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VA RESEARCH AND NONPROFIT VA RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

AND

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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CONTENTS

May 16, 2002

	Page
VA Research and Nonprofit VA Research Corporations and Education Foundations	1

OPENING STATEMENTS

Chairman Buyer	1
Hon. Jerry Moran, Chairman, Subcommittee on Health	3
Prepared statement of Chairman Moran	41
Hon. Bob Filner, prepared statement of	43
Hon. Julia Carson	17
Prepared statement of Congresswoman Carson	41
Hon. Jeff Miller	44

WITNESSES

Baldwin, Wendy, M.D., Deputy Director for Extramural Research, National Institutes of Health	33
Laracuente, Antonio, Chairman, National Association of Veterans' Research and Education Foundations and Executive Director, Atlanta Research and Education Foundation	30
Prepared statement of Mr. Laracuente, with attachment	82
Mather, John H., M.D., Chief Officer, Office of Research Compliance and Assurance, Department of Veterans Affairs	6
Prepared statement of Dr. Mather	66
Roswell, Robert H., M.D., Under Secretary for Health, Department of Veterans Affairs, accompanied by Tim McClain, General Counsel, Jack Feussner, M.D., Chief Research and Development Officer, Veterans Health Administration; and Mindy Aisen, M.D., Director, Rehabilitation Research and Development, Veterans Health Administration	19
Prepared statement of Dr. Roswell	75
Slachta, Jr., Michael, Assistant Inspector General for Auditing, Office of Inspector General, Department of Veterans Affairs, accompanied by John Bilobran, Deputy Assistant Inspector General for Auditing	4
Prepared statement of Mr. Slachta, with attachment	45
Zieve, Franklin, M.D., president, McGuire Research Institute, Inc.	32
Prepared statement of Dr. Zieve, with attachment	91

MATERIAL SUBMITTED FOR THE RECORD

Statements:	
The American Legion	99
Disabled American Veterans	104
Paralyzed Veterans of America	106
Written committee questions and their responses:	
Chairman Buyer to Michael Slachta, Jr., Assistant Inspector General	111
Congresswoman Carson to Dr. Robert Roswell, Under Secretary for Health, and Dr. John Feussner, Chief Research and Development Officer	117
Congresswoman Carson to Dr. John Mather, Chief Research Compliance and Assurance Officer	138
Chairman Buyer and Chairman Moran to National Association of Veterans' Research and Education Foundations	160
Chairman Buyer to Dr. Franklin Zieve	179

VA RESEARCH AND NONPROFIT VA RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS

THURSDAY, MAY 16, 2002

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
JOINT WITH SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The subcommittees met, pursuant to notice, at 10:20 a.m., in room 334, Cannon House Office Building, Hon. Steve Buyer (chairman of the Subcommittee on Oversight and Investigations) presiding.

Present: Representatives Buyer, Carson, Snyder, Hill, Moran, Boozman, and Filner.

OPENING STATEMENT OF CHAIRMAN BUYER

Mr. BUYER. I'll bring this hearing to order. Good morning. I first would like to also thank my colleague, Chairman Moran. This is a joint hearing today. I also want to thank Ranking Democratic Members Julia Carson and Bob Filner for their cooperation.

Since this is a joint hearing, Chairman Moran and I will both share the gavel. Today's hearing will focus on four areas: (1) follow-up of the hearing held in April 1999 on the suspension of medical research at West Los Angeles and Sepulveda VA medical facilities; and the status of VA's medical research accreditation program; and, third, review of the management and effectiveness of VA research and education foundations; and (4) intellectual property rights of the government and investigators with respect to VA inventions and discoveries.

In April of 1999, this full committee's two subcommittees held a hearing to find out what happened at the West Los Angeles and Sepulveda VA medical facilities that caused the suspension of all medical research at those facilities. What we learned at that hearing and at subsequent hearings held in September of 2000 was very alarming.

We learned that at least eight medical facilities were in noncompliance of VA regulations that govern VA research involving human volunteers. We also found out that veterans were used as human research subjects without their prior informed consent. In fact, one of the veterans had even refused his consent not once but twice. The veterans in question were elderly and sick, and they

were betrayed by the VA system that was supposed to take care of and protect them.

How could this have happened when the VA is subject to the regulatory requirements of the "common rule," which is derived from the federal policy for the protection of human subjects? The VA is one of 17 federal agencies who are co-signataries to the common rule. In fact, the VA has incorporated the common rule in its own regulations. VA is legally bound to adhere to the regulations, which include detailed descriptions of informed consent and the structure and responsibilities of Institutional Review Boards. It is important to note that all VA research is subject to the regulatory requirements of the common rule.

During today's hearing, we hope to learn what the VA has done since the 2000 hearing to ensure that veterans who participate in medical research have not been harmed in any way. Furthermore, at this point in time, we would like to know if we can feel reasonably confident that veterans who participate in medical research are doing so willingly.

Another issue that is paramount to patient safety is the need to ensure that Institutional Review Boards are adequately funded and sufficiently staffed to perform their oversight responsibilities and ensure the protection of all subjects, some of which of whom are our most vulnerable.

Since we serve as the watchdog for veterans' issues, including VA research, I want you to know that we intend to hold a hearing in September on VA medical research and the role played by VA research corporations and education foundations to foster valid VA scientific research.

Ms. Carson and I think and recognize that many accomplishments made by the VA in discovering new drug therapies and developing medical devices have benefitted not only veterans but all Americans. For instance, the VA invented the implantable cardiac pacemaker, developed the nicotine patch, performed the first successful liver transplant, and developed the predicate for the first oral vaccine for smallpox.

The question then is: Does the VA reap the benefits of the research and development? I'm not entirely clear on what arrangement the VA has with respect to patent rights and revenues generated by new discoveries. We hope to hear today how the VA plans to make certain that they get their rightful share of royalties that are collected.

The many discoveries made by the VA through its biomedical research have saved lives and alleviated the pain and suffering associated with many diseases. However, there is a hidden risk attached to performing the necessary scientific research, in that something can go wrong.

I guess one of the most tragic examples is what happened at Johns Hopkins when volunteers participating in its clinical trials died. This is indeed tragic, and we want to do everything we can to make sure this doesn't happen at one of our VA research facilities. We must make sure that the strictest standards in protecting human subjects participating in medical research are in place. Unfortunately, the West Los Angeles VA medical facility is not the only facility that has had restrictions placed on its medical re-

search. We need only look at the VA medical facility right here in the nation's capital to find a flagrant disregard for the protocols governing medical research. Fortunately, no one was harmed at the Washington, DC or Martinsburg facilities.

However, we cannot overlook the fact that the Office of Research Compliance and Assurance identified numerous areas where these two facilities were in noncompliance and both had restrictions placed on their human subject research. This is not good. We can do better, and it is the role of Congress to make sure that all possible precautions are taken to protect our veterans.

We look forward to all of the panels today.

And sort of, as a sidebar, this issue of the Federal Government assisting in medical research, and then companies and corporations then reaping the royalties and benefits, whether it is corporations or universities, take UCLA, for example. There is a lot of money UCLA has received from the Nicoderm patch. I have not seen tuition go down any. That doesn't happen. And yet the taxpayer needs to ask the question: What are we getting out of this?

Yes, there is a benefit to society, but there is a real question about the royalties. And I am very interested in the comments of the panels today. If they could deliver their opinions to us, I think it would be important.

What is happening, for edification to the panels and listeners, there are some conferences that are going on right now. We are doing the welfare reauthorization bill, building off of the successes of the bill that we had done, but there are still yet some differences.

We are going to go ahead and proceed. And I am going to ask unanimous consent that Mr. Len Sistek, counsel for Ms. Carson, be permitted to ask questions on her behalf. A statement of Ms. Carson will be submitted for the record, without objection. And we will go ahead and proceed with this hearing.

I will yield to Mr. Moran for any comments he may have. Chairman Moran.

OPENING STATEMENT OF HON. JERRY MORAN, CHAIRMAN, SUBCOMMITTEE ON HEALTH

Mr. MORAN. Chairman Buyer, thank you very much for your cooperation in holding this hearing. The VA has a longstanding medical research and development program, and I know it is a source of pride for this committee and for the VA. It has made a difference for many of our veterans, our sick, and disabled in the Armed Forces.

There are many things that VA investigators can be proud of. There are many instances in which things they have done have made a difference. They have been recognized with a Nobel prize on three occasions, and the Albert Lasker Medical Research Award, sometimes called the U.S. Nobel Prize, which has been utilized to recognize the excellence in science and medicine at the VA.

Our VA researchers have published literally thousands of papers referenced in journals across the entire spectrum of medicine and bioscience, including the New England Journal of Medicine, the Lancet, and journals of every medical discipline.

Its research is one of the VA bedrock programs. It provides vital link to VA academic partnerships in 107 of our schools of medicine, and forges relationships with other health care professionals and health care professional schools.

While research is an acknowledged hidden treasure at the VA, it has also been the source of some challenges in recent years, as seen during committee-held hearings in 1999 and 2000, on the problems of research activities at several VA facilities, particularly the largest one in Los Angeles.

More recently, problems surfaced in VA facilities in Baltimore, Durham, Washington, DC, and some other sites. The committee has expressed concern in the past about the adequacy of the VA's informed consent practices, its conflict of interest policies, and its internal research management practices, including the effectiveness of supervision exercised by VA Institutional Review Boards, the resources committed to IRBs, and VA local research management including proper recordkeeping, and other documentation requests.

I would like to note for the record that the problems observed in VA research are duplicated in university biomedical research programs outside the VA, and even some of our nation's most prestigious universities. Many of these cases have come to light in the press in recent years, so the VA is not alone in regard to these concerns.

Today, we will reexamine some of the VA programs in research with a focus on the legislation we passed to give the VA authority to set up nonprofit foundations to assist VA managed extramural research fund such as NIH, corporate, and philanthropic grants.

I look forward to the testimony of our witnesses today, and I am also very interested in the VA's experience to date with intellectual property law, and the VA's technology transfer program, which I believe is another success story for VA's research.

Mr. Chairman, I thank you again for your cooperation, and look forward to our discussion today.

[The statement of Chairman Moran appears on p. 41.]

Mr. BUYER. Good morning.

Mr. SLACHTA. Good morning.

Mr. BUYER. Mr. Slachta, if you would please proceed. We are going to proceed with the 5-minute rule. And we appreciate you being here.

Mr. SLACHTA. Yes, sir.

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; AND JOHN H. MATHER, M.D., CHIEF OFFICER, OFFICE OF RESEARCH COMPLIANCE AND ASSURANCE, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF MICHAEL SLACHTA, JR.

Mr. SLACHTA. Mr. Buyer, Mr. Moran, members of the committee, I am accompanied by Mr. John Bilobran, the Deputy Assistant Inspector General for Auditing. As you know, we are here today to

report on the Office of Inspector General's work related to the VA's nonprofit research corporation. I will summarize my written testimony, and I ask that the testimony be provide for the record.

As delineated in our written testimony, from fiscal years 1994 to 1997, we have published three reports that have identified a need to improve accountability and oversight related to the administration of funds by VHA research corporations. Issues that we have reported include:

In a fiscal year 1994 audit of one research corporation, we found that the corporation's board of directors and officers had not established sufficient written policies and procedures to ensure the stewardship of their corporation's activities, or developed an effective internal control structure.

In another 1994 report, we reviewed a million dollars of $3.6 million in expenditures spent at three research corporations and identified about $625,000 that was spent on activities not directly related to research. We found that funds were spent for salaries of medical residents and on staff travel not clearly related to research or administration. And we found that funds were spent for non-research-related conferences, honorary gifts, awards, entertainment, other non-research expenditures.

In a fiscal year 1997 report, we found that one medical center provided radiology and laboratory services to an affiliate medical school, but the research corporation, not the medical center, billed and received payment from the school for the services.

Since fiscal year 1993, we have also issued four other reports that addressed issues related to VA's management of the research program. Although these reports do not directly address funds administered by the research corporations, the issues reported were related to VHA's administration of the research program and control over research funds.

In these reports, we made recommendations to strengthen controls over the use of research funds, personnel, and medical care fund reimbursements. In response to our recommendations, VA agreed to publish national policy for the operation of research corporations that included guidance for administration, accounting, budgeting, and oversight.

VA published such a policy chapter governing nonprofit research corporations in May 1994. In our view, that policy did not adequately address expenditures controls, and did not provide adequate guidance over the appropriate use of research funds. Subsequently, in November of 2001, VHA published VHA Directive 1200; and in December 2001, VHA published the handbook 1200.17, to provide further guidance for governing research corporations.

In response to the committee's questions regarding the monitoring and accountability requirements for VA's research corporations, we obtained responses to the questions from the Under Secretary for Health, the Executive Director of National Association of Veterans' Research and Education Foundations, and the chairman, Office of General Counsel's Corporations Panel. We compiled their answers and have included them for your information to our written testimony.

At the committee's request, my staff reviewed the responses provided. To date, we have focused our review on determining whether

the required reports were submitted to the Congress for fiscal year 2000.

Our work included verifying that each VA research corporation required to obtain an independent financial audit and report corporate information to the Internal Revenue Service was in compliance and accurately reported timely information. We found no evidence to lead us to believe that the information VA reported to Congress was not complete and reliable.

Based on our current review, we found that 18 of the 88 research corporations reported total annual revenues of more than $3 million in fiscal year 2000. Accordingly, as an observation, there may be an opportunity to reduce administrative and overhead expenditures associated with maintaining 88 individual financial management and payroll systems, obtaining annual audits, meeting Internal Revenue Service reporting requirements, and other administrative costs by consolidating and reducing the number of research corporations and redirecting those funds to direct support of research.

This concludes my testimony. Mr. Bilobran and I would be please to answer any questions that you and the members of the committee may have.

[The prepared statement of Mr. Slachta, with attachment, appears on p. 45.]

Mr. BUYER. Dr. Mather.

STATEMENT OF JOHN H. MATHER

Dr. MATHER. Mr. Buyer, Mr. Moran, Mr. Filner, good morning. Thank you for this opportunity to appear before you. And I would ask that my written testimony be entered into the record of this oversight hearing.

Mr. BUYER. No objection.

Dr. MATHER. The focus of my remarks this morning will be on the progress that has been made in establishing the Office of Research Compliance and Assurance. It is usually referred to as ORCA, since Dr. Kaiser, the then Under Secretary for Health, announced his formation in April 1999.

I have some additional information on the reinvigoration of the human subjects research program at the West Los Angeles VA Medical Center, now the Greater Los Angeles Health Care System, since September of 2000.

Finally, I will also briefly discuss some of ORCA's involvements in the VA's program for the accreditation of human research protection programs at VA medical centers.

At the outset, I want to emphasis that ORCA's primary concern is that every research subject involved in research conducted in VA medical facilities is afforded all of the protections to which they are entitled.

The overall purpose of ORCA is to promote enhancements in the ethical conduct of research in conformance with regulations and policies while simultaneously monitoring the extent of this compliance.

ORCA's structure, scope, philosophy, and product lines are all designed to reenforce this mission. My written statement provides further information on how this mission has been operationalized.

ORCA's regional office is taking the lead with central office oversight.

Throughout all of our work, ORCA's staff strived to keep the veterans needs and welfare in mind. To that end, we have developed, and are now distributing a brochure: "I am a veteran. Should I participate in research?"

The brochure is intended to be used by veterans and their families, who are interested about learning about participation in VA research. The brochure has a balanced view of VA research and summarizes patients rights and welfare when they enroll as subjects in research.

One of the features of the brochure that is expected to be very useful for the veteran is the one page list of questions that a veteran should be prepared to ask about participation in a research study.

In March 1999, the research program at the Greater Los Angeles Health Care System was suspended by HHS's Office for Protection from Research Risk, now the Office for Human Research Protections, often referred to as OHRP.

