,251	1,184,887	5,389,000	13,944,073	38.65%	19.82%
590 Hampton, VA	58,368	62,344	13,328	383,766	143,549	116,102	633,907	2,515,591	25.20%	15.65%
652 Richmond, VA	155,272	165,848	35,455	989,101	314,458	536,035	1,881,710	6,692,042	28.12%	18.04%
VISN 7	876,787	936,510	303,398	6,046,791	1,636,696	3,847,330	12,010,815	37,788,584	31.78%	20.11%
508 Atlanta, GA	366,074	391,009	126,673	2,362,879	586,514	1,210,069	4,476,704	15,777,383	28.37%	16.99%
509 Augusta, GA	112,799	120,483	39,032	803,635	233,980	605,390	1,681,339	4,861,524	34.58%	22.87%
521 Birmingham, AL	157,733	168,478	54,581	1,172,603	256,307	423,336	1,976,731	6,798,138	29.08%	15.60%
534 Charleston, SC	146,121	156,074	50,562	768,898	360,153	1,424,124	2,565,779	6,297,644	40.74%	33.93%
544 Columbia, SC	72,739	77,694	25,170	636,500	153,545	160,665	972,768	3,134,979	31.03%	15.62%
679 Tuscaloosa, AL	21,321	22,773	7,378	262,276	46,197	23,746	337,494	918,915	36.73%	13.21%
VISN 8	940,677	1,004,752	167,778	8,224,221	2,359,013	3,552,420	13,889,848	40,542,165	34.26%	19.79%
516 Bay Pines, FL	145,334	155,234	25,922	1,068,773	266,464	286,300	1,681,563	6,263,751	26.85%	14.04%
546 Miami, FL	171,305	182,973	30,554	2,278,751	409,095	810,992	3,474,575	7,383,048	47.06%	21.74%
573 Gainesville, FL	203,483	217,344	36,293	1,983,051	687,821	1,289,274	3,729,445	8,769,907	42.53%	27.76%

VETERANS HEALTH ADMINISTRATION
Indirect Cost Rates Calculation
VISN/Medical Centers
Fiscal Year 2000

VISN/Med Ctrs	VA Hdqtrs	VHA Central Office	VISN	Medical Center Administrative	Medical Center NIH	Medical Center Facilities	Total (1)	Direct Costs	IDC Rates Full On-Site	IDC Rates NIH On-Site
659 Salisbury, NC	55,626	59,415	9,921	421,760	93,553	95,695	642,418	2,397,432	26.80%	13.11%
672 San Juan, PR	137,339	146,694	24,496	1,145,145	487,964	308,961	1,762,634	5,919,148	29.78%	18.68%
673 Tampa, FL	227,590	243,092	40,593	1,326,741	414,116	761,198	2,599,214	9,808,879	26.50%	17.19%
VISN 9	733,337	783,290	438,491	5,701,124	1,725,967	3,180,412	10,836,654	31,606,059	34.29%	21.71%
581 Huntington, WV	42,117	44,986	25,735	404,394	107,966	630,132	1,147,363	1,815,184	63.21%	46.88%
596 Lexington, KY	119,601	127,748	73,092	913,185	283,408	424,574	1,658,199	5,154,666	32.17%	19.95%
603 Louisville, KY	99,782	106,578	60,970	967,137	324,125	371,546	1,608,013	4,300,481	37.34%	22.39%
614 Memphis, TN	190,289	203,251	106,659	1,376,324	370,150	608,398	2,484,921	8,201,258	30.30%	18.03%
621 Mountain Home, TN	78,623	83,979	48,041	572,198	189,214	87,796	870,637	3,388,572	25.69%	14.39%
626 Nashville, TN	202,926	216,749	123,994	1,467,886	451,104	1,057,966	3,069,521	8,745,898	35.10%	23.47%
VISN 10	523,149	558,784	211,838	4,092,482	960,592	1,523,857	6,910,111	22,547,182	30.65%	16.76%
539 Cincinnati, OH	147,700	157,760	59,808	1,869,194	117,720	469,587	2,704,049	6,365,691	42.48%	14.96%
541 Cleveland, OH	290,829	310,639	117,765	1,665,288	720,397	966,707	3,351,229	12,534,427	26.74%	19.20%
552 Dayton, OH	84,621	90,385	34,265	558,000	122,475	87,563	854,834	3,647,064	23.44%	11.50%
VISN 11	542,378	579,323	326,975	4,263,332	1,347,314	2,393,098	8,105,106	23,375,926	34.67%	22.20%
506 Ann Arbor, MI	233,658	249,574	140,862	1,813,049	628,412	915,435	3,352,577	10,070,404	33.29%	21.53%
553 Detroit, MI	141,255	150,877	85,156	1,078,047	347,712	499,775	1,955,110	6,087,939	32.11%	20.12%
583 Indianapolis, IN	167,465	178,873	100,957	1,372,236	371,190	977,888	2,797,419	7,217,583	38.76%	24.89%
VISN 12	855,931	914,233	262,393	7,278,876	1,728,980	4,563,513	13,874,946	36,889,691	37.61%	22.57%
537 Chicago, IL	259,547	277,226	79,566	2,944,958	576,839	1,289,735	4,851,032	11,186,182	43.37%	22.20%
578 Hines, IL	318,077	339,743	97,509	2,196,194	634,168	1,413,566	4,365,089	13,708,770	31.84%	20.45%
607 Madison, WI	87,013	92,940	26,675	870,620	130,753	734,389	1,811,637	3,750,166	48.31%	28.58%
695 Milwaukee, WI	191,294	204,324	58,643	1,267,104	387,200	1,125,823	2,847,188	8,244,573	34.53%	23.86%
VISN 13	364,382	389,202	49,386	2,341,581	792,721	1,267,014	4,411,565	15,704,477	28.09%	18.23%
437 Fargo, ND	37,676	40,243	5,106	330,730	84,947	12,537	426,293	1,623,816	26.25%	11.12%
618 Minneapolis, MN	326,706	348,959	44,279	2,010,851	707,774	1,254,477	3,985,272	14,080,661	28.30%	19.05%
VISN 14	262,841	280,745	40,280	2,933,832	531,357	1,527,134	5,044,832	11,328,172	44.53%	23.33%
584 Iowa City, IA	195,538	208,858	29,966	2,088,522	405,672	1,011,267	3,534,151	8,427,487	41.94%	21.97%
636 Omaha, NE	67,303	71,887	10,314	845,310	125,685	515,867	1,510,681	2,900,685	52.08%	27.27%
VISN 15	314,614	336,045	160,107	2,356,014	496,227	1,962,762	5,129,542	13,559,541	37.83%	24.11%
452 Wichita, KS	22,254	23,770	0	114,514	44,113	94,881	255,419	959,135	26.63%	19.29%
543 Columbia, MO	65,762	70,241	36,014	532,953	108,389	441,710	1,146,680	2,834,263	40.46%	25.48%
589 Kansas City, MO	87,903	93,890	48,139	776,797	127,606	724,941	1,731,670	3,788,512	45.71%	28.57%
657 St. Louis, MO	138,696	148,143	75,955	931,750	216,119	701,230	1,995,773	5,977,631	33.39%	21.42%
VISN 16	983,415	1,050,401	171,591	7,676,863	2,261,793	5,419,304	15,301,573	42,384,113	36.10%	23.33%
580 Houston, TX	333,936	356,682	58,521	2,167,586	726,707	2,847,037	5,763,762	14,392,283	40.05%	30.04%
586 Jackson, MS	92,801	99,122	16,263	983,735	273,202	355,299	1,547,220	3,999,625	38.68%	20.92%
598 Little Rock, AR	247,592	264,458	42,640	2,153,833	530,807	722,481	3,431,004	10,670,971	32.15%	16.94%
629 New Orleans, LA	132,553	141,582	23,229	1,030,964	358,947	1,002,637	2,330,965	5,712,892	40.80%	29.04%

VETERANS HEALTH ADMINISTRATION
Indirect Cost Rates Calculation
VISN/Medical Centers
Fiscal Year 2000