The problems with serious and egregious violations of the regulations to which the VA subscribes, known as the "common rule," and VA's own policies and procedures. The research program was immediately placed on administered probation. Although suspension was soon lifted by OHRP, the VA put in place an approved and detailed research program recovery plan.

There were immediate improvements and evidence of compliance with the regulations for the protection of human subjects. In spring 2000, a new associate chief of staff for research and development was installed, which triggered the date one year later for review of the assigned probationary status.

ORCA conducted an intensive and comprehensive follow-up review of the Greater Los Angeles Health Care Systems Research Program in April of 2001. The conclusion endorsed by the Under Secretary for Health was that sufficient progress had been made to warrant the lifting of probationary status, and authorization was given to the medical center to submit documents for the activation of a new federal-wide assurance.

The follow-up review report contained recommendations for additional improvements in the research program. ORCA has been reviewing the implementation of the recovery action plan, which responded to the report's recommendations. Almost all of the recommendations have been implemented and should be completed within the next 3 months. This will then result in a written closeout letter from ORCA.

In summary, the Greater Los Angeles Health Care System's Research Program is now demonstrating that it is dedicated to the protection of veterans and its human research activities. This has been a difficult and complicated process to accomplish, which has necessitated the allocation and expenditure of many additional resources.

For the balance of my time, I would like to briefly discuss ORCA's relationship with the VA's accreditation program for human research protection programs. ORCA has a direct liaison with the human research protection program of accreditation spon-

sored by the National Committee for Quality Assurance, often referred to as NCQA, and on the contract of the VA through the Office of Research and Development.

Until just recently, ORCA has acted in a general advisory capacity offering its ideas and suggestions. Now that the contractor for this accreditation program, NCQA, has begun to notify VA medical centers, it has surveyed all of the accreditation status, the level of activity for ORCA has significantly increased.

NCQA has made determinations of accreditation status at 11 of the 23 sites it has surveyed, issued notice of not accredited at three VA medical centers, and accredited with conditions at another eight VA medical centers. These accreditation determinations are of great concern, especially those designated as not accredited.

ORCA makes immediate contact with the VA medical centers that are not accredited to make a preliminary assessment of the situation. Within 48 hours, a focus review team of one or two ORCA staff is on-site to make a focused assessment as to whether human subjects enrolled in the research protocols might adequately protect and determine, as far as possible, whether there has been any medical harm.

An evaluation is also made as to whether there is any serious or egregious non-compliance with the regulations. So far, the three completed focus review reports are reassuring, but they're insufficient to make a complete determination of the extent and magnitude of possible regulatory noncompliance.

Each of the VA medical centers that receive notification of not accredited were surveyed several months ago by NCQA, and all of them have indicated an intent to appeal within a 30-day limit. Filing an appeal with NCQA freezes the notification until NCQA's appeals power considers additional information provided by the VA medical center and renders a final decision.

ORCA needs in-depth and current information about the VA medical center's human research protection program activities; has created a systematic post-accreditation review, referred to as a SPA, to fully address the situation at VA medical centers when NCQA gives a not accredited designation, or conducts an on-site SPA review at the VA medical center.

The SPA's charter defines a purpose for these reviews, and the expectation is to assess the full scope and significance of the issues that relate to the performance of a VA medical center's human subject's research activities. The SPA report including recommendations, is available 2 weeks after the team completes its on-site review, and the first SPA report is due the end of this week.

During the course of the on-site review, serious and egregious noncompliance with the regulations that protect human subjects may become apparent. If so, ORCA may issue a suspension or restriction on the VA medical center's assurance.

While the final SPA reports have yet to be issued, ORCA has issued a restriction on the assurance at one of the VA medical centers that was not accredited for serious but not egregious noncompliance with several provisions of the common rule.

When the SPA report is completed, ORCA decides on the next steps and elicits a recovery action plan from the VA medical center, which must substantially address the recommendations.

As needed, ORCA will notify the other regulatory agencies such as OHRP and the FDA. Eventually, when the recommendations have all been fully implemented to ORCA's satisfaction, the VA's Office of Research and Development will be notified. This will signal that consideration might be given to a new review of the VA medical centers human research protection program through the NCQA's accreditation program.

In summary and in conclusion, in the last 3 years since the Under Secretary for Health announced the establishment of this office, ORCA has committed considerable time and much energy to achieve the required expertise and competence.

The die has been cast to firmly establish ORCA as the primary office within the VA for oversight of the VA research enterprise in regard to the responsible conduct of research. This role and responsibility has been fulfilled in collaboration with other VA offices, the relevant other federal departments and agencies, and nongovernmental organizations.

Over the next few years, the foundation that has been established in ORCA will allow for the elaboration of an even more robust research enterprise where the rights of human subjects will be continuously protected.

Again, I appreciate the invitation to discuss these important issues with you, and I will be pleased to try and answer any questions you might have.

[The prepared statement of Dr. Mather appears on p. 66.]

Mr. BUYER. Thank you very much. A letter was sent from me, as Chairman of the Oversight Subcommittee. Did you see the responses to the letter?

Mr. SLACHTA. Yes, sir, I have.

Mr. BUYER. How would you characterize these responses?

Mr. SLACHTA. I would generally characterize them as incomplete.

Mr. BUYER. Aren't you kind? Let's use that as a baseline.

Mr. SLACHTA. Yes, sir.

Mr. BUYER. They almost remind me of the interrogatories sent to the President during impeachment. I mean these are not—these are very—this a very poor document.

Mr. FILNER. Mr. Chairman, I wonder if you would, for the record, tell us what the letters are, because I am not sure what you are referring to.

Mr. BUYER. On March 22, I sent a letter, a 6-page letter, requesting the IG review of a long list of questions that had arisen in the reports, and what I can do is I will pause at this moment. I will share these. You ought to take a look at these responses, and I will move on to another question.

Okay. Let's just move to another question. We will allow Mr. Filner to take a look at them.

You know, we are not asking questions to be bothersome. This is the taxpayers' money and we are interested, and there are also people out there which we are very sensitive about, and we will come back to that.

I am curious in understanding this relationship with the research corporations. There are 88 of them?

Mr. SLACHTA. Yes, sir, 85 active.

Mr. BUYER. Eighty-five. And a director of a research corporation, are they also—or some of them can be VA employees?

Mr. SLACHTA. The director is supposed to be the medical center director.

Mr. BUYER. So all of them are VA employees?

Mr. SLACHTA. Yes, there are five directors. There should be two public directors, two non-VA employees.

Mr. BUYER. Okay. Now, in your testimony when you had cited that in another IG report about this $625,000, that's back in 1994.

Mr. SLACHTA. Yes, sir.

Mr. BUYER. Right?

Mr. SLACHTA. Yes, sir.

Mr. BUYER. So they are supposed to be doing annual audits, is that correct?

Mr. SLACHTA. Yes, sir, they are, with certain limitations, yes.

Mr. BUYER. And is that being done?

Mr. SLACHTA. We looked at the reports for fiscal year 2000, and the audits were being performed.

Mr. BUYER. Okay.

Mr. SLACHTA. We found one facility that was not timely, but it still was done.

Mr. BUYER. All right. Since I am also participating in something called Enron and Arthur Andersen, let's define the word "audit," okay?

What's an audit, and what are you looking at?

I know what it is. But what is the definition that is being used?

Mr. SLACHTA. The audit that was required for the research corporation was an audit of their financial statements. So the audit that was performed for most of the corporations was done by independent public accountants on the reasonableness of their statements.

There were some additional auditing Circular VA: 122 requirements on those corporations receiving federal funds, and those were done by the Department of Health and Human Services.

Mr. BUYER. So the audit is more of an accounting, follow the dollar——

Mr. SLACHTA. Yes.

Mr. BUYER (continuing). Checks and balances?

Mr. SLACHTA. Correct.

Mr. BUYER. Are they auditing what they are actually spending to support VA research and medical care appropriations?

Mr. SLACHTA. They are auditing the reporting of the funds on how they are being spent.

Mr. BUYER. So the answer is no?

Mr. SLACHTA. I can't say yes or no, because I have not reviewed their audits.

Mr. BUYER. All right. So let me ask this. I am always bothered if someone is spending money that should not be spent—having spent, and then they get merit bonuses, and things like that. Did that occur?

Mr. SLACHTA. I am not aware of any bonuses being paid to the research corporations, to the directors of the research corporations—in fact, the directors are VA employees, and they should not be receiving any renumeration on their research corporations.

Mr. BUYER. They are dual-hatted, though.

Mr. SLACHTA. Yes, sir, they are. There is no question about that.

Mr. BUYER. So you could have a director get a merit bonus, and claim it was for these activities, not related whatever with the research corporation?

Mr. SLACHTA. That is possible. Oh, absolutely, that is possible.

Mr. BUYER. Uh-huh. How does this system work? Is it a good system or a bad system?

Mr. SLACHTA. It was set up by——

Mr. BUYER. The question is, is it too much responsibility for one person, or is it working all right?

Mr. SLACHTA. I can't answer the question as to whether it is too much responsibility. In some of the corporations, it is working well. In other corporations, you have got problems. You have got individuals who are not monitoring. They are not performing their oversight activities. In others, it seems to be okay.

Mr. BUYER. All right. I am asking you for your personal opinion here. If you have got 85 of them out there, it is working in what kind of percentage?

Mr. SLACHTA. I am really not in a position to respond to that. I have not done a systematic review of research corporations since 1994.

Mr. BUYER. Right, but you are going to.

Mr. SLACHTA. Yes, sir, obviously.

Mr. BUYER. It is a question of—from the system analytical approach—that is what I am sort of asking here, is the system right or not, or are you saying it is the human element? If it is the human element, then obviously it is about management, management styles, and some are proactive and some are reactive, you know.

Mr. SLACHTA. If I might, you are always going to have the human element in anything, no matter what you are doing. So you are going to have individual problems.

The questions that come to our mind, the questions that we looked at, are basically the same questions that every auditor has, it is the monitoring and oversight of the activities that go on. Is there sufficient monitoring and oversight of the corporations? Who does it? Those are the questions we think that really need to be answered.

Mr. BUYER. All right. I have some questions for Dr. Mather. But at this time, I yield to Mr. Filner for questions he may have.

Mr. FILNER. Mr. Chairman, on the questions that you would ask, I yield to you my time to pursue those if you'd like.

Mr. BUYER. So I have it back? Have you seen these answers?

Mr. SLACHTA. Oh, yes, sir.

Mr. BUYER. Let me ask this question. When you see this, and you see these types of answers coming from the VA to this committee, what do you—what is your reaction? What do you do about it? I know what I'm going to do about it. What do you do about it?

Mr. SLACHTA. We thought they were incomplete. If you do not mind, I would like Mr. Bilobran to explain some of the issues that we have with the questions.

Mr. BUYER. Only if that is a handoff and not a punt.

Mr. SLACHTA. Oh, no. It is not a punt.

Mr. BUYER. All right.

Mr. BILOBRAN. Mr. Chairman, I think we would agree that the responses are, in general, inadequate to give the committee an overview of the operations of research corporations. Some of the responses raise the specter that VA and VHA does not have good visibility over the operations of the research corporation.

There are two or three responses, in what I would consider to be significant areas, where VHA has responded that they do not have the information to respond to the question. There are several questions where the response appears to be too short and incomplete to give—and, perhaps, even avoiding a direct answer to the question. We need to follow up with VHA and respond to the committee with more complete answers.

Mr. BUYER. Dr. Mather, have you seen this?

Dr. MATHER. Yes, sir, but I do not know anything about that.

Mr. BUYER. Oh, wow.

Dr. MATHER. Mr. Chairman, it does not come under the purview of ORCA, which is why we have not spent time on the issue.

Mr. BUYER. I understand. I was just curious. You know, I can't decide whether this is intentional evasion, ignorance, laziness, or just did not want to be bothered. I do not know how to interpret it. But I am going to ask of you, in your review, you have been around enough to know how to—you know, what this is.

I am just going to let it chill for a moment, because I do not react very well to this type. We are here to do a job. You are there to do a job, everybody is, and Congress should not be treated like this.

Mr. Filner, let me yield back to you. I will put it down before I say something I regret.

Mr. FILNER. Mr. Chairman, I just want to submit my opening statement for the record.

[The statement of Congressman Filner appears on p. 43.]

Mr. BUYER. It will be submitted for the record. Dr. Snyder, you are recognized.

Dr. SNYDER. Thank you, Mr. Chairman. Mr. Chairman, I want to be sure I am looking at the same—and I apologize for coming in late. We are talking about this Exhibit 1, Compiled Responses to the Questions in the Committee, that is what we are talking about?

Mr. BUYER. Yes.

Dr. SNYDER. Mr. Bilobran, would you—I have 5 minutes in this. Until that red light goes off, would you use my 5 minutes and go page-by-page, and let us know, and the committee know, which of these answers you—which of these answers you consider acceptable, which you consider unacceptable, and for what reasons.

And, you know, I don't know what the extent of your looking into this is. But if you want to, you know, punt, in the chairman's words, on some of them—but would you please go through that for me?

Mr. BUYER. Can I add one? What is your greatest concern?

Dr. SNYDER. Yeah, which question caused you the most heartburn? But I'd like you to go page-by-page through it in the time that I have.

Mr. BILOBRAN. Well, let me answer the question about greatest concern first. I think from our perspective, the greatest concern

would be those responses that would indicate that VA and VHA does not have good visibility over the activities of the research corporations.

When the corporations were established, they were created to facilitate research. They were created because there was a perception that research—non-VA funding that was administered by universities to conduct research at VA medical centers was subject to extraordinarily high overhead charges from the university, and that the idea was that by creating these not-for-profit corporations affiliated with VA medical centers, we would be able to avoid those charges.

Dr. SNYDER. If you wouldn't mind, if you could go—we have got 15 pages, and about 4 minutes left. That gives you about 18.2 seconds per page.

Mr. BILOBRAN. Beginning on page 3 of Exhibit 1, there is a question to identify the current VA-approved research projects that are funded through VA research corporations delineating the type of research that is conducted.

The first bullet was drug trials for pharmaceutical companies. And the response says that one-half of foundation revenues come from the private sector and include grants from pharmaceutical companies, as well as other private sector organizations.

That would be the first incomplete response in the sense that it does not directly answer the question, how much comes from pharmaceutical companies? And I might say that the anecdotal information that we have is somewhat different from that response, so we would have to have that clarified.

The next series of questions relates to other categories of research; and the response is that we do not have this data. And that would be a major concern that we are not able to accumulate that data.

Question—What was the percentage that was spent on overhead. The answer was that expenses averaged about 10 percent? Again, we need clarification of what that means. Are we talking about just charges that have been established by the not-for-profit for overhead—charges against the researchers' funds that are held on account? Are we talking about all indirect costs that might be——

Dr. SNYDER. It also seems like the question there was—my attitude towards that question would be that you were supposed to go through each corporation and say what is overhead expense.

By this question, one could have had a 50 percent overhead expense, and others could have had a 1 percent overhead expense, and the average would be about something—yeah.

Mr. BILOBRAN. Indeed, well, two or three questions later there is a question on the range of overhead expenses? And that range goes from 0 to 43 percent.

Dr. SNYDER. Oh, yeah, yes.

Mr. BILOBRAN. Farther down on page 4, there is a question, what were the criteria for considering an expenditure, a research expenditure?

And the answer is—if an expenditure is related to research, it is considered to be a research expenditure, a somewhat circuitous response that does not—I think needs clarification.

Dr. SNYDER. No.

Mr. SLACHTA. Oversight questions.

Dr. SNYDER. I am sorry?

Mr. BUYER. Oversight questions.

Mr. BILOBRAN. Where is——

Dr. SNYDER. Page 5.

Mr. SLACHTA. One of the concerns that I had, in particular, as a manager, is the oversight functions. The oversight is being pressed down to the executive review at the research corporation, the board of directors, the local facility.

And it says in here, "What oversight functions are in place to review these reports, compiled in accordance with requirements?"

Dr. SNYDER. I am sorry, sir. Where are you at?

Mr. SLACHTA. I am sorry, page 5.

Dr. SNYDER. Page 5.

Mr. SLACHTA. Right, and it dealt with the oversight being at the facility level. Network fiscal officers, as well as personnel, Office of General Counsel—well, that's local general counsel, and the Office of the Inspector General.

The Office of the Inspector General has not looked at research corporations in a long time, and the Office of the Secretary. Well, that is the compilation. That is at the summary level. Nobody is looking at the facility level, and I think that is a major issue that needs to be looked at.

Mr. BUYER. I ask unanimous consent the gentleman from Arkansas be granted an additional 5 minutes to complete his line of questioning.

Dr. SNYDER. Thank you, Mr. Chairman. If you would just continue, please. That increases your per second per question, but we have still got 10 pages to go. You have 5 more minutes.

Mr. BILOBRAN. Going to page 6, "What is the total amount VA received from donated funds for 2001, and how was it accounted for?" And the response is that we do not have data for total VA donations.

Again, it does not address why—what that specific response means. Do we have information on some of them, but not all? And it certainly does not address——

Mr. BUYER. Because if you don't even know how much money you got in, there is no way you can be accountable.

Mr. BILOBRAN. Exactly. And I guess this points to another of our concerns, which is related to the utility of the annual report in providing federal oversight of these activities.

Is this report sufficiently detailed and comprehensive to provide the oversight? These responses seem to point to the need to improve the detail and the scope of the annual reporting.

And next. During the past 5 years have any research corporations earned revenues from general fundraising, investing, and/or business-like activities?

And the response is that a few corporations have participated in minimal fundraising, and some participate in the CFC, and that they invest funds and instruments backed by the full, faith, and credit of government.

I would like to see a direct response to the balance of the question, with regard to business-like activities. Who is responsible for any monitoring? And provide documentation of those reviews.

The response is that IRS, as well as each corporation's accountant, auditor, and board of directors provides monitoring to ensure that all revenues and expenditures are consistent with the corporation's tax exempt purposes, and are reported accurately. Fundraising expenditures are reported in Form 990 and interest. Again, I think that the——

Dr. SNYDER. Well, that's an acknowledgement there is no VA monitoring at all.

Mr. BILOBRAN. It appears to be an acknowledgement that there is no VA monitoring.

On top of page 7, what oversight requirements are in place to monitor research corporations?

Each corporation has a board of directors that has responsibility. In addition, the corporation has a CPA accountant and an external auditor. Further, the Inspector General, the Comptroller General, and the IRS, and government of the state in which the corporation is incorporated, have the right to examine the records of a corporation at any time.

Again, this response indicates those organizations and elements that have rights to monitor. It does not address what I would perceive to be the intent of the question, which is "Who in VHA monitors the activities of the corporation, and how is that monitoring taking place?"

Expenditures are directly related to research. This was a——

Dr. SNYDER. I am sorry, sir. Where are you at?

Mr. BILOBRAN. I am sorry, page 8, roman numeral VIII.

Again, the question was: Please list the amount each research corporation spent in 2000 and 2001 on the following, and the response is that the corporations are not required to report the above categories of expenditures.

It raises the question of whether or not they could be required to report, or whether the information could, in fact, be provided. It points to the question of the detail of accounting information on expenditures that may be available in the field, and whether or not it is maintained in a manner to be able to answer that question.

The response further indicates that guidance is published in regard to what expenditures are considered proper versus improper. The guidance is provided in the attached handbook. I believe that, to my knowledge, that is in fact straightforward—all of the guidance is available is in that handbook.

Dr. SNYDER. Mr. Bilobran, my time is up. I will yield back.

Mr. BUYER. I would ask unanimous consent that the gentleman is doing such a great job that we go ahead and complete the document, with no objection.

Dr. SNYDER. We are determined to get through the 15 pages, Mr. Bilobran.

Mr. BILOBRAN. There is a question of a conflict of interest in advocacy issues.

Dr. SNYDER. Again, where are you at, please?

Mr. BILOBRAN. I am sorry, page 9, roman numeral IX.

Dr. SNYDER. Oh, right, got you.

Mr. BILOBRAN. And the response is that the question is probably best answered by NAVREF. And NAVREF, in fact, did provide a

response, but I would be interested to see VHA's position in answering questions regarding conflict of interest.

And I believe it perhaps points back to the remarks the chairman made a little bit earlier with regard to whether or not the current structure for management and directorship of the corporations is in fact working effectively. Because, in part, it deals with VA officials who have to wear two hats—one to administer the medical center and one to administer the research corporation.

Question—What percent of funds for the research corporations are spent for advocacy issues?

Dr. SNYDER. We are now on page 10?

Mr. BILOBRAN. On page 10. And, again, the response from the Department defers to NAVREF, and points to the potential that we do not have visibility over how that category of funds is spent.

Several other questions are posed by the committee that are answered in a similar fashion—NAVREF is asked to provide the answer for the question. I would like to see—I would like to know why the Department is unable to answer the question.

Mr. SLACHTA. Thirteen.

Mr. BILOBRAN. I am sorry?

Mr. SLACHTA. Move to page 13 on the research consultations.

Dr. SNYDER. What page are you on now please, Mr. Bilobran?

Mr. BILOBRAN. Page 13, roman numeral X, Research Funds Expended for Consultation Service and awards, were any research corporation funds expended for consultative services during the 1998 through 2001, and for each expenditure identify the corporation who spent the fund.

The Answer is that VA does not collect information on consulting fees paid by corporations, however, such fees, if any, are reported on IRS, Part II, Form 990. Again, this points to the question of whether or not we have visibility over that kind of expenditure, or whether we are able to obtain that information.

Dr. SNYDER. One detailed question, Mr. Bilobran, is Form 990, Part II, to the IRS, is that a public document?

Mr. BILOBRAN. Yes. Question—for 1998 and 2001, were any research corporation funds spent on awards, media, and other public relationship efforts?

Answer—Some corporations make donations, some activities are designed to educate the general public. Members of Congress are often invited guests. Again, I don't believe there is adequate detail in the answer—either pointing to an incomplete answer, or the inability to obtain the information.

Next question. For each award, identify the research corporation that made the expenditure, the research from which it was made, and the amount of each award, and identify the recipient of the award, and reason for the award.

Again, the question is that that the corporations are not required to report awards, raising the question of whether or not the information is or is not available.

Question—please list the internal controls that ensure medical care appropriations are appropriately reimbursed for services and resources used to support research protocols. And the answer is that the board of directors and facility management are responsible

for ensuring that medical care appropriation is appropriately reimbursed.

Dr. SNYDER. That, by definition, is not an internal control is it?

Mr. BILOBRAN. No, it does not—the answer does not describe what ability we have here centrally to ensure that that is accomplished. It does not describe a control itself.

Question—What has VA done to develop and implement the recommendations from the 1994 OIG report?

Dr. SNYDER. I am sorry.

Mr. BILOBRAN. That is on page 15, roman numeral XIII.

Dr. SNYDER. Yes.

Mr. BILOBRAN. The VA response is that provisions specifying use of commonly accepted accounting practices and other recordkeeping guidance were added to the handbook. Additionally, corporations follow recordkeeping procedures and accounting principles established for nonprofits by FASB, and the American Institute of Certified Public Accountants.

Again, it describes what governing policy or criteria are available. It does not touch on the—what steps have been taken to ensure that the recommendations are implemented as intended.

Dr. SNYDER. Thank you. Thank you, Mr. Chairman.

Mr. BUYER. Thank you. Thank you, Dr. Snyder, for taking us down that path. I would like to yield to Ms. Carson for any questions she may have.

Ms. CARSON. Thank you very much. Dr. Mather, in your testimony, you addressed your lack of regulatory authority and your need to forge a different paradigm. ORCA embraces what you refer to as an ACE approach.

How do you know if the ACE approach is working? How will you measure success?

Dr. MATHER. Madam, the ACE approach represented in the testimony is sort of a paradigm of balancing our roles of being supportive and also having to oversee to make sure there is compliance with those regulations that support an adequate human subjects research protection program.

We think that since we are not a regulatory entity ourselves, we have to balance off what is on the left-hand column, as we call it, which is the issue of assurance of consultative and educational activities, against the responsibility to assess, to enforce, and be a little bit of a cop. So that is the sense of what that paradigm is about.

We spend, certainly, a lot of our time thinking through how we can fulfill both roles, being both supportive and also being a clear oversight entity. VA medical centers I think still remain a little bit ambivalent about us, as to which side of that we are going to come down on in many circumstances.

Clearly, we have a responsibility when there are issues of research improprieties that are brought to our attention, we investigate them, and we do, and we have a mechanism for doing that through these focus reviews, and these special inquiry force team reviews. But we also have developed a program called our "Multiassessment Program," which is a prospective way of helping facilities get their program in shape.

We have a self-assessment program where we have been able to give to VA medical centers in a very detailed way, indeed, as ref-

erenced in my testimony, a CD-Rom, which has all of those regulations set forth, so they understand what it is that they are supposed to do. And we are willing to come in later to help them make sure that they understand what they have done in that regard in an on-site review.

Ms. CARSON. Thank you. Thank you, Mr. Chairman.

Mr. BUYER. Thank you. A little follow-up. Dr. Mather, what is the present status of the protection of human subjects now at West L.A. VA Medical Center?

Dr. MATHER. Mr. Chairman, I hope my reference in my oral testimony moved to the answer of that question. As of today, they have I think some several recommendations coming out of a follow-up review that we did in April of last year.

And I am assured by my regional office director on the West Coast, as of yesterday, that he estimates that those few items will be, as it were, cleaned up within the next month or so. He intends going back there and making quite sure that those recommendations are completely fulfilled before he advises me on providing the facility a closeout letter, which, in essence, closes out the issues there at West L.A.

I personally visited there a couple of times, and it is very clear that they have a dedication from the director, and more especially the ACS, for research and development, Dr. Yamaguchi, to get it right and do it right.

Mr. BUYER. Do you have any concerns about the resources that have been relocated to bring about the "recovery," and is it enough?

Dr. MATHER. Everything that I have seen at West L.A., sir, that you are referring to I think indicates that the director has certainly taken a lot of medical care funds to add to that activity to do what is necessary.

They have added three Institutional review boards, over and above the original two that they had. They have certainly hired a lot of additional staff to get the job right.

Mr. BUYER. When you have a VA medical center that received a not accredited rating, should the VA medical centers whose human subject research programs remain in that status be allowed to continue with their programs, or be shut down?

Dr. MATHER. Mr. Chairman, I think when we received the first indication of a place being not accredited, we were somewhat alarmed, because we were not exactly sure what that meant. The surveyors had been into the facility, been there several months ago, so one could posit that the situation had gotten worse, it stayed the same, or in fact had even gotten better, in terms of improvement.

So we went there, as I indicated in my testimony, to do a focus review to really answer two questions: is there anybody today who is a human subject enrolled in an active research program being harmed, I mean, literally medically harmed, physically and mentally?

And we have found in each of the three places, now that we have been in to do these focus reviews, we have been assured, and we have done a scrambling job to do that, as you can imagine, this place for a couple of days, there is no evidence of anybody's being actively harmed.

Are there sufficient protections? Which is the other part of that question we want answered. And, that is, are there serious or egregious noncompliance with regulations so that human subjects enrolled in the research are put in some degree of harm or jeopardy?

The place that we went to and finished our first systematic post-quotation reviews, the SPA, I was out there at the end of that visit a couple of weeks ago and we were concerned that there were some serious matters that needed to be attended to, some seven serious violations of the common rule regulation.

And I was really in no position but to issue a restriction letter right there on the spot, which says that their actual research protocols cannot accrue any new human subjects into those protocols until they had all been reviewed in conjunction with the IRB and the principal investigator.

Mr. BUYER. What facilities that have been reviewed are not accredited?

Dr. MATHER. They are the North California Health Care System, sometimes known as the Pleasant Hill VA Medical Center; the second is the Pittsburgh Highland Drive Division; and the third is the Providence VA Medical Center.

Mr. BUYER. Mr. Boozman, you are recognized. Do you have any questions?

All right. Ms. Carson, do you have any follow-up? All right.

We want to thank you for coming, your testimony. And, Mr. Slachta, we will have follow-up with you, I am sure.

Mr. SLACHTA. Yes, sir.

Mr. BUYER. Thank you.

Mr. SLACHTA. Thank you, Mr. Chairman.

Mr. BUYER. Thank you.

Our second panel will be the Honorable Dr. Robert H. Roswell, who is the Department of Veterans Affairs Under Secretary for Health. I will ask him to introduce his—do you have any staff with you? If you do, please introduce them. You are now recognized.

STATEMENT OF ROBERT H. ROSWELL, M.D., UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY TIM McCLAIN, GENERAL COUNSEL, JACK FEUSSNER, M.D., CHIEF RESEARCH AND DEVELOPMENT OFFICER, VETERANS HEALTH ADMINISTRATION; AND MINDY AISEN, M.D., DIRECTOR, REHABILITATION RESEARCH AND DEVELOPMENT, VETERANS HEALTH ADMINISTRATION

Dr. ROSWELL. Thank you, Mr. Chairman. It is a pleasure to appear before the committee today. With me this morning, I have Mr. Tim McClain, our general counsel; Dr. Jack Feussner, the Chief Officer for our Research and Development Office; and Dr. Mindy Aisen, who directs our rehabilitation research and development office.

I appreciate the opportunity to appear before you to discuss nonprofit research corporations and educational foundations and the Department of Veterans Affairs Human Studies Protection Program. With your permission, I will briefly summarize my submitted statement, and then be prepared to respond to your questions.

Mr. BUYER. No objections.

Dr. ROSWELL. My formal statement discusses the background, operational functioning, and accomplishments of the research and educational corporations. These corporations have helped VA research by increasing flexibility, with respect to staffing and handling of donated funds and grants.

Also, as a result of the Millennium Act, we are now able to establish corporations to facilitate educational activities of the Department. Such activities would include work-related instruction and training for VA employed staff, as well as broad, instructional, and learning experiences directed toward improving and maintaining the health of the veteran patient.

As of June 1, 2001, 88 research and/or education corporations had been chartered; of these, 85 remain active. Recently, two facilities have established education corporations that are separate from research corporations already serving those facilities.

Revenues from a variety of sources, but excluding dollars appropriate for VA health care are increasing through the VA research corporations. With these increased revenues, the expenditures in support of VA research and education are increasing and the expertise of management is improving steadily, as evidence by corporation audits.

Mr. Chairman, you also requested that I provide an update of VA's activities to assure that VA research is conducted in accord with the highest standards, and with the highest regard for research participant safety and health. As you know, VA undertook significant efforts in this regard following hearings conducted by the House Veterans Affairs Committee in 1999 and 2000.

My formal testimony discusses these efforts in some detail. However, the creation of the Office of Research Compliance and Assurance or ORCA and the leadership VA has provided to establish an external accreditation process for research programs are noteworthy, and are leading the nation in many respects.

Dr. Mather has testified earlier about ORCA activities and accomplishments regarding the accreditation program. I am very pleased that VA has worked with the National Committee for Quality Assurance, or NCQA, a private non-profit, accrediting organization dedicated to improving health care quality to develop this accreditation process.

NCQA has developed accreditation standards and will survey and determine the accreditation status of all facilities conducting human subjects research every 3 years. Accreditation site surveys began in September of last year.

Survey results and accreditation reports will be valuable learning tools for all who have a role in VA research, and will significantly add to our oversight and assurance activities.

Also in your opening comments, Mr. Chairman, you asked, and I would like to respond about intellectual properties. VA has made considerable progress in asserting its right to intellectual properties developed with support from VA research programs and resources. And we would be happy to answer questions concerning that.

To conclude, the VA is committed to assuring that its investigators follow the highest standards for assuring respect of the rights, dignity, and safety of research participants. We believe the ap-

proach VA is taking with this continued emphasis on training and education, independent oversight, and mandatory external accreditation will result in a system-wide human subjects protection program that will place VA at the forefront of ethical science.