VISN/Med Ctrs	VA Hdqtrs	VHA Central Office	VISN	Medical Center Administrative	Medical Center NIH	Medical Center Facilities	Total (1)	Direct Costs	IDC Rates Full On-Site	IDC Rates NIH On-Site
635 Oklahoma City, OK	115,727	123,610	20,281	696,768	185,528	333,486	1,289,872	4,987,726	25.92%	15.61%
667 Shreveport, LA	60,805	64,946	10,656	643,977	186,602	158,364	938,748	2,620,617	36.19%	18.37%
VISN 17	524,936	560,693	67,567	3,352,080	871,325	2,119,040	6,624,316	22,624,177	29.28%	18.31%
549 Dallas, TX	202,503	216,297	26,065	1,267,360	437,657	628,806	2,341,031	8,727,664	26.82%	17.32%
671 San Antonio, TX	235,855	251,921	30,358	1,772,950	598,583	847,966	3,139,050	10,165,115	30.88%	19.33%
674 Temple, TX	86,578	92,475	11,144	311,770	(164,915)	642,268	1,144,234	3,731,398	30.67%	17.89%
VISN 18	489,316	522,646	144,317	3,759,431	1,506,220	2,442,430	7,358,140	21,089,001	34.89%	24.21%
501 Albuquerque, NM	234,761	250,752	69,239	1,722,964	545,886	1,516,441	3,794,157	10,117,937	37.50%	25.87%
504 Amarillo, TX	33,718	36,015	9,945	305,832	89,725	108,693	494,003	1,453,216	33.99%	19.14%
644 Phoenix, AZ	124,718	133,213	36,784	717,849	268,764	179,458	1,192,022	5,375,206	22.18%	13.82%
678 Tucson, AZ	96,119	102,667	28,349	1,012,986	601,845	637,838	1,877,959	4,142,642	45.33%	35.41%
VISN 19	322,726	344,708	167,183	2,748,032	728,385	1,608,856	5,191,505	13,909,131	37.32%	22.80%
554 Denver, CO	193,100	206,253	100,032	1,657,417	529,340	688,704	2,845,505	8,322,383	34.19%	20.64%
660 Salt Lake City, UT	129,626	138,456	67,151	1,090,615	199,045	920,152	2,346,000	5,586,748	41.99%	26.03%
VISN 20	771,122	823,648	515,528	7,078,334	1,861,686	4,288,400	13,477,032	33,234,526	40.55%	24.85%
531 Boise, ID	55,141	58,897	36,864	524,257	128,775	274,722	949,881	2,376,523	39.97%	23.33%
648 Portland, OR	306,645	327,533	205,006	3,306,602	852,227	2,742,813	6,888,598	13,216,080	52.12%	33.63%
663 Seattle, WA	409,336	437,218	273,658	3,247,475	870,684	1,270,865	5,638,552	17,641,923	31.96%	18.49%
VISN 21	1,023,355	1,093,062	146,763	7,779,988	2,965,188	10,547,298	20,590,466	44,105,501	46.68%	35.77%
459 Honolulu, HI	31,092	33,210	4,459	348,896	158,818	10,022	427,678	1,340,024	31.92%	17.73%
570 Fresno, CA	36,522	39,010	5,238	211,653	75,438	32,422	324,845	1,574,069	20.64%	11.98%
612 Martinez, CA	141,126	150,739	20,239	1,189,781	574,910	1,231,842	2,733,727	6,082,366	44.70%	34.84%
640 Palo Alto, CA	428,445	457,630	61,445	2,953,391	946,041	4,425,650	8,326,561	18,465,542	45.09%	34.22%
654 Reno, NV	41,987	44,825	6,019	345,731	112,172	174,868	613,410	1,808,724	33.91%	21.00%
662 San Francisco, CA	344,203	367,849	49,364	2,730,536	1,097,609	4,672,494	8,164,245	14,834,776	55.03%	44.03%
VISN 22	1,233,568	1,317,594	472,946	9,755,474	3,523,910	9,882,150	22,661,732	53,165,467	42.62%	30.90%
600 Long Beach, CA	245,568	262,295	94,808	1,712,512	956,794	1,019,235	3,334,418	10,583,726	31.51%	24.36%
605 Loma Linda, CA	97,561	104,206	37,666	799,574	314,605	1,155,480	2,194,487	4,204,765	52.19%	40.66%
664 San Diego, CA	305,548	326,361	118,022	2,655,765	706,688	2,974,393	6,380,090	13,168,613	48.45%	33.65%
691 VA Greater Los Angele	584,891	624,731	222,450	4,587,623	1,545,823	4,733,042	10,752,737	25,208,163	42.66%	30.59%

(1) Total of Administrative and Facilities columns: NIH column is included in Administrative column.

VETERANS HEALTH ADMINISTRATION
Allocation of Headquarters Administration Costs
Fiscal Year 2000

SCHEDULE V

Common Activity	Total Expenditures	Allocated to Research	Excluded	Adjusted Allocation
Central Office:				
Office of the Secretary	5,672,973	93,021		93,021
Office of Congressional Affairs	2,824,572	211,843	211,843	0
Office of HR and Administration	115,229,590	2,353,850		2,353,850
Office of Management	38,374,752	1,381,398		1,381,398
Office of Info. Resource Mgmt.	25,374,748	477,378		477,378
Office of Policy and Planning	11,008,767	119,134		119,134
Office of Public and Intergov. Affairs	7,040,373	95,047	95,047	0
General Council	56,277,563	557,517		557,517
Office of Inspector General	47,296,821	2,364,841		2,364,841
Board of Contract Appeals	1,322,906	22,772		22,772
Board of Veterans Appeals	45,224,789			0
	355,647,854	7,676,801	306,890	7,369,911
Depreciation	955,465,854	23,000,462	23,000,462	0
Bad Debt	6,899,997	121,123	121,123	0
Inter-entity & Paid by Others				0
Employees Benefits	4,287,852	(70,309)		(70,309)
FECA	367,939,806	6,033,192		6,033,192
Judgement Fund	149,153,074	1,930,810	1,291,193	639,617
Unfunded Annual Leave	32,082,788	498,500		498,500
	1,515,829,371	31,513,778	24,412,778	7,101,000
Total	1,871,477,225	39,190,579	24,719,668	14,470,911

Veterans Health Administration
Indirect Cost Calculation
Fiscal Year 2002

Calculation of Research Related Costs

Medical Centers Costs	17,332,315,288
Less STN 101,200, & 358	264,953,604
Research salaries	310,993,567
Net medical Center costs	16,756,368,117
Medical Center direct Research costs (	613,241,223
Medical Center Admin Costs (100% applicable to Research)	198,443,136
VISN Admin costs	126,031,657
applicable to Research (3.530518%)	4,449,570
VHA Central Office costs	41,988,437
applicable to Research (3.530518%)	1,482,409
VA Hdqtrs costs (100% applicable to Research)	37,471,373
Less: depreciation	23,000,462
Excluding depreciation	14,470,911

Indirect Cost Rate Calculation

		%
Medical Center direct costs	613,241,223	
Medical Center Admin Costs	198,443,136	0.32359719
VISN Admin costs	4,449,570	0.00725582
VHA Central Office costs	1,482,409	0.00241733
VHA Hdqtrs Admin costs	14,470,911	0.02359742
	218,846,027	0.35686777
" " " " depreciation	23,000,462	0.03750639
	241,846,489	0.39437415

VETERANS HEALTH ADMINISTRATION
Medical Center Administration and Facilities Costs
Listing of Cost Centers
Fiscal Year 2000

Cost Center Name	Cost Center Number
Center Administrative Cost:	
* Library	822600
* Director's Office	840100
VISTA	840200
Continuing Education	840300
* Security Service	840700
* Chief of Staff	840900
Chief Medical Admin.	841100
Contractual and Fee Service	841300
Medical Records	841400
Office Operations Section	841600
Quality Assurance	841900
Fiscal	842100
* Human Resource Management	843100
* Acquisition & Materials Management	844100
* Information Resource Management	847000
Research Administration	810100
ORCA	811200
ACOS Salary	8409
Center Facilities Cost:	
Chief Field Engineer	850100
Occupat. Health, Safety, Fire Protect	850300
Project Management Engineer	850400
Plant Operations	851100
Transportation	852100
Grounds Maintenance	853300
Recurring Maintenance	854100
Non-recurring Maintenance	854200
Operating Equipment-M&R	855100
Biomedical Engineering	855500
Environmental Management Service	856100
Pest Management	856200
Environmental Sanitation	856400
Textile Care Processing	857000
Textile Management	857100
Design Management	857500

HENRY G. KIRSCHENMANN, JR.
CERTIFIED PUBLIC ACCOUNTANT
5303 MANORFIELD ROAD
ROCKVILLE, MARYLAND 20853

September 16, 2002

Steve Buyer
Chairman
Subcommittee on Oversight and Investigation
Committee on Veterans Affairs
U.S. House of Representatives
335 CannonHouse Office Building
Washington, DC 20515

Dear Chairman Buyer:

This is in response to your letter of September 12, regarding my participation as a witness at the Hearing scheduled for September 19. Your letter requested confirmation hat I will be a witness, and requested copies of my testimony statement, and a statement disclosing the amount and source of any federal grant or contract I received related to the subject matter of my testimony.