Mr. Chairman, I very much appreciate the committee's support of these efforts over the years. This concludes my statement. My colleagues and I would be happy to answer your questions.

[The prepared statement of Dr. Roswell appears on p. 75.]

Mr. BUYER. Thank you very much. There is plenty of testimony about money for oversight, but no testimony about money for the Institutional Review Board.

What is the Office of Research and Development sending to the field in recurring funds nationwide to cover the IRB expenses?

And how much, if any, did this go up after West L.A. shut down?

Dr. ROSWELL. Currently, approximately, $380 million is distributed from our medical care appropriation to VA facilities in support of the research mission. There is a research adjustment to the veterans equitable resource allocation or VERA model that distributes these monies based pro rata on the amount of funds administered through the research program.

In addition to that, almost $380 million in appropriated medical care dollars, an additional $45 million from the research appropriation is distributed by the Office of Research and Development to the research programs within VA to provide administrative oversight in support of activities including IRB functions.

Most recently, we have actually moved to a uniform charge for IRB review of protocols submitted by non-VA investigators including pharmaceutical companies seeking to do drug trials and other types of activities.

Mr. BUYER. Well, you have permitted a proper segue for me. I have been up here for 10 years. And I, like a lot of members here, we fund a lot of research whether it is at our land grant institutions for agriculture and food safety, or there is a medical arena, or environmental, there is a lot of research tax money goes out there to press the bounds of science and other things.

Society benefits, yes, but there are people that make a ton of money off of that. And it is something that has—it has bothered me. It is one of those things that sticks in my craw a little bit.

And so, let me turn to you—is it Aisen, Dr. Aisen? I do not control the ag budget, so I can't complain about that one. But this is an arena where we do have control over oversight.

And so, let's talk about some of these products that we, the taxpayer, has helped finance, and now it is in the marketplace, and somebody else is making profit. I use the example of UCLA.

Do we even know what type of monies are being made off of our joint research? Yet, we, the government, then get nothing in return, or the VA. And these other entities just profitize then off really what the taxpayer had set up.

Dr. AISEN. Well, with your permission, thank you for the question. You know, if we go back far enough I think one could calculate hundreds of millions of dollars. You have alluded to a number of the inventions that came out of VA.

One that you didn't mention was the cardiac angioplasty stint currently marketed by Johnson and Johnson. The VA does not

make any money from that. And that is something of great value to many people, but also a great profit generator for that company.

I think it is important to remember that although VA has had the ability to take ownership of intellectual property since 1950. And 1956, officially, it was published in the Federal Register, the mechanism for doing that, it wasn't the culture to do that.

And you alluded to Nobel Prize winners like Rosalind Yallow, who invented the radio immunoassay, and put that into the public domain. And she has been, in her autobiography, she says, "I have no regrets about that. It was a different culture."

But things started to change dramatically in the mid-1990s, when universities woke up and realized that by joining with corporations they could realize not only dissemination of research but revenues. And since Dr. Feussner's tenure in research and development, there has been a real effort to assert fairly VA's ownership rights.

In part, that became a major thrust of his work, since the research realignment advisory group made a point of telling him to exercise VA's ownership rights. So, actually, VA has not—do I have to stop speaking?

Mr. BUYER. Oh, no.

Dr. AISEN. Okay. Actually, VA has not really changed policy, but has become more participatory, and I suppose more systematic, and to some more assertive about taking ownership rights.

And so we have, without an increase in staff, actually, just with reorganizing the staff we have within the research and development office, begun to systematically educate the field about when a research finding is an invention; and so, how they can protect themselves, and not publish before they disclose to us, so that we can help them with the patenting process.

So we now have a very clear disclosure process. We have forged a close relationship with the Office of General Counsel and now have a good working relationship, in terms of advising them when we think there is research worth taking ownership of, and they then look at the legalities of whether there is a right.

So our numbers of disclosures have gone up rapidly. Our numbers of cases in which we take ownership has gone up substantially. Our numbers of patents have increased a great deal. We have begun to realize revenues.

We have also forged relationships with the majority of our significant academic affiliates. And I say significant when we have a research program that is funded in the range of a million dollars or more a year. So I think that we are working hard to do our job.

Mr. BUYER. This is rather all new, isn't it?

Dr. AISEN. Since Dr. Feussner, I would say, and it has been escalating. Success builds on success, I would say.

Mr. BUYER. And what do you anticipate when you said revenues are beginning to generate? And when those revenues come in, where do they go?

Dr. AISEN. That is the easier question, where the revenues go? We have a well-developed policy for that. When revenues come in, we keep 15 percent for the technology transfer program, for administrative costs, because we do have costs, which I could tell you about. But 85 percent goes back to the field.

This is money after the inventor gets his or her share, which will either be determined by the university community in which they are working, or by the federal guidelines, if they are not a university,

Mr. BUYER. What is the field?

Dr. AISEN. I am sorry. The VA medical center that particularly nurtured the inventory.

So, in other words, if there is an inventory at the West Roxbury VA, that inventory will get his or her share of the revenues as the inventory; and then whatever money comes back to us, we keep 15 percent; and then 85 percent goes back to that VA medical center; 50 percent for that inventor's laboratory; another 25 percent for the research program at that VA; and then another 10 percent.

That adds up to 85 percent for the medical director to use to sort of celebrate for the veterans that their medical center nurtured an invention. And it is my hope that that will engender a feeling of pride and engender a greater intellectual climate and excitement about doing research.

Mr. BUYER. I hate to dominate the time on this. But as we—if this is going to be coming—if we are at the beginning of something new here, is that equation the right equation to be using?

Dr. AISEN. We thought hard about developing that equation. We have gotten nothing but positive response from the field, from the VA medical centers, and the inventors.

Mr. BUYER. Say, for example, the one, the Nicoderm patch, and millions and millions of dollars now are pouring in, that VA medical center ought to just become then the premium medical center then. Is that what you are saying?

Dr. AISEN. You know, I suppose that will be a nice problem to have. I think that most of the time—and this may get me into something that is more difficult to describe. Most of the time, the major inventions are with dual appointment people, people who are affiliated with medical school, and the VA medical center, so we share those revenues when that happens.

But, yes, if there is a huge hit, there is that possibility that one particular place would get more income than others. And I guess it would be at the pleasure of the Secretary to decide.

Mr. BUYER. Do you have any idea how much in millions of dollars you think the government gave up by not doing what they should have been doing since 1956?

Dr. AISEN. I think it is probably in the tens to hundreds of millions of dollars.

Mr. BUYER. Astounding figure probably, isn't it?

Dr. AISEN. Yes.

Mr. BUYER. All right. Ms. Carson.

Ms. CARSON. Yes, and thank you very much, Mr. Chairman. I have a very brief question.

In 1996, 1997, and 1998, respectfully—respectively—VA applied for zero, one, and two patents. How many patents did the VA file for in the last 3 years?

Dr. AISEN. In the last 3 years, in 2000, VA alone applied for three. And VA, in conjunction with its affiliates, applied for 27, so that is a total of 30 in 2000; in 2001, VA alone applied for 11; and

in conjunction with our affiliates, another 34; and then, year-to-date, VA alone has applied for 16.

Ms. CARSON. Okay. Do you know what the status of those are?

Dr. AISEN. The ones that have been issued? The total that have been issued are five. Five have been issued. But there are licensing discussions going forward in anticipation of the issuing of the patents.

Ms. CARSON. Thank you. Mr. Chairman, may I ask one question?

Mr. BUYER. Yes.

Ms. CARSON. Mr. McClain, this refers to the Chairman's exhibit. Exhibit 1, item 9, expresses concern with a potential conflict of interest regarding legal services and sharing of VA legal counsel.

Is there any ethical problem with this arrangement? How would a state's canon of ethics view this?

Mr. MCCLAIN. Ms. Carson, thank you for the question. We don't see it as a conflict of interest. Our client is and will always remain the Federal Government. One thing that we have with these research corporations, the reason that they were formed, was a unity of interest with VA in the research area.

If, at any time, those interests would diverge, then we would stop giving any advice to the research corporations, because our client always is and remains the Federal Government. We provide legal advice to the research corporations on federal matters to—in order to clarify things for them, and to allow them to function properly under the laws and regulations of the Department and the Federal Government. And that is the extent of our advice.

Ms. CARSON. Okay. I have one other question, Mr. Chairman, if you don't mind. Dr. Roswell, or Dr. Feussner, whichever. When a non-federal organization conducts research at a VA research facility with funding by the NIH, I would assume that VA incurs indirect expenses as a result of hosting that research.

What are the indirect resource requirements for hosting this research? Is VA reimbursed for any of it?

Dr. FEUSSNER. Well, there is a divergence of opinion on that question, ma'am, between us and our colleagues at NIH. At the moment, the answer to your question is no. When NIH-funded research is conducted largely in a VA facility, the entity responsible for the grant is either the university that is affiliated, or in rare cases the nonprofit foundation, and under those circumstances the VA does not recover indirect costs.

We call them facility and administrative costs. NIH calls them operations and management costs. We have been discussing this matter with the NIH for some time.

Ms. CARSON. Do you potentially benefit from the research that is conducted at a VA facility?

Dr. FEUSSNER. Yes, ma'am. I think all of us benefit. I think veterans benefit; I think the VA benefits; I think the NIH benefits; I think it is a win-win for the Federal Government. And, in the past, from 1968 to 1989, in fact, the NIH did provide a 15 percent add-on to the VA to support these revenues.

That policy was changed in 1989. I am not exactly sure why. I would not vote for that change if I were asked. And we have been discussing this matter directly with leadership at the NIH for the

past several years, trying to find common ground. And I should say that they have been open to these discussions.

Ms. CARSON. When you say 15 percent add-on that has summarily been discontinued, the 15 percent add-on was to your benefit?

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON. VA, then?

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON. But then they dis—NIH discontinued the add-on?

Dr. FEUSSNER. The NIH discontinued the add-on with concurrence of the VA, yes, ma'am.

Ms. CARSON. With the concurrence?

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON. Well, now, wait a minute. Mr. Chairman?

Dr. FEUSSNER. That was in 1989, ma'am.

Ms. CARSON. Okay. I am confused.

Dr. FEUSSNER. I am sorry.

Ms. CARSON. Sorry. We get confused sometimes in Congress. The VA concurred with——

Dr. FEUSSNER. The discontinuance.

Ms. CARSON (continuing). Discontinuance——

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON (continuing). Of receiving resources, to put it simply?

Dr. FEUSSNER. Yes, ma'am. In 1989, there was agreement, just as before that time, there was agreement between the NIH and the VA to accept those dollars in 1989. There was agreement between the NIH leadership to discontinue that arrangement.

Ms. CARSON. Is that because VA had so much money, they didn't have anywhere to put it?

Dr. FEUSSNER. Well, actually, that is a fair question. And I think that no is the answer to that question. But there was some concern back in 1989 whether the VA would be able to be responsive to NIH requirements for tracking and managing the finances. I think that was a valid concern at—perhaps, a valid concern at that point.

So it wasn't that there was too much money. I think there might have been concern within both departments that the VA didn't have the appropriate financial mechanisms in place to track the money appropriately.

Ms. CARSON. I am sorry. Mr. Chairman, please let me ask one more question. I realize I have exhausted my time.

VA facilities provide space, et cetera, for the research conducted by NIH?

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON. And, at one point, they had a 15 percent add-on to accommodate the costs of research being conducted at the VA facility?

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON. Comparatively—and this is probably an elementary comparison—but if you rent a place, and you pay rent to the place where you rent, then it is—is it any of your business what happens with the rental income?

Dr. FEUSSNER. Well, yes, ma'am.

Ms. CARSON. I use that analogy because if you are providing the resources—pardon me—the space, et cetera, for NIH research, then you are saying that NIH had some criteria, in terms of tracking what you did with the money that you received from NIH——

Dr. FEUSSNER. Yes, ma'am.

Ms. CARSON (continuing). For the use of your facilities?

Dr. FEUSSNER. Well, the NIH is another federal entity like us. And they have strict guidance that the money that is allocated is spent in the way in which it was intended. And we, as another federal entity, in my opinion, should comply with that requirement to manage and track the monies to show good financial faith. And so I do think it is reasonable for the NIH to make that request. Yes, ma'am.

Dr. ROSWELL. If I may, Ms. Carson, none of us at the table were involved in the rationale or the formulation of the decision to concede the 15 percent indirect in 1989. So it would only be conjecture on our part what led the Department to decline—or to ask that those revenues not be accepted.

I think what is clear is that today, we are extremely confident of the oversight of our research programs, the financial management of those programs, and believe that we should in fact have the ability to receive the indirect or the FNA costs from NIH, and would very much like to be able to receive those costs today.

Ms. CARSON. Thank you very much. And I yield back time that I didn't have.

Mr. BUYER. Mr. Boozman.

Mr. BOOZMAN. Yeah, on the patents, did you say that we have really been aggressively pursuing that for the last 3 years? Is that kind of the timeframe, or——

Dr. AISEN. I would say so. I would say so. I would say it began in 1997/1998, but in full force probably around 2000.

Mr. BOOZMAN. Okay. Did we try and go back? And, I mean, is there a statute of limitations on that that we would try and go back as far as any of the others that maybe slipped?

Dr. AISEN. To some extent. If we were—we decided, you know, to set some limit on this if we found out that people had not disclosed, which was a requirement always. The typical way things were handled was people disclosed; VA employees disclosed.

The Office of General Counsel handled that, and as a rule of thumb gave back ownership. If that was the case, that was—they were legally covered, and they did what they needed to do with the property.

If people had not disclosed, we did start to ask them why they hadn't disclosed. And there were situations where people had not disclosed, other parties had gone ahead and patented, and we asked to be included in ownership. And that has happened.

Mr. BOOZMAN. Do we cut off people that do not disclose?

Dr. AISEN. So far it hasn't come to that, but it is their obligation to disclose. It is the obligation of the ACOS, the Associate Chief of Staff of Research, to make sure that his staff knows to disclose.

We remind them all of the time with faxes. We maintain a web page. We really try to educate the VA employees. Yes, if they don't disclose, they are reminded, et cetera, et cetera, we will stop paying them.

Dr. FEUSSNER. We had a case that was so—I don't know what the word is—but so blatant—that we have had to cut anybody off for——

Dr. AISEN. No, we haven't. People will come around.

Mr. BOOZMAN. So we haven't cut anybody off, but you don't feel like we have had a case that was so——

Dr. AISEN. People have in the end complied. They have argued, but they have complied.

Mr. BOOZMAN. Okay.

Dr. AISEN. The other avenue that—that is in terms of disclosing. There have been—if VA takes ownership, people have an appeal route. And, at first, there were a great many appeals. And that has now fallen to about zero, because we think we have communicated, and we think there is a very good understanding now between the field and VA Central Office about what their obligations and rights are.

Mr. BOOZMAN. So you feel comfortable that if we have people that are not playing by the rules—and I guess, you know, in everything there are people like that.

Dr. AISEN. Right.

Mr. BOOZMAN. You feel comfortable that you have the authority to cut those people off or——

Dr. FEUSSNER. Well, we would have the authority to cut off their research support, yes, sir.

Mr. BOOZMAN. Okay. Thank you.

Mr. BUYER. Mr. McClain, I have a sense that Senate Bill 2132, if it comes out of the Senate, it will head over here to the House. And so I have got some questions on it.

It appears about the VA's opinion regarding the extension of tort claim protections to a non-government entity, and at the same time open up appropriate health care monies to these entities, I mean, I am just curious about your job. This would be a tough one.

Tell me about your opinions about these two provisions.

Mr. MCCLAIN. Well, Mr. Chairman, the first provision is covering the employees under the Federal Tort Claims Act, we have supported for many years. So we do support that provision in the bill. They are without compensation employees, and we believe that they should be covered under the Federal Tort Claims Act.

The second provision that you mentioned is probably the greater issue, as far as we are concerned, and that is the ability—giving the nonprofit corporations the ability to enter into contracts with the Department. We oppose that provision. We opposed it in testimony before the Senate committee.

The main reason is that this would change significantly, this rather small issue would change the dynamic significantly, of the VA as it relates to its nonprofit corporations.

Right now, as they are formulated, there is almost an in trust sort of relationship, a trustee sort of relationship of the money that is received by the corporation to be used for VA, the benefit of VA research.

By statute, we have the director of the medical center and two other VA employees on the board of directors of the nonprofit corporation. If we now enter into contractual relationships with the nonprofit, now we are beginning to act in more of an arm's length

sort of relationship. This creates tremendous conflict of interest problems. I talked before, in response to Ms. Carson's question regarding the unity of interest, and I think that that dynamic will change if we begin to incrementally move away from the current status that we have today.

Mr. BUYER. I guess being a lawyer myself, words have definition. And so I always pay attention to words. So when you use the word "revenue," the monies in that research corporation, what are they? Are they public or private? And if so, are they defined and described?

Mr. MCCLAIN. Well, I am not the expert on the appropriations part of it.

Mr. BUYER. You are the General Counsel. Is it actually written somewhere?

Mr. MCCLAIN. As to what those monies are?

Mr. BUYER. Yes.

Mr. MCCLAIN. Well, the monies, as I understand it, come from private companies. I think that they would be private monies. There are other monies that come from NIH and federal sources. They certainly would start out to be public monies.

Mr. BUYER. And then they become comingled?

Mr. MCCLAIN. Yes.

Mr. BUYER. Do they lose their identity?

Mr. MCCLAIN. I don't have an answer.

Dr. ROSWELL. Possibly, I can speak to that. I at one time, earlier in my career, actually served as a member of a board of directors for a VA nonprofit research corporation. The source of funds can be varied—pharmaceutical companies, other people engaged in supporting research in the VA, private donations is another source of funds. No appropriated VA health care dollars, however, enter the corporation.

Typically, when funds enter a corporation, they are for a designated approved research project, and those are cost-accounted separately. Most of the nonprofit research corporations do charge an administrative fee, as you heard earlier, from 0 to 43 percent, with a median cost of around 8 or 10 percent. That money goes into the general operating expense for the corporation.

All of the corporations, as you know, are 501(c)(3) nonprofit corporations. The annual audit review and they also have liability insurance to make sure that operations are in accordance with the law. So I think, for the most part, the accounting mechanisms in place to attract these dollars are very effective.

Mr. BUYER. To go back to this issue on protections of intellectual property, patents, do you, in the Office of General Counsel, do you now have a patent lawyer, or have you always had one?

Mr. MCCLAIN. Mr. Chairman, we do now have a patent lawyer. He came on board about 6 months ago. We had been using private counsel up till then to do these patent applications. We now have an experienced person, a lawyer, on board who is handling that now for the Department.

Mr. BUYER. Since this is an evolutionary change of culture—I will try to take the word you said, Dr. Aisen—tell me about what that relationship is then with some of the companies in America?

I don't care whether it is Johnson and Johnson, one that was described, or other companies. Are they—or universities—are they a little bothered now of saying, "What is the Federal Government doing getting into the private business here?" I am just curious about relationships.

Dr. ROSWELL. I would say, Mr. Chairman, that corporate America is not averse to this. Corporate America, if you will, the health care industry, is eager for the receipt of new technology, and is well-accustomed to paying the cost associated with the research and development that leads to new technology.

If there has been a difficulty in our efforts to assert the government's rights to its intellectual properties, it has probably been with our affiliated medical schools, who before were the beneficiaries of the majority of intellectual properties developed by the VA.

Despite that difficulty, I think that there has been remarkable progress through Dr. Feussner's office. We currently have 53 cooperative technology administration agreements with our affiliated medical schools; that is, a joint and mutual agreement that provides that we operari agree to share the intellectual properties.

Even when those agreements don't exist, we still have an opportunity to negotiate for our rights during the disclosure process and the general counsel has been quite helpful. At my level, I am working with the Association of American Medical Colleges, who represents all of the medical schools we are affiliated with to enhance that relationship, and to continue to move this effort forward.

Mr. BUYER. The last comment I have is recognized from—at least from our standpoint here with the American taxpayer. I think the taxpayers trust us to make these decisions, to press the bounds, and to work cooperatively with entities in our society; they reap a benefit. But they also want to have access to these technologies and these new discoveries. And when they are denied access relative to costs, all of the stuff gets traced back, and they view it rather simply, as saying, "Do you mean to tell me my tax money finances this but I can't afford to gain access to that particular drug, or device, or procedure?"

And then it is only going to those of whom X, Y, and—it just—then you end up messing up the whole science applications with politics, and you lose on PR. It gets into a mess.

But you have a great story to tell, and you should be telling it, because you can have an impact with other departments and agencies to be more proactive in doing this and selling your story.

Mr. Boozman, or Mr. Carson, do you have any other questions?

Ms. CARSON. No, sir.

Mr. BUYER. All right. Thank you very much for coming.

Ms. Carson, I yield to you.

Ms. CARSON. I just wanted to have permission to put my opening statement in the record, Mr. Chairman.

Mr. BUYER. Ms. Carson has moved that her opening statement be submitted into the record. Hearing no objection, so ordered.

[The prepared statement of Congresswoman Carson appears on p. 41.]

Mr. BUYER. On the third panel, we will now recognize Mr. Antonio Laracuente.

Mr. LARACUENTE. Thank you.

Mr. BUYER. Chairman of the National Association of Veterans' Research and Educational Foundations, and Executive Director of the Atlanta Research and Education Foundation, Dr. Franklin Zieve.

Dr. ZIEVE. Good.

Mr. BUYER. And also is president of McGuire Research Institute is Mr.—I am confusing everyone. You are the president of McGuire. I should just look up.

Mr. Hickman, Executive Director of the Brentwood Biomedical Research Institute.

Mr. HICKMAN. Yes, sir.

Mr. BUYER. And Dr. Wendy Baldwin is the Deputy Director of Extramural Research at the National Institute of Health. And you were invited here.

Let's just go ahead and open them up. Who wants to go first? Go ahead.

STATEMENTS OF ANTONIO LARACUENTE, CHAIRMAN, NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION FOUNDATIONS AND EXECUTIVE DIRECTOR, ATLANTA RESEARCH AND EDUCATION FOUNDATION; FRANKLIN ZIEVE, M.D., PRESIDENT, McGUIRE RESEARCH INSTITUTE, INC.; AND WENDY BALDWIN, M.D., DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH

STATEMENT OF ANTONIO LARACUENTE

Mr. LARACUENTE. Good morning, Mr. Chairman, and members of the subcommittees. Thank you for the opportunity to present testimony this morning. I am Antonio Laracuente, Executive Director of the Atlanta Research and Education Foundation, and Chairman of the National Association of Veterans' Research and Education Foundations.

NAVREF is a membership association of the 83 VA- affiliated nonprofits. As many investigators, ACOS's for research, and administrators have said, these foundations are a tremendous asset to VA. Their ability to support VA research and education goes hand-in-hand with providing the best possible care for our veterans.

I am the first to acknowledge that managing a VA-affiliated nonprofit is challenging. Like all state-chartered tax exempt corporations, the VA nonprofits must comply with local, state, and federal requirements.

In addition, management must comply with 38 U.S.C. 7361, and the VA implementing guidance in handbook 1200.17. All told, the corporations are highly regulated with oversight by many different entities. This is provided in my written statement.

Over the past 14 years, the foundations have experienced tremendous growth, and have taken advantage of opportunities to support the increasingly diverse VA research program. Research personnel, the boards, and the medical center management quickly recognized the value of the nonprofits, and due to the potential for scrutiny, have worked hard to manage them well.

Boards have been proactive in developing policies and procedures. Reports are sent to CO annually, and the audit requirements imposed by Congress in 1996 has raised awareness of financial accountability and internal controls. Also, boards better understand our oversight and fiduciary responsibilities, and are learning to exercise them effectively.

Is there room for improvement? Of course. The corporations are at different points in their business life cycles. But we feel strongly that all are headed in the right direction. Every one associated with the nonprofits is acutely sensitive to the possibility that poor management of one corporation has the potential to reflect badly on all of the nonprofits.

This is the main reason that so many corporations are engaged in educational activities provided by NAVREF and others. You have also asked whether the VA nonprofit partnership is effective. I am confident that the partnership is highly effective and beneficial to the VA, and, more importantly, its veterans.

The corporations are an integral and essential component of facility research programs. They fill in the gaps when VA resources fall short. And, more recently, they were helping facilities meet increasingly complex and stringent human research requirements by hiring research compliance and Institutional Review Board staff.

Currently, VA appropriated funds for these needs are inadequate at the facility level. Extremely low operating costs and a unique relationship with VA medical centers have allowed the corporations to expend an average of 90 cents of every dollar on direct support of VA research and education.

Expenditures are for research equipment and supplies, space renovations, travel, and salaries for research personnel. Using my Atlanta foundation as an example, we fund numerous small, but essential, renovation projects that include design and remodeling of laboratories.

Over the last 3 years, these costs have totaled over $70,000. We have donated $355,000 to enclose a 1500 square foot patio in order to provide the research program with much needed laboratory space; partnered with the VA to purchase $120,000 high tech microscope by allocating $9,000 to renovate a room to house it in.

AREF has a young investigator award program that funds up to three $25,000 grants per year, so that young investigators who hold VA clinical appointments may collect preliminary data and compete for grants at the national level.

Finally, AREF has partnered with a medical center to develop a clinical study center. While VA pays a clinician director, AREF annually invests over $200,000 to staff the center and pay for training in human studies compliance. This center is the centerpiece of our program, and is the most important contribution that AREF has made to the medical center.

This group works with the university IRB to ensure that our veteran patients receive the highest quality of care, while assuring that they participate in a safe research environment. In addition to these tangible benefits, there are significant intangible benefits.

AREF assist the Atlanta VA in recruiting clinician investigators by supporting recruitment travel costs, and often pays to upgrade the laboratory to suit a new investigators particular needs. Effi-

cient services are provided by AREF. Increased principal investigator satisfaction and productivity help VA retention rates.

AREF helps make up for inadequate VA travel funding by supporting the costs of attending scientific meetings to disseminate VA research findings. I believe that all of these illustrate the VHA nonprofit partnership—that the VA nonprofit partnership is far more effective than anyone had expected in 1998.

The corporations cannot replace a robust federal appropriation for VA research program and medical center support. However, they can help leverage appropriated dollars in a way that benefits the research program, VA facilities, VA staff, and VA patients.

I would like to take—I would like to ask for 1 minute to respond to the VA IG's comment regarding consolidation if I may. In our opinion, the consolidation of foundations would minimize the current oversight that is afforded through local administration and control.

We feel strongly that these corporations currently run with great efficiency and provide prompt service and response, and ultimately consolidation would minimize the support provided locally to all PI's and veterans.

I also would like to say that all foundations, at this point and time, can respond to the detail of questions as submitted by Congress to VA.

This concludes my prepared remarks. I would be pleased to answer any questions.

[The prepared statement of Mr. Laracuente, with attachment, appears on p. 82.]

Mr. BUYER. Dr. Zieve, I would like to yield to you for any comments that you may like to make.

STATEMENT OF FRANKLIN ZIEVE

Dr. ZIEVE. I am here representing a specific research program of the research corporation, McGuire Research Institute, in Richmond, where I am also associate chief of staff for research, and have been for 25 years.

Our program and my written statement, which I would like to have entered into the record, if I could——

Mr. BUYER. So ordered.

Dr. ZIEVE (continuing). Concern sort of the intersection of human subjects protection and the corporations because we found in 1999, after the Duke shutdown, which is what really got our attention, we did a detailed review of our program. And, at that time, we were using the Institutional Review Board of our affiliate, Virginia Commonwealth University.

And after we had really immersed ourselves in the regulations, it was clear that this was grossly deficient, and that we had to set up our own program immediately, which we started to do. And this we got a great impetus in this because our university got an FDA warning letter, and anyone who read that letter would realize that they were about to be shut down.

And so, we started, set up our separate independent IRB on September 1st of 1999. We have met weekly ever since, and put together our program. The expenses were very high. In the first year we spent, I put in my written statement, we spent a total of about

$470,000, all of which came from the research corporation; and our ongoing expenses net are about $400,000 a year.

There are five things that we are spending our money on, I think all of which are key to our program: the professional IRB, the investigational pharmacy, an extensive program, our research database, and our research day. And I think all of these pieces, while expensive, we feel are worthwhile, and we feel that this is the most important use for our money.

I would particularly point your attention to our McGuire IRB database, which we paid for the development of, which has been now put into place at 19 VA medical centers, and should benefit the system.

I guess I will stop and answer any questions you have.

[The prepared statement of Dr. Zieve, with attachment, appears on p. 91.]

Mr. BUYER. Dr. Baldwin. Would you like any comments based on testimony you have heard?

Dr. BALDWIN. I am prepared to make an oral statement.

Mr. BUYER. Sure.

Dr. BALDWIN. Would you like me to do that? Thank you.

Mr. BUYER. It would be wonderful.

STATEMENT OF WENDY BALDWIN

Dr. BALDWIN. I am really pleased to appear here to reflect on our relationship with the VA in a very important area of biomedical research. You have raised important topics of efficiency and oversight of protection of human subjects, and of course intellectual property.

These are issues that we think are very important to the support of basic research and of clinical research, which is where many of our VA collaborations are. The partnership that NIH has with the VA is rather complex because we may fund research directly at a VA institution; the VA foundation, or at a university, where one of the performance sites is a VA site. So it is really not possible to have just one view of how the NIH interacts with the VA.

When we make grant awards they are guided by our grants policy statement, which does have some specific features relative to our support of other federal agencies. For example, it would be inappropriate of us to pay other federal employees salaries through our extramural program.

On the other hand, it is certainly quite possible that when there is a research relationship with another entity that there would be additional administrative costs over their routine and, or indirect costs, or administrative costs, and those are costs that we would be willing certainly to sit down with the VA to discuss.

I am very pleased, frankly, to hear the report of the IG this morning that there really have been improvements in oversight and auditing. Because for us to move forward in an avenue like this, we have to have an opportunity to have a dialogue about what those additional costs are, and our ability to document them if we are going to develop a collaborative relationship. Now we already pay indirects to the VA Foundations, but not where the award is directly to another federal agency; e.g. the VA.

You have already had some discussion of intellectual property issues, and there it is probably useful to remember that the pro-

gram that I am discussing, the extramural program of the NIH, functions under the Bayh-Dole Act. The Bayh-Dole Act is very clear about where intellectual property rights are vested and that is with the institutions to which we make awards.

And so, we have made clear that our applicant institutions understand what their obligations are under Bayh-Dole, then they can go on to work out relationships with their inventor on their campus, or whoever they are collaborating with.

The most difficult situations occur when people have joint appointments. That is certainly an issue, but really that is an issue that has to be worked out between the universities and the VA. Our position, certainly through Bayh-Dole is clear.

Human subjects protection. I would just like to echo the comments that you have heard this morning. Human subjects protections are extremely important, and it is an issue that we take very seriously. The NIH supports research on how to do research well in consideration of ethical issues and, also support training in this area. Finally, this year we probably will have about $40 million that goes directly to improve those systems through research advocate programs, or through direct support to Institutions. We are very aware of the kinds of circumstances that have been pointed out to you.

The importance, not just to the IRB—and I just want to point this out because sometimes we focus so much on the IRB. And, yet, there are very important protections that come through data safety monitoring boards, or the data safety monitoring procedures, that must not be forgotten, and we are trying to be supportive of them as well.