I will appear as a witness and my testimony statement has been submitted. My testimony will address my study of the indirect costs of research conducted at V.A. facilities which I conducted for the Veterans Health Administration. The amount of the contract under which the study was performed was $30,000.

Sincerely,

Henry G. Kirschenmann, Jr.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

Post-Hearing Questions for
Robert H. Roswell, M.D.
From the Honorable Steve Buyer
And the Honorable Julia Carson
Regarding the September 19, 2002, Hearing
On VA Research Activities

1. In your testimony, it states that over 50% of your major university partners have signed cooperative agreements with the VA. Please provide a complete list of the institutions that have not signed such an agreement with the VA? Please provide the funding stream for the last ten years?

Response: Please refer to the Attachment for the list of major university partners that have not signed Cooperative Technology Transfer Agreements (CTTAs) with VA. VA and NIH research funds expended at VA facilities during the past 10 years are also listed.

2. According to the IG, GAO, and the Subcommittee, nonprofit research corporations are not monitored or reviewed by the VA at the local or departmental level. Please comment on this assessment and explain how you plan to strengthen oversight of the corporations.

Response: Both the IG and GAO investigations verified the sufficiency of local review. However, both organizations recommended that departmental review be strengthened, and VA agrees with that assessment. The Office of Research and Development (ORD) will establish a program office to monitor the non-profit corporations (NPCs). The office will receive and analyze all audits, management letters, and congressionally mandated reports to identify trends and to ensure that NPCs appropriately account for all funds, respond to auditor comments, and utilize best practices. In addition, the office will conduct systematic site reviews of financial practices, reports, and audits.

3. When Dr. Garthwaite testified before the Subcommittee on September 28, 2000, he stated that the first draft of a complete revision of the Research Development Policy Manual was under review within the Veterans Health Administration. Has this handbook been published? If not, when will it be published?

Response: VHA is transitioning from manual-based policies to a system of policy directives and implementing handbooks. ORD has published two directives that govern basic research policies, one directive dealing with hazardous materials, and fourteen handbooks. Three handbooks are in the review and concurrence process; we anticipate they will be issued by the end of February 2003.

4. For several successive years the American Heart Association has urged the VA to establish heart disease and stroke centers. Please provide the Subcommittee with a status report on these initiatives?

Response: ORD currently funds several centers that focus on either heart disease or stroke, and over the past ten years, VA investigators have conducted research on the

two topics at a total cost of more than $630 million. The Rehabilitation Research and Development Service supports the Center for Brain Rehabilitation Research at the Gainesville VA Medical Center. Two of the eight quality enhancement research initiatives (QUERI) that the Health Services Research and Development Service funds study chronic heart disease and ischemic heart disease, respectively. The Medical Research Service funds two cardiology and two stroke Research Enhancement Award Programs (analogous to Centers of Excellence).

5. In 2000, the GAO recommended that the VA determine funding levels needed to support human subject protection activities at medical centers and ensure an appropriate allocation of funds to support these activities. The VHA responded that the Office of Research Development had provided preliminary guidance to VISN Directors on the needed IRB staffing levels and had commissioned a formal Health Systems Research and Development study to gather real data to direct our resource allocation decisions. Has VA completed this study?

Response: VA has completed the study, and the authors have submitted for publication an article detailing their findings, since they will be of interest to other research facilities. The study concluded that: "A biomedical institutional review board is an expensive operation. In the past, it may have been easy to use internal funds and to rely on donated time. However, with changes in regulations and the push to accredit IRBs and to certify IRB administrators, the IRB costs are increasing. Over time this will place greater burden on small IRBs, particularly those at academic medical centers where administrative reimbursement from the National Institutes of Health is capped at 26%." VHA is closely analyzing the study to determine the optimal allocation of available funds to support human research protection programs.

6. How many VA research facilities are not accredited? Please provide a list of the facilities and the names of their Associate Chief of Staff of Research and Development (ACOS-R).

Response: Currently, five VA research facilities had received a designation of "Not Accredited" from NCQA. All five appealed the designation. Three appeals were accepted, and the status was changed to "Accredited with Conditions" for these VA research facilities. Two appeals have been denied. The five facilities that have appealed and the responsible officials are listed below.

Site	Responsible Official	Position	Appeal Status
Martinez, CA	George M. Kaysen, MD	ACOS/R&D	Denied
Pittsburgh (HD) PA	Martin Sax, PhD (Ret.)	ACOS/R&D	Accepted
Northampton, MA	Deborah Lambert-Huber	R&D Coordinator	Denied
Providence, RI	Robert Swift, MD	ACOS/R&D	Accepted
Biloxi, MS	Gustave F. Sison, Jr., PhD	R&D Coordinator	Accepted

7. Are there outstanding issues that need to be resolved on standardization of accreditation criteria?

Response: The National Committee on Quality Assurance (NCQA) received over 300 comments on Version 2 of the draft standards issued September 12, 2002. The comment period closed October 4, 2002. Comments came from within VA as well as from interested parties outside VA. The great majority of the comments on general issues in the standards were challenges to, or requests for clarification of, accreditation program policies and procedures. Other commenters asked for clarification on investigational drugs and other definitions. Some issues included questions on how factors and elements scored as "not applicable" affect the overall scoring and requests for clarification on accreditations considerations. There were also comments on standards and elements in each of the domains of the accreditation program to be resolved.

NCQA has reviewed all of the comments and proposed a disposition for each of the suggestions. NCQA has also shared the comments with the VA Advisory Group. The VA Advisory Group is composed of representatives of several VA offices, such as the Office of Research and Development, the Office of Research Compliance and Assurance, the National Center for Ethics, Network Directors, and VA research staff. NCQA and the Advisory Group will discuss final disposition of each comment in the near future.

It is expected that revisions to the final set of standards will be published some time within the next two months, so that sites can become familiar with them before accreditation applications can be filed with NCQA and surveyor visits resume.

8. How will VA assuage NIH concerns that any future funding to cover indirect costs associated with NIH grants for research conducted on VA facilities will not be raided to fill a VA healthcare funding shortfall?

Response: If NIH establishes a rate of reimbursement to cover additional expenses incurred to support NIH-funded research conducted in VA facilities, the funds received from NIH will be used only for VA medical research support activities and not for any other purpose.

9. Have any additional surveys been conducted since last May? If so, what is the status of those surveys?

Response: NCQA has not conducted additional surveys since May 2002. Accreditation surveys will resume some time later in FY 2003.

10. Are veterans who sign up for human subject research in VA studies safer than non-veteran human subjects in non-VA research studies?

Response: VA does not have access to data that would permit such a comparison. However, VA is confident that it conducts a human research protections program that is

second to none. VA is the only health care system that has an independent quality assurance organization evaluating 100 percent of its sites where humans participate in research. Over the past three years, the Office of Research and Development has committed tens of millions of dollars to support Institutional Review Boards, fund investigator training, and evaluate the conduct of research, especially in clinical trials. VA also has an Office of Research Compliance and Assurance (ORCA) with direct access to the Under Secretary for Health. ORCA's scope of activities, besides matters related to human subject protections, includes oversight of animal welfare and researcher safety issues. This office is also responsible for tracking and investigating, as needed, all allegations of research misconduct and research improprieties.

11. In response to questions raised at last May's Hearing, VA indicated that of the 12 VA Medical Centers that were surveyed by the National Committee for Quality Assurance for Human Research Protection Program accreditation, nine had been notified of "Accredited with Conditions" status. Three had been notified of an initial "Not Accredited" status, and are currently appealing. What is the status of ORCA's follow up on these initial accreditation surveys, and have all conditions since been ameliorated? Please explain.

Response: Presently, 23 site visits have been completed, and final reports have been issued for all. As of October 21, 2002, five sites had received an initial "Not Accredited" status from NCQA. All five sites formally appealed. Two of these sites have had their appeals denied. Three appeals were successful, and the status was changed to "Accredited with Conditions."

Officials of VA's Office of Research Compliance and Assurance (ORCA) have visited all five of these sites and performed Focus Reviews. They also have performed Systematic Post-Accreditation (SPAR) visits at the five sites that filed formal appeals. All of the sites gave ORCA detailed plans for correcting deficiencies. ORCA accepted these plans and has closely monitored their implementation. The plans for correction and fulfillment of the recommendations from the SPAR visits have been completed at two sites and they have received "close-out" letters. These are two of the VAMCs that were successful in their appeals of "Not Accredited" status.

ORCA does not automatically conduct site visits when a facility has a designation of "Accredited with Conditions." Rather, each site report is evaluated for non-compliance with regulations and policy, and ORCA's Regional Office Directors communicate directly with the facilities to decide on actions necessary to correct noncompliance. Depending on the nature of noncompliance, the ORCA follow up could consist of written communications or may require a site visit.

Attachment to Question 1: Major University Partners without CTTAs.

VA Medical Center	Affiliated University	VA Funds	NIH Funds
Seattle, WA	University of Washington	$93,872,139.00	$84,075,871.00
Boston, MA	Boston University	$83,619,698.00	$37,561,713.00
Durham, NC	Duke University	$78,550,882.00	$36,105,256.00
West Haven, CT	Yale University	$74,182,706.00	$71,389,544.00
Cleveland, OH	Case Western Reserve University	$63,509,915.00	$44,833,178.00
Ann Arbor, MI	University of Michigan	$54,521,250.00	$55,527,828.00
Decatur, GA	Emory University	$52,276,727.00	$27,196,931.00
Nashville, TN	Vanderbilt University	$53,391,926.00	$31,651,865.00
Bedford, MA	Boston University	$37,867,119.00	$9,492,424.00
Miami, FL	University of Miami	$40,939,190.00	$15,285,471.00
Little Rock, AR	University of Arkansas	$35,920,074.00	$38,002,254.00
Pittsburgh, PA	University of Pittsburgh	$36,512,124.00	$24,459,352.00
Birmingham, AL	University of Alabama at Birmingham	$29,805,298.00	$23,271,384.00
Philadelphia, PA	University of Pennsylvania	$30,181,274.00	$55,341,965.00
Indianapolis, IN	Indiana University	$26,840,244.00	$44,199,653.00
Washington, DC	George Washington University	$27,604,529.00	$34,723,793.00
East Orange, NJ	University of Medicine and Dentistry of New Jersey	$26,646,022.00	$7,532,506.00
New York, NY	New York University	$25,259,091.00	$41,987,385.00
Omaha, NE	University of Nebraska	$26,528,075.00	$13,760,257.00
White River Junction, VT	Dartmouth College	$23,109,297.00	$21,839,514.00
Bronx, NY	Mount Sinai School of Medicine	$21,225,575.00	$36,286,943.00
Northport, NY	State University of New York at Stony Brook	$16,896,128.00	$7,774,712.00
Detroit, MI	Wayne State University	$16,187,631.00	$4,811,745.00
Albuquerque, NM	University of New Mexico	$17,244,736.00	$11,774,378.00
Tampa, FL	University of South Florida	$15,608,743.00	$2,510,543.00
Lexington, KY	University of Kentucky	$16,371,185.00	$17,353,964.00
Augusta, GA	Medical College of Georgia	$15,869,176.00	$6,254,335.00
Albany, NY	Albany Medical College	$14,322,745.00	$6,417,764.00
Buffalo, NY	State University of New York at Buffalo	$14,937,973.00	$18,957,912.00
Bay Pines, FL	University of South Florida	$6,914,584.00	$101,456.00
TOTAL		**$1,076,716,056.00**	**$830,481,896.00**

CHAIRMAN BUYER TO RICHARD J. GRIFFIN, INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS

Questions for the Record
Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations
September 19, 2002
Hearing on VA Research and Nonprofit VA Research Corporations
and Education Foundations

1. **Your testimony stated that VA has offered to compile national data on research corporation expenditures and fund use. How long should it take VA to accomplish this? Will you monitor this important effort? If so, how?**

   In VA's response to the Subcommittee's questions on VA-affiliated nonprofit research and education corporations (NPCs), we noted that VA offered, should the Subcommittee request it, to compile and report detailed financial data to the Subcommittee. VA cannot quickly report the information the Subcommittee requested under the NPCs' varied accounting systems.

   NPCs currently use a variety of financial reporting systems and do not consistently use the accrual basis accounting method for financial accounting purposes. As a result, it will take VA significant administrative effort to collect, organize, aggregate, format, and report the information requested by the Subcommittee. In addition, much of the information would be potentially unreliable considering the inconsistencies we identified in the NPCs' financial reporting systems and the accounting methods used. However, we believe that if VA takes action to standardize the financial reporting of the NPCs, the requested information would be more easily obtainable and there would be better assurance that the information collected and reported would be complete, reliable, and meaningful.

   The Office of Inspector General (OIG) plans to provide future oversight of the NPCs by reviewing, on a selected basis, the NPCs' active compliance with legislative requirements, and reviewing allegations and complaints received through the OIG Hotline.

2. **Please provide the Subcommittee with the IG's position on the proposal that would grant nonprofit corporations with the power to contract services to the VA? How would this change the relationship between the corporations and the VA?**

   We do not support granting the NPCs legislative authority to contract services to VA. The NPCs were established to provide VA researchers a flexible funding mechanism to administer non-VA funds. The rationale was that VA did not have an appropriate entity or mechanism that could account for and administer

non-VA research funds that would also provide the flexibility researchers needed. The National Association of VA Research and Education Foundations (NAVREF) now proposes to expand the authority of the NPCs to receive and administer research funds appropriated to VA, and to contract with VA to conduct research.

NAVREF provides no evidence that VA is incapable of effectively administering appropriated research funds or that administration by a non-governmental entity has inherent advantages. Providing the NPCs with the authority to administer appropriated research funds would effectively limit the Department's ability to control how appropriated funds are expended. Accordingly, we believe this is an unnecessary and potentially problematic expansion of the NPCs' authority.

NAVREF also proposes to expand the role of the NPCs from providing a platform to administer funding for VA research, to that of a developer, marketer, and seller of research-related services to VA. As indicated below, we see several potential problems associated with such authority.

- Granting the NPCs authority to sell services to VA creates a built-in incentive for the NPCs to market their services to the Department. Consequently, the NPCs will sell services to VA that have in the past, been donated.

- Granting NPCs authority to contract with VA can infringe on inherently governmental functions associated with the acquisition, use, and disposition of equipment and capital property.

- NAVREF has taken the position that one of the most significant benefits to be achieved through new contracting authority will be the facilitation and streamlining of procurement of high-priced research equipment. The NPCs have indicated a desire to acquire high-priced equipment, house and operate the equipment at VA facilities, and sell unused capacity to outside customers. Granting this authority would potentially place VA employees on the NPCs' Boards of Directors in the position of overseeing management of non-VA contract activities. We do not think that such responsibilities are appropriate.