You have heard a great deal about how the VA has strengthened their human subjects protections, and we are very happy to see this. I will say the remaining challenge is that institutions could be faced with the VA, OHRP, and the FDA, requirements as well as with their own institutinal requirements and expectations.

I would hope that we would be able to harmonize those in a way that we didn't see precious funds going into duplicative, or hopefully not conflicting activities. So I am very happy to answer any of your questions. I have a long-term professional commitment to biomedical research, and a very strong personal commitment to veterans. So I welcome your interest in these important topics.

Mr. BUYER. Mr. Hickman, do you have any comments?

Mr. HICKMAN. No, sir. I am just here to answer questions, if I can.

Mr. BUYER. That is the best opening statement today. Thank you.

Ms. CARSON. Can I ask a question, Mr. Chairman?

Mr. BUYER. Sure, just a second.

Ms. CARSON. You want me to wait, okay.

Mr. BUYER. Just a second. I have a question on human subject protections you talked about. I only want to take a step back, okay? Sometimes we accept, we step in and say, "Well, gosh, is this the way things are? Is this the way things are done?" So I am going to ask a question, because I don't know the answer.

If I were to look out there at the industry of medical research, how much—how many of the protocols of medical research are

being done using veterans as human research subjects? Would anybody know the answer to that?

Mr. LARACUENTE. I can speak to my facility. And our facility runs about 210 current active protocols on human subjects, including veterans, but that is a mid-size facility.

Dr. ZIEVE. Ours is 294, but I can't answer your question of where the VA fits in the greater picture.

Mr. BUYER. Let me just say this. If Congress were to come in and say, you know, "we are going to fund medical research. But these veterans, they have served their country when other people didn't go serve their country. Why would we subject them to medical research? We are not going to do that to them anymore. We are not going to do that at all. They have already served their country, why push the bounds of science and use them as some form of guinea pig," some critic may say, "and we will just let others volunteer for that. We are just not going to let the VA participate in that."

What effect does that have out there then?

Dr. ZIEVE. Profound.

Mr. BUYER. Ah, now I am getting closer.

Dr. ZIEVE. Profound.

Mr. BUYER. Now define "profound."

Dr. ZIEVE. There are risks, obviously, which we all hear about, and benefits of being a subject of having the opportunity to voluntarily participate in a clinical research trial. And the best I can—example I can give you is a lot of the current AIDS therapies, a lot of the current cancer therapies, the state-of-the-art therapy is currently experimental.

And there are a lot of—these are conditions for which there are not clearly—therapies right now that are as effective as we would like them to be, and sometimes an individual patient's best hope is to get into a research study. There are a lot of other people who will not, who even despite that, will not want the extra effort, because being in a research study does create extra work for the subject, too.

Mr. BUYER. Is the psychology of the veteran participant any different from someone who has not been instilled with military ideals?

Dr. ZIEVE. I think so.

Mr. BUYER. I do, too.

Dr. ZIEVE. I think so, and I say that as someone who is a veteran, a researcher, and a subject in research studies.

Mr. BUYER. Now let me ask this question. Since these individuals were instilled with military ideals and have this sense of virtue, and honor, and service to country, that many others may know the words, but not live by them, does the present system take advantage of this so-called sense of duty that they are doing it, yes, for themselves, but they are doing it to serve some more greater or nobel cause?

Dr. ZIEVE. Let me rephrase that a little bit, because we had this discussion when we were talking about whether we could rely on trying to improve the university's IRB and program, or whether we had to set up our own.

We felt an important issue here was that you could regard, for just the reasons you are saying, you could regard the population of

veterans who are taken care of in veterans hospitals or not as a vulnerable population; and that therefore it was necessary to have the entire process be, first of all, a little more stringent than the outside world, and I am a believer in that.

And, secondly, that it had to be carried out by people who were very attuned to this. If I can give one personal example, I referred a patient of mine, in one of my clinics, to one of my colleagues who was doing a flu shot study, a VA cooperative study, a few years ago, comparing the ordinary flu shot with a nasal flu vaccine. And as tends to be the case with some large trials, it was a long and rather turgid consent form, this. And my colleague, the man who was doing the study, started going through this with my patient and he cut him off. He cut him off. He said, "Look, I don't want to know any of that. What I want to know is am I going to help someone by doing this?" And the answer was, "You are not going to help yourself, but you could conceivably help someone else." And the guy said, "Well, where do I sign?"

I mean this, you know, mentality really exists, and I think it is very important that the whole process be done by people who are attuned to it, and I think some extra controls have to be put in, which is what we——

Mr. BUYER. Is that opinion in the minority, or is that shared by others?

Dr. ZIEVE. I can't answer that. It may be. You have got to remember my affiliation with the VA goes back over 50 years, so since I was a child. I grew up on the grounds of the Minneapolis VA. So I may be a little more attuned to this than most.

Mr. BUYER. I think you are right.

Ms. Carson.

Ms. CARSON. Thank you very much, Mr. Chairman. I have a quick question for Dr. Baldwin, and thank all of you for being here today.

The VA/NIH partnership highly valued by both agencies. As well as being mutually beneficial, is it reasonable to expect that NIH would help support the infrastructure costs of its partners?

Now let me also add, so we can make this brief for you, in March of 2001, the NIH Institute Director supported an indirect cost rate for grants to—I believe—foreign institutions, but, NIH declines to provide anything to the VA facility. I might have that kind of messed up, but maybe you could unmess my mind up.

Dr. BALDWIN. We have an invitation to the VA, if they would like to sit down with us to help us establish a plan.

Ms. CARSON. I am sorry——

Dr. BALDWIN. I would be happy to sit down with the VA to establish what would be an appropriate level of compensation for additional costs. In terms of stewardship of federal funds, it is important that we be able to have that discussion and construct a level that is appropriate, justified and documented.

I have heard 20 percent; I have heard 15 percent; I heard 10 percent today; I have heard 5 percent from our auditors; we have 8 percent of the suppressed indirect costs rate that is used on some other mechanisms. I would be pleased to have that discussion with the VA to see if there is a way to document what would be an ap-

propriate and equitable compensation for costs that are above and beyond appropriated costs, which we cannot augment.

I am not saying there are not additional costs, but we have to have a process in place. We have not had contact from the VA for the last year or so, but I would be happy to meet on that topic.

Ms. CARSON. Foreign corporations?

Dr. BALDWIN. Excuse me?

Ms. CARSON. Foreign corporations, is there any——

Dr. BALDWIN. Not corporations, no.

Ms. CARSON. Foreign corporations, is there any validity to the rumor that NIH does, in fact, have partnership providing support and direct costs for foreign corporations?

Dr. BALDWIN. Not foreign corporations. Starting in October 1, 2001, we changed our policy in regard to foreign institutions.

Ms. CARSON. Institutions may be the better word.

Dr. BALDWIN. Foreign institutions, universities, and clinics, yes, that is correct.

Ms. CARSON. You do have a relationship with foreign institutions?

Dr. BALDWIN. Not very many of them, but, yes, that is correct.

Ms. CARSON. Okay. And you are willing to sit down with VA here in America?

Dr. BALDWIN. Yes, I am willing to sit down with the VA here in America and determine what would be an appropriate level. We have had many levels discussed.

Ms. CARSON. Thank you, Dr. Baldwin.

I have no further questions, Mr. Chairman.

Mr. BUYER. Mr. Boozman.

Mr. BOOZMAN. Thank you.

Mr. Laracuente, you mentioned that you are developing some self-assessment and improvement program standards. Where are the standards coming from?

Mr. LARACUENTE. They come from a variety of sources including FDA, VA, the VA guidance documents, the NIH, HHS, and we have the Clinical Studies Center heading up that process right now.

Mr. BUYER. I am looking at these systems. I don't want to pick on you, Dr. Zieve, but you are very eloquent, you are very refreshing, so I am going to pick on you.

Dr. ZIEVE. Pick away.

Mr. BUYER. You are the director. Also, you are the medical director of the corporation?

Dr. ZIEVE. No, I am chairman of the board of directors.

Mr. BUYER. I am sorry, chairman of the board of the corporation.

Dr. ZIEVE. And I am associate chief of staff for research at the VA hospital, and I run the diabetes program there, which is my real hat.

Mr. BUYER. Is it easier for a major corporation out there to turn to you to do the protocols of a particular device or a drug than something else?

Is it easier for them to turn to you; or if there is a relationship to this particular drug for us, I will tell you what, we will pay you $2 million. It may really only costs $300,000 to actually do it. You get to keep the extra money. You get to call it overhead. There are

no such thing as per diems. You can spend that money on however you want.

Is there something going on here that does not feel right or sense right?

Dr. ZIEVE. I regret to say that I have never had an offer like that.

Mr. BUYER. All right. Well, I have got to ask you.

Dr. ZIEVE. However, the majority of pharmaceutical trials, which represent roughly 80 percent of the influx of funds into McGuire Research Institute, are usually budgeted on a per patient basis, and it is a very careful thing. You get so much per physical exam; you get so much for having your nurse go over the patient; you get so much for the blood drawing fee; the labs are usually done centrally; and out of this all it—and we compete with other, you know, private sector entities, and anyone else who could do the trial.

In general, what we compete on is not generally being expensive, but the quality of the product. In other words, if a pharmaceutical company is—let's suppose it is one of the trials which is involved to bringing a drug to market, rather than assembling data on post-marketing on different ways to use the drug, the worst disaster in the world for them is to have data they can't rely on, or to have a site that they have to shut down because they have doubts about it because everything is not being done right.

The big competition, the big way we compete for funds is by offering a good product; that if you put a study here, we will see that everything is done right.

Mr. BUYER. We are almost circuitous. It is also because you have access to what you called a vulnerable population. So if you have scientists, medical researchers out there that do not share the dimension of your testimony, and they are so eager to participate, problems could occur.

Dr. ZIEVE. Problems could occur. There are many inherent conflicts in this which is the reason for having such a careful setup of—you know, that is the reason that you have all of these regulations, which when you actually look at all of the hoops that, for example, an IRB must jump through, a lot of them seem, you know, to be tremendously ornate.

But, nonetheless, the meticulous procedural safeguards are an important thing here. Now one of the things that we did—let me, if I could just take a minute to describe one particular thing because it was a fundamental decision we made at the very beginning.

When we looked at the university IRB, we were sharing, and then we shared Duke's experience. We talked to them, and we looked at what we needed. And we felt that there was a problem with the bid of having an IRB that was made up of volunteers, because you either tended to get people who had a lot of free time, which probably aren't the people you want; or you got people who had some personal gain out of being on the IRB, who had a conflict of interest, which was just the people.

So right at the beginning, we made the decision that we wanted to have a separate paid professional IRB that was paid for their IRB duties, per se, so they wouldn't have pressure brought on. Their pressure would be to protect the institution, to protect the

veteran, not to approve this project so investigator X gets money. I think that is a real concern you are bringing up.

Mr. BUYER. How does someone end up with 43 percent overhead?

Dr. ZIEVE. I would suspect—I don't know, because ours is not. I will tell you with our overhead rate, we routinely charge 10 percent until the IRB, until we set up the IRB and the investigational pharmacy, and then we had to increase it to 15 percent just for that.

I would suspect that that is probably—the high rate is probably a relatively small corporation that is administering almost entirely federal grants. Because with federal grants, you tend to have some perverse incentives because you only get money if you spend it; whereas, if you are administering private sector money, your goal is to keep your administrative expense to an absolutely minimum.

Dr. BALDWIN. Mr. Chairman, could I comment on that?

Mr. BUYER. Yes, go ahead.

Dr. BALDWIN. I am afraid I wouldn't want to leave any misunderstandings from Ms. Carson's question, because the question about paying indirects to the VA directly was the one that we were discussing. We currently pay about 15 percent to the VA foundations, so we are paying indirect costs to the foundations, and it is about 15 percent.

Mr. BUYER. Oh, okay, good. Mr. Hickman, with regard to West L.A., have you been involved in the recovery at West L.A.?

Mr. HICKMAN. Well, I am not sure, Mr. Chairman. I came on board 3 months after the shutdown, and everyone was scurrying around at that time trying to put things back together in R&D, and they needed a lot of help from the corporation.

Mr. BUYER. Well, tell us the story.

Mr. HICKMAN. Sure. Actually, the corporation hired about nine people the first year to work in R&D to support the staff. Most of those were IRB people and support staff that were working with the IRB coordinators to put the IRB process on track and get it up to the standard that was required.

In addition to that, there were other things that we were doing to support the research operation. We staff a clinical research center at the hospital, and we pay for the staffing, and for the supplies there. We also supply equipment. We provide seed money for pilot studies for grants when we can afford it.

Now even though we weren't involved in any of the events that led to the shutdown, the shutdown did significantly impact the nonprofit corporation, both financial and operationally. Over the past 3 years, our business has declined, so that our income has declined about 49 percent.

And a lot of that has to do with the fact that when the shutdown occurred, we documented over a million dollars worth of business that walked away where there were contracts on the table we were negotiated and the companies walked away.

We can't document business that didn't come to us during the period that we were on probation, but we are sure that there were a lot of companies that were reluctant to bring their studies to us during that period of time.

And there has been just a slow decline in the pharmaceutical business. Doctors are more reluctant to take those studies on at

our site for a number of reasons. We see our salvation, in the long term, to be the handling of federal grants. And that is what I would like to make a comment on.

We have our own federal-wide assurance. We already handle a small number of R01 grants, and we are fully capable of handling a lot more. The problem for us is that virtually all of the NIH grants are being administered by UCLA, even though most of all of the work is being done at the VA facility, which means the VA gets nothing back in terms of FNA costs, or anything else.

Whereas, if we were doing those, administering those grants, virtually all of the FNA money that we collect would be going right back into the VA infrastructure to support the research program. And that would amount to millions of dollars literally.

Right now, we are averaging about $400,000 a year in direct support to the research program; over the last 3 years, about a million-and-a-half dollars, most of that to support the IRB function. I pay the salaries of two of the people, the coordinator, and two of the other IRB staff people.

Mr. BUYER. Well, thank you for your work.

Mr. HICKMAN. Thank you. I appreciate that.

Mr. BUYER. Mr. Boozman, do you have anything?

Mr. BOOZMAN. No, thank you.

Mr. BUYER. By way of opening, we will have a follow-up hearing in September. The lingering concerns on—with regard to human subjects protections will continue. I agree with Dr. Zieve. You mentioned about a special, and yet vulnerable, population, because of their sense of duty.

I will anticipate the IG's findings. We will have sidebar conversations with the VA with regard to the—how they responded to the letter of inquiry from this committee. We will examine the funding relationships between the VA and NIH, and make sure that that is done. And we will have another hearing this September.

Thank you, and this hearing is now concluded.

[Whereupon, at 12:35 p.m., the subcommittees were adjourned.]

APPENDIX

PREPARED STATEMENT OF CHAIRMAN MORAN

Thank Chairman Buyer for his cooperation in holding this hearing.

VA's longstanding biomedical research and development program is source of pride for Committee, the VA and for sick and disabled veterans of our armed forces. Over the years of its existence, VA investigators—

- Perfected antibiotic therapy for tuberculosis
- Established first effective medication for schizophrenia
- Did seminal radio-immunoassay ["radio-immuno-ASSay"] research that led to what we know today as "nuclear medicine."
- Invented the Computerized Axial Tomogram, A.K.A. the "CAT Scan."
- Won the Nobel Prize in medicine three times, as well as the Albert Lasker Medical Research Award (sometimes called the "U.S. Nobel Prize") numerous times, and many other recognitions of excellence in science and medicine.

VA researchers has published literally thousands of learned papers in refereed journals across the entire spectrum of medicine and bioscience, including the *New England Journal of Medicine*, *The Lancety*, and journals of every medical discipline.

Its research is one of VA's bedrock programs—provides a vital link to VA's academic partnerships in 107 schools of medicine, and with other health professions schools.