In a statement for the record, NAVREF provided examples of situations they say reflect the benefits of providing NPCs with authority to contract with VA. We have analyzed the following examples offered by NAVREF:

- **Scenario 1**: When a VA facility does not have a qualified technician needed to conduct tests for a research project, it could contract with a NPC. The NPC hires a qualified technician to run the tests and bills VA on a per test basis.

- **OIG observation**: This scenario implies a noncompetitive procurement that will not ensure VA pays reasonable prices for the services received. The Government should generally acquire goods and services through competition.

- **Scenario 2**: When a VA facility has insufficient funds to purchase or lease high-cost research equipment and to pay qualified staff to operate it, VA researchers could contract with a NPC to obtain access to the equipment. The NPC can lease the equipment, renovate VA facilities to house the equipment, and hire staff to operate the equipment. The facility could then contract with the NPC for part-time VA use of the equipment. To recoup some of the cost of the lease, the NPC could sell excess capacity to other public and private users or make services available to university researchers.

- **OIG observation**: The VA's Capital Investment Methodology is a capital planning process that helps fulfill requirements of the Government Performance and Results Act of 1993 (GPRA) and the Clinger-Cohen Act of 1996. The process requires that capital investment proposals be clearly tied to Department goals and objectives. This proposal to acquire capital assets would circumvent VA strategic capital planning, and potentially put VA in a noncompliant position relative to GPRA, Clinger-Cohen, and VA strategic goals and objectives. In addition, as a result of potential sales of these services, VA's exposure to liability will increase.

- **Scenario 3**: An education service could execute a 30-day contract with a NPC to provide meeting planning services for a VA-funded training program. Lacking a staff member with the skills and time required to administer the conference, the education service could contract with the NPC to process registrations and fees, arrange and pay for catering, and duplicate and assemble the training materials.

- **OIG observation**: Conference management services are generally acquired through competition and are often set aside to meet small business goals and objectives. The proposal may result in a possible conflict of interest and provide the NPC with an unfair advantage over other bidders. Competition also provides better assurance of price reasonableness and helps ensure that the vendor offering the best value to VA receives the award.

- **Scenario 4**: A VAMC could contract with the NPCs to efficiently process fees for research patients and reimbursements for the patients' travel and meal costs.

- **OIG observation**: Again, it appears that NPCs have begun to focus on how to develop, market, and sell services to VA, rather than to function as a flexible funding mechanism.

Accordingly, the OIG does not support granting NPCs authority to contract services to VA.

United States General Accounting Office
Washington, DC 20548

October 25, 2002

The Honorable Stephen E. Buyer
Chairman, Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
House of Representatives

The Honorable Julia M. Carson
Ranking Member, Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
House of Representatives

The enclosed information responds to your follow-up questions concerning our testimony before the Subcommittee on September 19, 2002, on the Department of Veterans Affairs' (VA) use of nonprofit research corporations. The first question asked for our views on a proposal to allow VA to transfer appropriated funds to nonprofit corporations through contracts. The second question asked for the status of VA's actions in response to recommendations in our September 2000 report, *VA Research: Protections for Human Subjects Need to Be Strengthened,* GAO/HEHS-00-155.

If you have any questions or would like to discuss this information, please contact me at (202) 512-7101 or Michael T. Blair, Jr., Assistant Director, at (404) 679-1944.

Sincerely yours,

Cynthia A. Bascetta
Director, Health Care—Veterans'
Health and Benefits Issues

Enclosure

This enclosure details your questions and our responses, which supplement information in our testimony before your Subcommittee, *VA Health Care: Nonprofit Corporations Enhance VA Research, but Would Benefit from Increased Oversight* (GAO-02-1103T, Sept. 19, 2002).

Transfer of Appropriated Funds to
Nonprofit Research Corporations

1. **Please provide the Subcommittee with your views on a proposal to grant VA the ability to contract for services with nonprofit research corporations. In your opinion, how would this change the relationship between the corporations and VA?**

We see no apparent advantage to VA from a proposal that would allow the direct transfer of VA appropriated funds to nonprofit corporations through contracts, since VA already has the ability to obtain services from nonprofit corporations. Further, the proposal would require VA headquarters to oversee the transfers to ensure the appropriate use of these funds—an added burden since VA headquarters does not currently oversee and monitor corporations' financial activities. Also, extensive funding transfers might cause nonprofit corporations to become dependent on VA funding.

VA and nonprofit corporations currently have options for sharing resources among projects funded with VA appropriations and those funded externally. For example, nonprofit corporations can now purchase equipment and share their use among multiple research projects. These shared services or "recharge centers" allow numerous researchers, including those funded by VA appropriations, to use the equipment and pay a portion of associated operation and maintenance cost. Under current procedures, VA pays its portion of operation and maintenance cost directly to the vendor.

Further, the proposal might also apply to the use of nonprofit corporation employees to assist in research funded with VA appropriations. However, VA—in addition to the ability to temporarily hire employees—already has the flexibility to enter into agreements to reimburse nonprofit corporations for the salaries of their employees who work on VA-funded research projects. Through these agreements nonprofit corporation employees who have been employed for at least 90 days, such as research technicians, can temporarily work on VA-funded research projects. Contracting for the services of nonprofit personnel under the proposal could be very similar, but might also include a fee to cover the nonprofit's administrative expenses.

We also note potential problems with the relationship that would exist under the proposal. For example, allowing the transfer of these funds to nonprofit research corporations could create opportunities for inappropriate use of appropriated funds. Because of this possibility, the proposal would increase the need for high-level oversight of local nonprofit activities, which, as we discussed in our September 19, 2002, testimony, is not being done. Moreover, if the proposal were implemented so that VA funding became a major component of nonprofit corporations' revenue, they could become increasingly dependent on already limited VA research appropriations, redefining their mission of serving as a flexible funding

mechanism to facilitate VA research and education. Further, VA officials object to the proposal since it may cause nonprofit corporations to operate more like contractors whose goal is to sell services, capture indirect or overhead costs, and maximize revenue from VA appropriations.

VA Actions in Response to GAO Recommendations on Human Subject Protections

2. Have all the GAO recommendations made in 2000 to strengthen Human Research Protections been completed by VA? If not, please provide a status report.

In our September 2000 report *VA Research: Protections for Human Subjects Need to Be Strengthened,* we made recommendations for improving human subject protections. VA's actions in response to our recommendations are discussed below.

Recommendation: **To strengthen VA's protections for human subjects, the Acting Secretary of Veterans Affairs should direct the Under Secretary for Health to take immediate steps to ensure VA medical centers, their institutional review boards (IRB)—whether operated by VA or not—and VA investigators comply with all applicable regulations for the protection of human subjects by:**

- **providing research staff with current, comprehensive, and clear guidance regarding protection for the rights and welfare of human research subjects.**

  While VA has provided some guidance to research staff, it has not fully implemented this recommendation. In September 2001, VA's Office of Research Compliance and Assurance (ORCA) issued a guidebook describing standard operating procedures for IRBs and distributed a self-assessment tool for evaluating the quality of human subject protection at VA facilities. Since the guidebook and the assessment tool are optional they might not be used. However, VA is formalizing its policies and requirements in a handbook for protecting human subjects in research that all facilities must follow. According to VA, the handbook will provide current, comprehensive guidance regarding the responsibilities of investigators and IRBs in protecting the rights and welfare of human research subjects. Although a preliminary draft was issued in December 2000, VA does not expect to issue the handbook in final form until early 2003.

- **providing periodic training to investigators, IRB members, and IRB staff about research ethics and standards for protecting human subjects.**

  VA has implemented this recommendation. ORCA has developed standardized educational and training activities for investigators, IRB members, and staff on protecting human subjects in research. Further, VA requires investigators who apply for VA research funds to complete training on human subject protection. Further,

ORCA issues biweekly information letters and sponsors seminars and conferences on research ethics and standards for protecting human subjects.

- **developing a mechanism for handling adverse event reports to ensure that IRBs have the information they need to safeguard the rights and welfare of human research participants.**

  VA is in the process of implementing this recommendation. In September 2001, ORCA issued guidance on IRB operating procedures to each medical center, including what information investigators should include in adverse event reports to IRBs and how IRBs should review the data and determine any necessary action. ORCA is leading an effort to simplify VA adverse event reporting requirements and make them consistent with the requirements of other federal agencies, such as the Office for Human Research Protections and the Food and Drug Administration. In doing so, ORCA has been coordinating with these agencies to discuss federal government-wide adverse event reporting requirements. VA, as a result of these efforts, plans to publish a directive including the new requirements within the next year. When this directive is complete, ORCA plans to use it as a basis to monitor local IRBs' handling of adverse event reports.

- **expediting development of information needed to monitor local protection systems, investigators, and studies and to ensure that oversight activities are implemented.**

  VA has implemented this recommendation. VA has begun several agency-wide initiatives to monitor local oversight activities. VA contracted with the National Committee for Quality Assurance (NCQA) in April 2000 to review and accredit the human protection programs at VA medical centers every 3 years. The NCQA accreditation process includes reviewing local research policies and standard operating procedures, IRB procedures and records, qualifications and training of IRB members and staff, and medical centers' implementation and monitoring of informed consent procedures. NCQA finalized its accreditation standards in August 2001 and VA medical centers have begun the accreditation process. NCQA has surveyed 23 medical centers, 19 of which have been "Accredited with Conditions," and 4 of which have not been accredited. Ninety have yet to be reviewed.

  When a medical center receives a final result of "Not Accredited," an ORCA team visits the center to determine if patients have been harmed, which could result in the suspension or restriction of the center's research program. In addition, ORCA conducts reviews of research programs whenever it receives a report of problems or has other reason to suspect them. Also, at medical centers' request ORCA reviews their research programs to help ensure that human subjects are protected.

- **determining the funding levels needed to support human subject protection activities at medical centers and ensuring an appropriate allocation of funds to support these activities.**

  VA is in the process of implementing this recommendation. It completed a study that estimates the cost of operating IRBs at small, medium, and large research programs. VA plans to use the study, which was completed in June 2002, to help determine funding levels for medical centers' human subject protection activities.

RESPONSE TO QUESTIONS FOR THE RECORD
Committee on Veterans Affairs
Subcommittee on Oversight & Investigations
Hearing on VA Research & Nonprofit Research Corporations
and Educational Foundations
September 19, 2002
Addressed to and Submitted by Henry G. Kirschenmann, Jr.

Question:

Would an offer by NIH to cover "incremental" costs cover "indirect" costs associated with NIH research at VA facilities?

Response:

As stated in my response to the following question, reimbursement of "incremental" costs, assuming they could be measured, would not cover the costs of those VA support activities commonly referred to as "indirect"..

Question:

What is the difference between incremental and indirect costs? How are each determined? What is the reliability of each determination?.

Response:

Indirect costs are those costs commonly referred to as `general and administrative' and `facilities' costs. `General and administrative' include the costs of such support activities as procurement, personnel, accounting & budgeting, information technology, research administration, general management, etc. In large organizations, such as the VA, these costs are grouped by organizational tiers; for example, costs incurred at the medical center level, those at the VHA level, those at the VA level, etc. `Facilities' include such costs as maintenance & repairs, utilities, janitorial services, etc. Only the costs of the facilities used for research at the medical centers were included in the rate calculation for VHA research.

The term incremental cost is used to describe those additional costs which an organization might incur as a consequence of undertaking a particular (invariably a new) project, or activity, or function. Essentially, it is used to estimate the likely out of pocket expenses that would be (are) incurred by an organization in performing the new undertaking. It is a useful measurement in those instances in which a new endeavor of significant size is to be undertaken, especially when the endeavor is unique and/or independent from other activities of the organization. It is a helpful management tool in that it can quantify the impact of such an undertaking upon an organization's available resources particularly its cash needs. It is unrealistic in other situations, however, in that it assumes the endeavor has no work impact and does not draw upon an organization's normal support activities. Thus, incremental costing has utility in assessing

the cost impact of a research function of an entity in comparison to an entity's other functions (like patient care), or for measuring the cost impact of a major, unique research project to be conducted within an entity's on-going research function and which will entail the need for a material increase in an organization's current resources to support it. Its use is problematic and subject to arbitrary judgements in situations in which the additional research is a project(s) akin to other comparable projects performed by an organization as part of its ongoing research function.

Incremental costing was considered, and rejected as impractical, when the OMB was developing its cost principles for colleges & universities, other nonprofit institutions, and state & local governments (Circulars A-21, A-122, and A-87, respectively). Instead, the OMB cost principles incorporate/apply the universally accepted rule that the costs of an organization's support services should be allocated to all those other activities of the organization in proportion to the estimated, reasonable benefit an activity derives from the service. The allocation rule is also adopted in the Federal Acquisition Regulations, the costing of patient care and other hospital activities under Medicare, the costing guide for hospitals published by the American Hospital Association, and those cost principles applicable to the costing of programs conducted within Federal agencies (which I cited in my testimony).

A very simple example of the difference between the two costing approaches. Assume an organization receives an award to produce some product, say to conduct a research project. To conduct the project, supplies must be procured; checks must be written to pay the suppliers and to pay the researchers and technicians who are involved in it; payroll and other personnel services for these people is involved; space in which to conduct experiments must also be provided and maintained; security and fire services need to be provided: people might need to be hired; staff supervision/oversight is required; project costs need to be controlled and accounted for; reports to sponsors need to be prepared and submitted; etc. Say also that the organization conducts numerous research projects.

Under an incremental costing system, if these services were provided within the existing resource of the organization, they would not be recognized as a cost of the project. They would only be recognized if a new employee had to be hired to write the checks, new space had to be procured to conduct the research, new personnel department staff had to be employed to hire and service the project staff; new accounting staff had to be hired to control and report on the project's costs; etc. What would be recognized would be the costs of the additions. If a second research project were undertaken the same rules would apply to it; that is, only the costs of any additions caused by the project would be recognized as a cost of the project. Incremental costing thus becomes the more impractical as more research projects are undertaken. And it can lead to the adding of otherwise unnecessary staff and space, and manipulations, as organizations are faced with a potential loss of reimbursement because of it.

Under the allocation concept, one would identify those support services from which a (research) project would derive benefit and apportion the costs of the services between

the project and all the other activities which also receive benefit from them. The apportionment would be calculated using some generally accepted measure, say for example, square feet of research space occupied, the number of total new hires, the total number of checks written or invoices paid, etc. or some more general approach as provided for in the cited costing principles.

Question:

If we assume, as was asserted at the hearing, that the requirement that VA cover indirect costs associated with NIH research at VA facilities is having unwanted impact on veterans healthcare, and that NIH is concerned that any "add-on" for indirect costs may be used for veterans healthcare, how would one resolve his conflict fairly?

Answer:

If one were to apply the allocation concept contained in the Federal cost principles, the amount of indirect costs associated with the research activity would be deemed to represent only research costs and would not include any medical care costs. This is the methodology/concept used under Medicare and the American Hospital Association guide, for example, to separate medical care costs from the costs of other activities (including research) conducted by hospitals and medical care centers.

As noted in my prior response, in large organizations, operations and support activities are typically performed at several tiers. At the VA, those tiers are the medical centers, and the regional, VHA, and VA headquarters tiers. The involvement of some of these tiers are, of course, more immediate to the research projects performed than others. One approach to reaching an agreement could be to exclude the costs of the less immediate tiers, e.g.; the VA headquarter tier, from consideration and recognizing the costs associated with the more immediate tier(s). The end result would be a compromise between both costing approaches. This could be done through agreement between the parties or, if agreement is not possible, through mandate by some empowered third party. The methodology I employed and the rates I calculated and submitted, would allow such a compromise.