While research is an acknowledged hidden treasure in VA, also been source of some challenges in recent years—

Committee held hearings in 1999 and 2001 on problems in the research activities of several VA facilities, including its largest in Los Angeles. More recently, problems surfaced in VA facilities in Baltimore, Durham, Washington, DC, and in other sites.

Committee has expressed concern in the past about adequacy of VA's

- informed consent practices,
- its conflict of interest policies,
- its internal Research management practices,

including the effectiveness of supervision exercised by VA Institutional Review Boards, the resources committed to IRBS, and VA local research management, including proper record keeping and other documentation requirements.

Would like to note for the record that the problems observed in VA research are duplicated in university biomedical research programs outside VA, even in some of the nation's most prestigious universities. Many of these cases have come to light in the press in recent years. So, VA is not alone in this regard.

Today, we will reexamine, some of VA's programs in research with a focus on the legislation we passed to give VA authority to set up non-profit foundations to help VA manage extramural research funds such as NIH, corporate and philanthropic grants. Look forward to VA's testimony and that of other witnesses on these topics.

Also very interested in VA's experience to date with intellectual property law and VA's Technology Transfer program - I believe another success story for VA research. Look forward to this discussion.

Thank my fellow Chairman.

PREPARED STATEMENT OF HON. JULIA CARSON

Thank you Mr. Chairman.

I too would like to welcome our panelists and our guests to this joint hearing.

At issue today is the third mission of the Department of Veterans Affairs—medical and health-related research.

Let me be clear—there is only one goal here—to effectively and safely conduct research to provide better healthcare and to improve the general health of veterans and other Americans.

In concert with this overarching goal, I encourage VA to also seek research opportunities with the promise to mitigate the impact of bio-terrorist events. Unfortunately this issue now has a place among our national priorities, just as the healthcare resources of VA have earned VA an important place in our effort to assure homeland security. The Administration must fully recognize the value of VA in this regard.

We all understand the purpose of medical and health research, but we do not necessarily understand the myriad of issues that impacts research in a large Federal agency such as the Department of Veterans Affairs. Today, we shall shed some light on the scope of those issues. We engage in this review to help facilitate a more effective research environment in VA.

A number of issues impact the conduct of VA research and the use of VA research facilities. I plan to review several of these issues during today's hearing.

Public Law 100–322 authorized the establishment of a nonprofit corporation at each VA medical center at which significant medical research is carried out, to provide a funding mechanism for moneys received from other-than-VA appropriations for research projects approved at the medical center.

Research Corporations provide a funding conduit with specified limitations on how those funds may be used. While the Corporations serve a clear and necessary purpose, we must assure that adherence to their original purpose remains steadfast. We can always create other potential funding conduits if research corporations were to become ineffective or un-accountable.

The VA Office of the Inspector General has conducted at least four reviews of the Corporations since 1993. In early reviews, the IG noted significant problems regarding accountability and misuse of funds. In recent audits of nonprofit corporations, the IG found minor problems with reporting. In today's testimony the IG reports that they found no evidence that the information VA reported to Congress regarding the Corporations was not complete and reliable. While performance and accountability seem to be improving, there are many unknowns, and continuing oversight is needed.

Another interest area with direct impact on VA research is intellectual property rights regarding the inventions and discoveries of VA scientists and investigators using funds from research appropriations.

A number of laws and policies impact who gets credit and who owns the intellectual property rights under a variety of circumstances under collaborative research.

We must sort through that labyrinth and assure VA gets due credit for its creative efforts. As a Federal agency, VA should benefit as a result of patent rights and other revenues generated as a result of their discoveries. Public Laws 96–480; 96–517; 99–502 and 104–113 all impact this issue.

An appreciable portion of VA research involves human subjects. With human subject studies we have tremendous opportunity to directly assess the impact of a new drug or new medical procedure.

Human subject research has great potential, but it also requires great safeguards. We must assure that adequate protections are in place to protect and inform the volunteers in such studies of their own personal risk - they must understand the process and the risks.

Between 1993 and 1999, the Human Subject Medical Research programs at the Sepulveda and West Los Angeles VA facilities were shut down because of research violations pursuant to human studies medical research activity. People, Congress, and the media all took notice of that problem.

Protections were needed.

In September 2000, VA established the Office of Research Compliance and Assurance or ORCA to oversee human research and protect our all-to-human subjects. Today, we will receive the testimony of Dr. Mather regarding the progress ORCA has made under his leadership. I will not hesitate to remind him—using a very well-worn quip—that his organization has one whale of a responsibility!

Additionally, regarding human subject medical research, we will review the progress of the National Committee for Quality Assurance. This private, non-profit accrediting organization has developed accreditation standards for human subject research. They are in the process of conducting surveys of VA facilities under those standards.

As Dr. Roswell notes in his statement,

> As of May 8, 2002, eleven (11) final reports have been issued, with eight facilities being "Accredited with Conditions" and three facilities receiving a preliminary result of "Not Accredited."

Dr. Roswell, I will later ask your panel to describe the survey process and elaborate on the meaning of "Accreditation with Conditions." We need to understand the process and the safeguards better.

Mr. Chairman—as you know, the National Institutes of Health, through the grant process; is the second largest source of all donations to VA research. This represents about ⅓ of the research pie at VA.

Cooperation between VA and NIH is important to maximize the effectiveness of research conducted at VA facilities. I asked you to invite Dr. Wendy Baldwin, the Deputy Director for Extramural Research at NIH to provide the views of her agency - I now thank you Mr. Chairman, for graciously extending that invitation to Dr. Baldwin.

Cooperation between principal federal agencies coupled with the express will to resolve problems is essential to success in results oriented government.

I plan to ask representatives of the principals to this research "partnership" how the cooperative effort could be streamlined.

Since the opportunity will now present itself, I plan to ask both Dr. Roswell and Dr. Baldwin if there are options for offsetting the indirect costs incurred by VA when NIH funds a project through some non-federal agency. I understand that until 1989 the VA received a 15% "add-on" to grants to compensate for indirect costs.

This no longer occurs—why?

Non-Federal organizations receive up to a 26 percent "add-on" to cover administration costs alone. Universities conducting "on campus" research receive "on average" about 50 percent additional grant funding to cover both facility and administration costs. We need to understand this process better and hope that VA, NIH and NAVREF representatives can shed some light on this process.

Mr. Chairman this is a rare opportunity to hear all sides of the story and hopefully to "Get Results!"

I yield back Mr. Chairman.

PREPARED STATEMENT OF HON. BOB FILNER

VA Research

Thank you, Mr. Chairman.

We have a unique opportunity presented to us here today to learn more about VA's efforts to improve the quality and safety of its medical research, to develop and cultivate its research accreditation and compliance processes and to explore the worlds of nonprofit corporations and intellectual property rights.

That's a whole lot of territory to cover in one hearing! Our agenda is an ambitious, but an important one. I would like to thank the panelists for their time and testimony. I also commend the leadership of the gentleman from Kansas for bringing us together for the purposes of conducting a joint hearing. We don't do this often. I hope, for myself personally and Members of both Subcommittees, to walk away from this hearing with a far better understanding of the complex issues surrounding medical research. I am just as anxious to also find ways to foster a more effective research environment in VA.

VA research has earned a fair amount of distinction in medical, scientific research and academic circles and has many accomplishments to its credit. I am fascinated with the breadth of research and the tremendous potential to improve the health and the quality of veterans' lives and countless others. I wonder how many cardiac patients with life-saving pace makers know that VA research helped their hearts to continue beating regularly or how many reformed smokers know that nicotine patches are the result of VA research. Recent studies at the VA medical center in San Diego have found a promising treatment for smallpox. This research takes on new significance in light of the heightened threat of bio-terrorism.

VA should receive far more national recognition for its numerous contributions and the funding needed to continue its groundbreaking effort. VA research has real-world applications—applications that have touched everyone here in this room—either directly, or through a family member, friend, coworker or neighbor-and certainly all of us who advocate on behalf of veterans.

I believe it is imperative, however, that we continue to ensure that this research is done responsibly-protecting the rights and dignity of our human subjects. We must not only learn from the lessons of the past, but continue to move the bar on research practices, education, accreditation and industry standards even higher. Fully meeting our fiduciary responsibilities and full accountability to taxpayers must continue to be the hallmarks of VA research.

A few week ago, we had a hearing on legislation that will go the House floor on Monday to expand VA's role in conducting research and education of vital national

importance on bio-terrorist related protocols. Once again, I am compelled to reiterate that VA be given a voice and a policy-forming seat at the Homeland Security table and the funding to support its expanded mission. The grassroots survival of our nation could very well depend on VA's highly effective and proven network of researchers, educators and health care providers across the country.

VA was front and center in numerous support operations at ground zero in New York City and here in Washington, DC. Where are the funds now to back this commitment and all of the rhetoric that has followed in the wake of these events?

We learned during that hearing from testimony given by Mr. Laracuente of the National Association of Veterans' Research and Education Foundations, about a 15 to 20 percent add-on that researchers across the country routinely receive with grants from the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to cover indirect costs for facility and administrative overhead. I asked VA to provide me with some additional background information on this issue. I thank Dr. Roswell and Dr. Feussner for their prompt and insightful response.

I am pleased that the Deputy Director of Extramural Research Programs, responsible for awarding research grants from NIH, Ms. Wendy Baldwin, was invited to join us today. I am eager to learn about NIH's policy decision to grant researchers across the country and in fact around the world, yet exclude VA researchers from receiving this added support. I sincerely hope we will develop some in-roads here today into understanding and hopefully, resolving these inequities.

I like this brochure VA recently developed to help veterans make informed decisions about participating in research project or clinical trial. I applaud these brave veterans, who continue to serve our nation, in an exemplary and selfless fashion. Dr. Zieve made a comment in his written testimony that struck a resounding cord for me when he stated that, "In all the publicity about VA research, the veteran volunteer gets far too little credit." Let's give credit where credit is due!

Thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. JEFF MILLER

Thank you Mr. Chairman.

I would like to thank the members of our panels present today. I appreciate your testimony and your assistance with this issue.

It is of the utmost importance that the VA, and any body that conducts medical research using human subjects, establish a system for ensuring accountability in informed consent. VA medical research is too important to not be done to the highest of medical and ethical standards. It has given veterans and all Americans many pioneering advances in medicine such as the development of the implantable cardiac pacemaker, the nicotine patch, the first oral vaccine for smallpox, and the performance of the first liver transplant.

It is also important to note that despite these wonderful advances in medical research, the VA has seen little in terms of revenues generated by these discoveries. Put simply, this is a situation that must be changed. A considerable amount of time, focus and funding go into VA medical research, and the VA must receive a good return on this investment.

I am thankful that we are having this hearing today to examine the situation and ensure that the VA has worked to correct past problems and to ensure that what occurred a couple of years ago is not repeated.

I would like to thank Chairmen Moran and Buyer for calling this hearing today to discuss this important issue. I look forward to the testimony.

NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VETERANS HEALTH ADMINISTRATION FACILITIES

TESTIMONY OF
MICHAEL SLACHTA JR.

ASSISTANT INSPECTOR GENERAL
FOR AUDITING

DEPARTMENT OF VETERANS AFFAIRS

HOUSE COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

May 16, 2002

Mr. Chairman and Members of the committee, I am here today to report on the Office of Inspector General's (OIG) work related to nonprofit research corporations and education foundations affiliated with Veterans Health Administration (VHA) facilities.

In 1988, Congress passed legislation granting VHA the authority to establish nonprofit corporations (NPC).[1] Prior to 1988, non-appropriated funds for VHA-approved research were generally administered through the VA Medical Center's General Post Fund (GPF) account or by an affiliated medical school. Congress expanded the authority of NPCs to include education in addition to research in 1999.[2]

During the period 1994-1997, we published three reports[3,4,5] that identified a need to improve accountability and oversight related to the administration of funds by VHA nonprofit research corporations.

A fiscal year 1994 OIG audit reported that a research and education foundation's board of directors and officers had not established sufficient written policies and procedures to ensure the stewardship of their corporation's activities, and had not developed an effective internal control structure. In addition, several of the largest corporate accounts were not designated for a specific research project and funds were used at the discretion of the researcher controlling the account. Also, we found that VHA had not provided adequate guidance regarding the types of expenditures research corporations could make

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[1] Veterans' Benefits and Services Act of 1988 (P.L. 100-322), May 20, 1988.
[2] Veterans Millennium Health Care and Benefits Act (P.L. 106-117), November 30, 1999.
[3] Audit of Atlanta Research and Education Foundation, Report No.: 4R3-A09-081, dated June 14, 1994.
[4] Review of VA Nonprofit Research Corporations, Report No.: 4R2-A09-078, dated June 14, 1994.
[5] Review of Nonprofit Corporations Established in the Veterans Health Administration, Report No.: 7R3-A19-064, dated March 20, 1997.

to facilitate VA research. We concluded the corporation did not maintain complete and accurate financial management and accounting records.

We recommended and VHA agreed that the research corporation establish an effective system of internal controls, develop policies and procedures to ensure expenditures facilitate VA research or related administrative overhead, and that VHA recover medical care appropriation resources inappropriately used to support AREF research.

In another fiscal year 1994 OIG report, we reviewed about $1 million of $3.6 million of expenditures spent at 3 research corporations and identified about $625,000 spent on activities not directly related to research. We found that the research corporation spent funds for salaries of medical residents and on staff travel not clearly related to research or administration. We reported that the 3 research corporations spent funds for non-research related conferences, honoria, gifts, awards, entertainment, and other non-research expenditures. In response, VHA agreed to publish national policy for the operation of research corporations that included guidance for administration, accounting, budgeting, and oversight. VHA published a new policy chapter governing nonprofit research corporations on May 20, 1994.[6] In our view, VHA's policy did not adequately address expenditure controls and did not provide adequate guidance over appropriate use of research funds. Subsequently, in November 2001, VHA published VHA Directive 1200 and VHA Handbook 1200.17 to provide further guidance for governing NPCs.[7]

In 1997, we issued a report in which we disclosed that a VA Medical Center (VAMC) provided radiology and laboratory services to an affiliated medical school, but the research corporation, not the VAMC, billed and received payment from the school for the services. As a result of poor record keeping, accountability to ensure Federal funds were used as Congress intended was lost.

Since fiscal year 1993, we have issued four other reports that address issues related to VHA's administration of research. Although these reports[8,9,10,11] do not directly address funds administered by the research corporations, the issues reported were related to VHA's administration of the research program and control over research funds. In these reports we made recommendations to strengthen controls over the use of research funds, personnel issues, and medical care fund reimbursements.

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[6] M-3, Part I, *Research and Development in Medicine - General*, subsequently rescinded by VHA Directive 1200 in November 2001.

[7] VHA published VHA Directive 1200 in November 2001 and VHA Handbook 1200.17 in December 2001.

[8] Audit of Allegations Concerning Research Administration VA Medical Center West Los Angeles, California, Report No.: 3R7-A99-044, dated January 25, 1993.

[9] Audit of Research and Travel Activities at VA Medical Center North Chicago, Illinois, Report No.: 4R4-A09-099, dated June 30, 1994.

[10] Audit of Allegations Concerning a Research Physician at Edward Hines, Jr. Veterans Hospital Hines, IL, Report No.: 8R4-A01-032, dated October 27, 1997.

[11] Evaluation of Financial and Administrative Controls in the Research Program at the VA Greater Los Angeles Healthcare System, Report No.: 99-00191-2, dated October 12, 2000.

In fiscal year 1993, we found that a private nonprofit research corporation operated at a VAMC without proper approval, written agreements, or management oversight. As a result, medical center's management oversight over funds, personnel, supplies, drugs, and animals used in the corporation's operations was limited or non-existent. We recommended establishing controls to account for the corporation's costs, ensuring VA costs were reimbursed, and the need for the corporation to obtain independent financial statement audits of the VA affiliated research and education corporation.