CHAIRMAN BUYER AND CONGRESSWOMAN CARSON TO NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION FOUNDATIONS

Questions and Responses for the Record
Committee on Veterans Affairs
Subcommittee on Oversight and Investigations
September 19, 2002
Hearing on VA Research and Nonprofit VA Research and Education Corporations

1. ***When VA Medical Centers consolidate, such as in the Chicago area, and as a result a medical center has two separate corporations attached, should the corporations be merged?***

   In some cases, there are valid reasons for merging the corporations and the corporations have done so, including those at Seattle and Tacoma, North Chicago and Hines. In other cases, there are equally compelling reasons for continuing to operate two separate corporations such as those at Sepulveda and West Los Angeles. Considerations may include:

   - Distance between the two facilities: the longer the distance, the stronger the case for separate corporations
   - Feasibility of providing high quality on site services (procurement, hiring, travel reimbursement, etc.): staff at one site may not be able to ensure prompt services at the other and may find it difficult to provide necessary monitoring and oversight
   - Ability to manage employees, retain control of equipment, maintain inventory and ensure compliance at two locations, one of which may be some distance away
   - Willingness of statutory board members to serve on two boards
   - Similarity of activities at each facility: one corporation may be administering federal grants while the other does not; one may participate in education activities while the other chooses not to do so
   - Facility cultures may require different nonprofit management structures and skills
   - Potential savings: a careful analysis would be required to determine whether consolidation would reduce operational costs such as insurance, accounting, and administrative staff; potential savings, if any, would have to be weighed against the other considerations identified above.

   Ultimately, the decision whether to consolidate rests with the boards of the two corporations. Because the senior leadership of the consolidated VAMC must serve on the boards of both corporations, that decision is likely to represent the best interests of VA and both facilities.

2. ***In justifying the need for the non-profits, NAVREF lists several examples of how the non-profits support the VA research mission: underwriting the cost of IRBs, funding maintenance and improvement of facilities and paying for research related travel. Can we reasonably expect that the non-profits would continue to donate these services to VA if they could sell them to the facility under a contract?***

   Yes. Our affirmative response is based on how the corporations manage funds internally. The corporations generally pay for the services they donate to VA from one of three types of accounts:

   1. Project accounts. An NPC-administered grant associated with a specific research project pays for the direct costs of that project. From the VA perspective, these are donated goods and services (such as research supplies and equipment, MRIs, blood tests, and work done by research technicians, nurses). From the corporation perspective, these are project costs.
   2. Residual accounts. After a project has ended, funds remaining may be available for the general support of research or education, subject to the corporation's policies and procedures. These funds are often used for the direct costs of projects, but also may be used for core costs

such as travel that may benefit all of a PI's research projects, common resource equipment, renovating a laboratory or a research technician working on two or more projects. Again, from the VA perspective, all of these are donated goods and services.

3. Board discretionary funds. Many corporations establish an administrative overhead rate that includes sufficient funds to operate the corporation as well as to support new initiatives at the board's discretion that best serve the facility's research program, including providing ongoing research infrastructure support for IRBs, animal facilities, etc. In its May 16 and September 19 testimonies, NAVREF cited many examples of board discretionary expenditures. As above, VA receives all of these benefits as donated goods and services.

We anticipate that allowing corporations to provide services to VAMCs on a contractual or reimbursement basis from appropriated funds will have no impact on expenditures from the above types of accounts and the corporation's interest in donating goods and services to VA. Rather, such authority will allow the corporation to better partner with VA to meet investigators' needs in situations where neither VA nor the corporation can afford the entire cost. For example, a corporation might be able to afford to lease a large piece of core equipment, but could not afford the ongoing maintenance or staffing costs. Allowing the NPC to bill VA research projects for the staff expense on a per use basis would provide the VA with the equipment at a minimal cost to the appropriation. VA would incur a cost only for its usage and the corporation would pay for the remainder with NIH or private sector grant funds. The net result would be VA PI access to the equipment regardless of whether the use was for NIH, private sector, corporation or VA-funded projects, but VA would pay only for the use incurred by VA-funded projects. For corporations that administer HHS grants, this would be done in a manner consistent with OMB Circular A-122 regulations that require uniform policies and procedures for both federally- and privately-financed activities of the organization.

The corporations' interest in contract/reimbursement authority is driven by a desire to do more for facility research programs, not less.

3. ***NAVREF maintains that the non-profits are more efficient and responsive to the research needs of investigators because they are not subject to Federal procurement and employment regulations. If the non-profits are authorized to contract with VA and under the terms of that contract are subjected to additional Federal regulation, would that reduce the efficiency and cost effectiveness of non-profit operations? Should we expect that complying with the additional regulatory requirement would increase your overhead costs? Would this additional expense be passed on to VA?***

It should be emphasized that VA has the option of rejecting a contract/reimbursement proposal from a corporation or declining to purchase the service if VA determines the cost proposed by the corporation is excessive or if the service can be obtained from another vendor at a lower cost.

No, compliance would not noticeably reduce the efficiency of non-profit operations for the following reasons:

- Much of the regulatory burden of compliance with regulations affecting federal expenditures falls on the agency expending the funds, not the recipient organization. VA would incur these expenses regardless of the payee.
- Many nonprofits are already administering federal, non-VA grants and contracts and as a consequence, are already in compliance with applicable statutes and regulations such as the Rehabilitation Act of 1974 (Affirmative Action), Americans with Disabilities Act, Executive

Order 11246 As Amended (Equal Opportunity Employment), Drug-Free Workplace Act of 1988, etc.

- Corporations that administer only private sector funds, or whose federal receipts fall below certain statutory or regulatory thresholds, would be unaffected.
- We anticipate that the contractual/reimbursement amounts from VA would be a very small percentage of overall corporation receipts and would not cause a decline in overall corporation efficiency.

For the same reasons noted above, we do not anticipate an appreciable increase in administrative overhead costs.

An additional cost, if any, as consequence of compliance with applicable federal regulations is a necessary cost of providing services to a federal agency. Such costs may be built into the contracted fee or reimbursement amount depending on the extent to which the corporation could afford to absorb such costs or could under write them from private sector funds. However, corporations (and any other entities such as universities subject to OMB Circular A-21) that administer HHS funds would be subject to the OMB Circular A-122 consistency requirements noted above.

4. ***VA has historically maintained that non-profit employees assigned to conduct VA approved research are not independent contractors but are performing a Government function subject to direction and control of VA. Isn't it inconsistent to argue that the non-profits should be able to sell its employees' services to VA under a contract but that these same employees should be protected from liability under the Federal Tort Claims Act?***

No. In NAVREF's view, it is consistent for corporation employees to be protected against personal liability regardless of the means by which VA acquires their services. Whether VA receives a corporation employee's services through a donation, in accordance with an Intergovernmental Personnel Act assignment, or pursuant to a contract or reimbursement, the employee performs a government function subject to direction and control of VA and under a federal appointment. Aside from a few administrative personnel, corporation employees work only on VA-approved research or education. They work under the supervision of VA employees. And they have VA without compensation (WOC) appointments.

Congress has acted previously to provide explicit FTCA coverage for employees and contractors of other congressionally authorized organizations and NAVREF is simply asking Congress to do the same for NPC employees. Precedents include:

- 5 U.S.C. § 8477 (making FTCA applicable to fiduciaries of Thrift Investment Fund)
- 15 U.S.C. §§ 4102,4105 (making members of Arctic Research Commission and certain scientists and engineers acting as advisors to Commission employees for FTCA purposes)
- 22 U.S.C. § 2504 (making Peace Corps volunteers federal employees for FTCA purposes);
- 39 U.S.C. § 409 (making FTCA applicable to tort claims arising from activities of the Postal Service)
- 42 U.S.C. § 233 (making remedy provided by FTCA exclusive for acts or omissions of commissioned officers or employees of Public Health Service in certain situations)
- 42 U.S.C. § 2212 (making FTCA exclusive remedy for acts of government contractors)

5. ***NAVREF is a private non-profit association comprised of VA non-profit corporations. Its operations are sustained by membership dues. How can the VA non-profits allow NAVREF to use these funds***

(money that would otherwise be conserved for VA research) in support of a position that is contrary to VA?

Funds used to pay NAVREF dues do not come out of research accounts. Organizations that provide funds to nonprofits provide project funds plus administrative overhead, generally from 10-25 percent of the project budget. The cost of NAVREF dues is a component of the corporation's administrative overhead calculation that determines the rate it charges research sponsors. If the corporation didn't have the expense, the rate it charged private sector sponsors could be lower. Therefore, NAVREF dues do not come out of funds that otherwise would be conserved for VA research.

NAVREF's member-approved mission is to support the VA-affiliated nonprofits and their interests. The corporations' primary interest is always VA research. Therefore, regardless of whether NAVREF agrees with VA on a particular issue, NAVREF's ultimate objective is always the betterment of VA research. As an organization, NAVREF has made a consistent effort to work with all stakeholders toward the common objective of enhancing the health of veterans. When presented with conflicting guidance on matters that affect the corporations' ability to support facility research programs, NAVREF seeks expert advice and assistance in developing a solution from both VACO and field personnel. Rather than supporting positions contrary to VA, we hope VA and the corporations share common objectives.

6. ***What is the argument for a law that would purport to authorize nonprofits to conduct research? If the non-profits are authorized to conduct research wouldn't this further confuse the issue of ownership with regard to intellectual property? How would this complicate existing Cooperative Technology Administration Agreements?***

While NAVREF has not formally requested a specific law authorizing nonprofits to conduct research, such a law would clarify that the corporations are authorized to conduct research. In NAVREF's view, 38 USC 7361 (a) already authorizes the corporations to conduct research. It says:

> The Secretary may 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.

Because the authorizing statute requires the corporations to obtain tax-exempt status, they **must** conduct research. IRS guidance states:

> To qualify as a medical research organization, the principal function of the organization must be the direct, continuous, and active conduct of medical research in conjunction with a hospital . . . (page 18, Form 1023, Additional Information).

Further, the Department of Health and Human Services has determined that an organization conducts research as one that is "engaged" in research:

> An institution becomes "engaged" in human subjects research when its employees or agents (Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. January 26, 1999 letter to Division of Human Subject Protections, OPRR, from

Director, Division of Human Subject Protections, OPRR, regarding Engagement of Institutions in Research and 45 CFR 46.102(d),(f).

Corporation employees, as well as the VA PIs who conduct corporation-funded research, meet these criteria.

However, NAVREF's position that the corporations already are authorized to conduct research in no way diminishes the fact that all of the research administered by the corporations is VA research, subject to VA policies, procedures and oversight.

That said, it is our understanding that General Counsel essentially puts a period after "flexible funding mechanism" in 38 USC 7361 (a) and maintains that the word "solely" in 38 USC 7362(a) refers to "to facilitate." In discussions with congressional staff involved in drafting the original legislation, NAVREF was told that "solely" was intended to limit corporation activities to research and education. Use of the word as a modifier of "flexible funding mechanism" was not contemplated. At the time, it was suggested that clarification could be achieved by moving "solely" to just before "research." NAVREF's main concern in this regard is that if General Counsel informed the IRS or HHS that the corporations are not authorized to conduct research, their tax-exempt status and ability to accept federal research grants could be compromised. In NAVREF's opinion, a simple clarification by Congress, not a law, would solve the problem.

In NAVREF's view, such a clarification would not complicate existing Cooperative Technology Administration Agreements. The corporations' rights to intellectual property are determined by federal laws applicable to other nonprofits, subject to constraints and pre-assignment of rights governed by the fact that they conduct VA research in VA facilities using VA resources and that the work is performed by VA-salaried employees or VA WOC appointees. The General Counsel opinion on whether the corporations conduct research is immaterial to CTAAs although General Counsel has recently agreed that corporations may own intellectual property.

However, VA's failure to incorporate in CTAAs an explicit statement that intellectual property resulting from corporation studies sponsored by pharmaceutical companies will be excluded from the terms and conditions spelled out in the CTAA has complicated—and in some cases seriously impeded—the corporations' ability to negotiate clinical research agreements with pharmaceutical companies. Understandably, pharmaceutical companies are reluctant to share their rights to intellectual property with universities that have played no role in the research or to give non-participatory universities the exclusive right to administer and manage each institution's respective interests in intellectual property. Pharmaceutical companies understand the VA role and are agreeable to appropriate sharing with VA, but not with uninvolved universities. In reality, the chances of new discoveries resulting from such studies are very small and many universities routinely agree not to assert rights to pharmaceutically sponsored research. However, despite many NAVREF requests, to date the VA Office of Technology has not incorporated in CTAAs appropriate language regarding corporation studies sponsored by pharmaceutical companies.

7. ***Please explain the contractual relationship between VA and the non-profits. How would this work? What enforcement mechanisms would be available to the non-profit if there were a dispute with VA over the contract terms? Wouldn't it pose a conflict if the facility Director, required by statute to sit on the non-profit board of directors, votes to sue VA (the Director's employer) for breach of contract? How would the Director balance the interests of the VA against those of the corporation?***

This seems to suggest that the corporations' interests and objectives have diverged from those of VA. Please elaborate.

Before responding to your questions, we wish to note that in view of continuing General Counsel and House Committee on Veterans Affairs opposition to use of VA's existing contract authorities for transactions between VA medical centers and corporations involving VA-appropriated funds, NAVREF has revised its stance. Per discussion with staff of the Subcommittee on Health and the Senate Committee on Veterans Affairs, NAVREF supports "reimbursement authority," a solution General Counsel finds acceptable.

The proposed revision to the corporation authorizing statute is the underlined segment below:

38 U.S.C. §7364. General Powers
(a) A corporation established under this subchapter may-
(1) accept gifts and grants from, and enter into contracts with, individuals and public and private entities solely to carry out the purposes of this subchapter; ~~and~~
New (2) in accordance with procedures established by the Secretary, be reimbursed by the Department for services provided solely to carry out the purposes of this subchapter; and
[(2) becomes (3)] employ such employees as it considers necessary for such purposes and fix the compensation of such employees.

Such "procedures established by the Secretary" would allow General Counsel to prescribe appropriate controls specifically for VAMC-corporation transactions.

However, to respond to your question, to the best of our knowledge, presently there are no contracts between VA and corporations. Until General Counsel imposed a blanket prohibition on VAMC/corporation contracts in December 2001, it is our understanding that a number of contracts had been executed and functioned without problems in accordance with two General Counsel opinions allowing corporations to use certain VA contracting authorities. If Congress were to re-instate contract authority, we anticipate that new contracts would work in the same manner as those executed previously. Further, numerous field contracting officers and VA attorneys assured NAVREF that if contracting authority were reinstated, the federal contracting processes provide sufficient controls to manage potential conflicts of interest and disputes should there ever be any.

The available enforcement mechanisms would be the same as for any other government contract and disputes, if any, would be managed in accordance with the Contract Disputes Act of 1978 as amended. Additionally, VA has an alternative disputes resolution authority that could be invoked as needed. We would recommend that all VAMC contracts with corporations contain an explicit statement of corporation cooperation with federalwide or VA dispute resolution procedures as appropriate.

In the event of a potential conflict in regard to a contract or reimbursement MOU, the medical center director and any other affected persons would recuse themselves from participating in the matter on behalf of the corporation. This is a common means used by nonprofits to manage potential conflicts. Recognizing that the director's first and foremost obligation is to VA, the director would be recused before the matter came to a vote. Posted on the NAVREF web site is a sample conflict of interest policy designed specifically to help corporations identify and manage potential conflicts. The IRS and each state also provide guidance on managing nonprofit conflicts of interest.

By virtue of the statutory requirement that the facility director must serve on the board of directors, the director, as well as every other member of the board, must constantly balance the interests of the VA and the corporation. Corporation boards members are acutely sensitive to their multiple responsibilities, which often include university appointments, and are accustomed to managing them appropriately. However, because VA and the corporation have the common objective of a productive and well-managed VA research program, VA and corporation interests are largely one and the same. While there may be some disagreement over the finer points, rarely are there disputes over items affecting VA interests and board meeting minutes generally reflect unanimous decisions by corporation boards.

NAVREF disagrees with the suggestion that "the corporations' interests and objectives have diverged from those of VA." Rather, in our opinion the growing complexity of managing a world-class research program has compelled VA and the corporations to work together more closely than ever before. Increasingly, VA personnel tell NAVREF that their facility research program could not survive without the support provided by the corporation. At the same time, without a functional VA research program, neither would the corporation survive. As a result, both VA and the corporations have a vested interest in supporting each other, not diverging.