In a fiscal year 1994 OIG report on research administration, we reported that administrative activities in Research and Development (R&D) Service needed improvement, and medical center Fiscal Service staff needed to take action regarding one researcher's travel. We recommended that the R&D service terminate a researcher's activities, that the R&D service use appropriate procedures to control the financial relationship between the researcher and fund donors, and use appropriate budget control mechanisms to administer funds donated for specific research activities.

Also a fiscal year 1997 report identified a lack of sufficient control over research funds and the activities of principle research investigators. We also found that VA's medical care appropriation had not been reimbursed for resources expended in support of research projects run by the investigators. We recommended that the Network Director eliminate the opportunity for principle investigators to control research funds, establish a "proposed use of funds" for every research donation, and ensure that conflicts of interest were avoided.

In fiscal year 2000, at the request of a former VA Under Secretary for Health, we performed an evaluation of financial and administrative controls in a VAMC's Research Program. The Under Secretary requested a review because VHA managers found numerous deficiencies in the Research Service's financial and administrative operations. Because of the seriousness of these deficiencies, VHA management requested that the OIG evaluate research operations, with the objective of providing independent assurance that all the major financial and administrative deficiencies had been identified and effectively corrected by the VAMC's management. We concluded that the major deficiencies in financial and administrative operations had been identified and effectively corrected, but continued management oversight was needed to ensure that problems do not recur.

In each of the aforementioned reports, VHA agreed with our recommendations and proposed acceptable implementation plans.

In response to your letters dated March 22, and March 25, 2002, in which you present a series of questions regarding the monitoring and accountability requirements for VA's NPCs, we obtained responses to the questions that you asked from the Acting VA Under Secretary for Health; the Executive Director, National Association of Veterans' Research and Education Foundations (NAVREF); and the Chairman, Office of General Counsel's (OGC) Corporations Panel.

The Acting Under Secretary for Health but deferred questions related to potential conflict of interest and advocacy issues between NPCs, the VA OGC and NAVREF. We forwarded the questions concerning conflict of interest and advocacy issues to those organizations. VHA's responses and responses received from the NAVREF organization and the OGC's Corporations Panel; are compiled in Exhibit 1.

At the Committee's request, my staff has reviewed certain aspects of VA research corporations and the responses provided by the Department. We have focused on determining whether the required reports were submitted to the Congress for FY 2000. Our work included verifying that each VA research corporation required to obtain an independent financial audit and report corporate information to the Internal Revenue Service (IRS) were in compliance, and reported timely information.

Under current law, VHA is required to provide an annual report to Congress identifying the research corporations, and contributions they receive each year. Title 38, United States Code, Section 7366 delineates the accountability and oversight requirements over these corporations. Research corporations with revenues in excess of $300,000 for any fiscal year shall obtain an independent audit of the corporation for that year. A research corporation with revenues between $10,000 and $300,000 shall obtain an independent financial audit of the corporation at least once every 3 years. The NPC shall include the most recent audit report in addition to the financial data in the corporation's report to the VA Secretary.

Our review showed that for FY 2000, the most recent reporting period, 88 VA research corporations reported total revenues of about $174 million.[12] Of these 88 research corporations, 85 reported receiving contributions. Sixty-one of the 88 corporations were required to obtain an independent certified financial statement audit based on reporting total revenues in excess of $300,000. We verified that all 61 NPCs complied with the requirement to obtain an independent audit, however one audit was not submitted in a timely manner. All 61 NPCs received independent audit opinions concluding that their financial statements present fairly, in all material respects, the financial position of the nonprofit corporations.

To determine whether the information reported to Congress was complete and consistent with the IRS information, my staff analyzed the Report of Independent Accountants, the NPC's Financial Statements, and the NPC's filed IRS Form 990 - *Return of Organization Exempt from Income Taxes* for the 30 of the largest revenue producing NPCs for the most recent reporting period. The IRS Form 990 is the primary source of data the Department uses to compile the Annual Report to Congress.

For one of the 30 largest research corporations, the independent auditors' reported non-compliance with U.S. Office of Management and Budget (OMB) Circular A-133 guidance and weaknesses in internal controls. That auditor reported two issues related to non-compliance. First, the auditor could not substantiate the methodology used to arrive

[12] Per VHA policies and procedures, corporate reports for the prior FY are due to VHA by June 1st of every year.

at the indirect cost rate charged to Federal programs. Secondly, the research corporation was not filing the required quarterly Federal Cash Transaction Report. In addition, the auditor also disclosed seven issues related to internal controls.[13]

We verified that all 15 of the 88 NPCs reporting $300,000 or more in Federal awards in FY 2000 complied with applicable OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations* requirements. Financial audits were submitted to VA by the research corporations consistent with the provisions set forth in, OMB Circular A-133. OMB requirements refer to the Single Audit Act and are intended to promote sound financial management, including effective internal controls over Federal awards. These audits add an additional level of accountability and oversight over Federal funds to help ensure entities are maintaining internal controls over Federal programs and complying with laws, regulations, and the provisions of contract and grant agreements. The audits do not determine if funds are used as Congress intended, or that research projects are adequately meeting VA associated strategic goals and objectives.

In reference to your questions regarding the amount of administrative overhead expenditures spent administering VA research corporations, the Under Secretary for Health responded that the percentage spent in each research corporation for administrative overhead expenditures in FY 2001 averaged 10 percent of total expenditures, citing IRS Form 990 - *Return of Organization Exempt from Income Taxes* as the source of this data.

We found that 7 of the 15 NPCs required to comply with OMB Circular A-133 requirements, also have Indirect Cost Rate Agreements established with the Department of Health and Human Service (HHS), as the cognizant Federal agency responsible for the negotiation and approval of indirect cost rates. We were advised that two additional research corporations were in the process of negotiating their indirect cost rate agreements with HHS. The review process that cognizant Federal agencies follow to negotiate and approve indirect cost rate agreements represents another level of oversight and monitoring over non-profit organizations receiving Federal awards and such reviews generally include an assessment to determine whether NPCs have procedures for determining the allowability of costs to Federal awards according to the applicable cost principles and other terms of awards.

We found that 18 of the 88 NPCs reported total annual revenues of more than $3 million in fiscal year 2000, but most reported less than $2 million in annual revenues. Accordingly, we believe there may be an opportunity to redirect more funds to direct support of research by consolidating and reducing the number of corporations. Savings would come from avoiding administrative and overhead expenditures associated with

[13] The seven issues are: 1) Absence of appropriate reviews -- Almost all accounts were unreconciled, cost center reports did not match claim forms, and transactions were not being recorded. 2) Accounting principles not applied appropriately. (No monthly closing or reconciliation, lease obligations improperly classified). 3) Expenditures not properly approved. 4) Internal controls intentionally (improperly) overridden. (Missing purchase orders, lack of approvals.) 5) Accounts lacked support documentation. 6) Lack of billing tracking or system. 7) Failure to safeguard physical assets from loss, misappropriation, or damage.

maintaining 88 individual financial management and payroll systems, obtaining annual audits, meeting Internal Revenue Service reporting requirements, and other administrative costs.

We found no evidence to lead us to believe that the information VA reported to Congress was not complete and reliable. However, we believe that annual reporting could be enhanced to give Congress improved visibility over the use of funds to ensure that research funds are used as intended. The annual report to Congress could provide detailed expenditure reporting to facilitate oversight by VHA. We also believe an opportunity exists to help ensure that funds are used as intended by Congress, by improving the visibility over research corporation operations.

Our observations are brought to your attention to supplement the information provided by VA in response to the series of questions by your Committee. This concludes my testimony. I would be pleased to answer any questions that you and the Members of the committee may have.

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

I. Does VA need Research Corporations?

Issue – Public Law 100-322, authorized the establishment of research corporations, was enacted to create a flexible funding mechanism to receive and expend money received from non-VA entities to conduct research. Subsequent to the enactment of the legislation, a law was enacted to expand the Secretary's authority to accept gifts. This provided greater flexibility to the VA in accepting and expending funds deposited in the General Post Fund.

Response provided by National Association of Veterans' Research and Education Foundations (NAVREF): *The research corporations were authorized by Congress in 1988 to accept and administer non-VA funds in support of VA research. This was accomplished in part to increase the funding available to support VA research and to ensure that such funding accrued to the benefit of VA rather than the affiliates or other nonprofits. In order to continue to do so efficiently and at minimal cost to VA, VA needs the research corporations.*

Advantages of having funds managed by corporations:

- *The corporations can negotiate federal indirect cost rates on grants.*
- *The corporations maximize funding opportunities by working with principal investigators to obtain grants and engaging in fund raising.*
- *The corporations earn substantial interest on accrued funds.*
- *The corporations can hire employees at will.*
- *The corporations use the most cost effective methods of procurement.*

Please note that the corporations use the gift authority to donate to VA millions of dollars worth of supplies, equipment, and research services each year.

In the corporations, the VA has an ally devoted to maximizing the resources available to support the VA research program.

- How many Research and/or Education Corporations are there?

Response provided by Acting Under Secretary for Health, Department of Veterans Affairs: *As of June 1, 2001, there were 88. Of these, 85 were active.*

- How many medical facilities have more than one research corporation?

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Acting Under Secretary for Health: *None. However, two facilities recently established education corporations that are separate from the research corporations already affiliated with these facilities.*

- How does VA monitor and evaluate the effectiveness of the Research Corporations?

Acting Under Secretary for Health: *Continuous monitoring and evaluation are provided by the VA personnel who serve by statute on the board of each corporation. Annual monitoring and evaluation are conducted through the annual reports that are due on June 1. A copy of the annual report is provided to the affiliated facility's Chief Fiscal Officer for review and comment.*

- With changes to the laws affecting the ability to accept and expend funds, what would be the downside, if any, to having funds earmarked for research or education managed by VA through the General Post Fund?

Acting Under Secretary for Health: *The corporations are a highly efficient means to acquire and manage both private sector and non-VA federal funds in support of VA research and education. Corporations can readily hire research personnel and provide timely services. Further, the VA corporations are subject to more layers of oversight and scrutiny— including their own board of directors, auditors, the IRS, VA OIG and Comptroller General, and state and local governments.*

- Assuming there is a need to continue having non-profit VA Research Corporations, is there a need to have more than one per medical center? One per VISN? One for the entire VA?

Acting Under Secretary for Health: *The current practice of one research corporation per facility provides the optimum on-site service to investigators as well as direct oversight by facility personnel. VISN corporations or one VA-wide corporation would have to comply with multiple state tax requirements, varying state labor management regulations and a variety of reporting and compliance matters.*

II. <u>How does VA ensure Research Corporation expenditures are used appropriately?</u>

Acting Under Secretary for Health: *Each corporation has a board of directors comprised of VA personnel as well as community members and an executive director who have direct responsibility for all corporation expenditures.*

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- In FY 2001, what funds were received for (a) research, and (b) education?

Acting Under Secretary for Health: *Research: $163 million, Education: $.7 million*

- In FY 2001, what percentage of the funds did the Research Corporations spend on (a) research, (b) education, and (c) training?

Acting Under Secretary for Health: *Research: 99%, Education: 1%*

- Identify current VA approved research projects that are funded through VA Research Corporations. Delineate the type of research conducted for:

  - Drug trials for pharmaceutical companies.

Acting Under Secretary for Health: *Approximately, 1/2 of foundation revenues come from the private sector and included grants from pharmaceutical companies as well as other private sector organizations, nonprofits and individual donors.*

  - Non-drug trial related research categorized by medical discipline including:
  - Research related to prostate cancer, respiratory cancer, and other diseases associated with exposure to Agent Orange.
  - Research related to woman's health issues.
  - Research related to diseases and conditions associated with service in Operation Desert Shield/Desert Storm.

Acting Under Secretary for Health: *VA does not maintain this data.*

- In FY 2001, what percentage of each Research Corporation funds was spent on "overhead" expenses?

Acting Under Secretary for Health: *The average was about 10%.*

- In the October 2001 report to Congress, it is reported that the rate for administrative overhead expenditures in FY 2000 averaged 10%.

  - What was the source of the data that was relied on for this figure?

Acting Under Secretary for Health: *The IRS Form 990.*

- What expenses are included in administrative overhead expenses?

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

Acting Under Secretary for Health: *Administrative salaries, personnel management, benefits management, office equipment and supplies, etc.*

- What are the criteria for determining what is an administrative overhead expense?

Acting Under Secretary for Health: *This is specified in Part II of IRS Form 990.*

- What was the range of overhead expenses among the Research Corporations?

Acting Under Secretary for Health: *0-43%*

- Of the 90% reported spent on approved research and education:
  - What percentage was spent on (a) approved research and (b) education?

Acting Under Secretary for Health: *Research: 99%, Education: 1%*

- What were the range of expenditures for research and the range of expenditures for education per Research Corporation?

Acting Under Secretary for Health: *Research: $608-$10.8 million, Education: $300-$81,310*

- What are the criteria for considering an expenditure a "research" expenditure?

Acting Under Secretary for Health: *If an expenditure is related to research, it is considered to be a research expenditure.*

- Are there any Research Corporations that have established a discretionary or "slush" fund for use by the Medical Center Director (any fund or account that has not been designated for a specific purpose)?

Acting Under Secretary for Health: *In 1994, OIG clarified that corporations must reimburse the medical care appropriation for research services provided over and above normal clinical care, and may not set up internal accounts in lieu of such reimbursements.*

III. **Section 7366 of Title 38 requires that every Research Corporation submit an annual report.**

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- What information is required to be submitted in the report?

Acting Under Secretary for Health: *See attached Appendix A of Handbook 1200.17*

- What oversight functions are in place to review these reports?

Acting Under Secretary for Health: *Data from the annual reports is compiled in accordance with requirements established by Congress. Facility fiscal officers, Network fiscal officers, as well as personnel in the Office of General Counsel, Office of the Inspector General, and Office of the Secretary review the compilation.*

- Who is responsible for reviewing and analyzing these reports?

Acting Under Secretary for Health: *Offices noted above are in the concurrence process.*

- What corrective or remedial actions have been taken within the last 5 years as a result of the review of the annual reports?

Acting Under Secretary for Health: *One corporation was site visited. Additional guidance on the importance of timely submissions was issued.*

- Do these annual reports provide sufficient information for the agency to identify non-research or non-education related activities (i.e. inappropriate expenditures)?

Acting Under Secretary for Health: *Expenditures are reviewed for appropriateness by the corporation's executive director, board of directors, accountant, and auditor prior to incorporation in financial statements and the IRS Form 990 that is included in the annual report to VA.*

- The reports submitted to Congress in 2000 and 2001 identify audit findings and recommendations taken from annual audits submitted pursuant to § 7366. These audit recommendations appear to be identical for both years. What specific actions have been taken to ensure implementation of these recommendations?

Acting Under Secretary for Health: *Each board of directors is responsible for taking corrective action.*

IV. <u>What are the overall revenues for Research Corporations?</u>

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

- For FYs 2000 and 2001, what was the total amount of VA appropriated funds spent on research?

Acting Under Secretary for Health: *The congressional appropriation for FY 2000 was $321 million and in FY 2001 was $350 million.*

- What is the total amount VA received in donated funds for 2001 and how was it accounted for?

Acting Under Secretary for Health: *RD does not have data for total VA donations.*

- Please list the specific amounts and sources each VA Research Corporation received in 2000 and 2001?

Acting Under Secretary for Health: *See attached list.*

V. <u>Do VA Research Corporations generate additional revenues for, or through the corporation?</u>

- During the past 5 years, have any research corporations earned revenues from general fund raising, investing, and/or business-like activities.

Acting Under Secretary for Health: *As indicated on their IRS Form 990s, a few corporations have participated in minimal fund raising and some participate in the Combined Federal Campaign. Corporations "invest" funds in instruments backed by the full faith and credit of the US Government.*

- Who is responsible for any monitoring? Please provide documentation of these reviews.

Acting Under Secretary for Health: *The IRS as well as each corporation's accountant, auditor and board of directors provide monitoring to ensure that all revenues and expenditures are consistent with the corporation's tax-exempt purposes and are reported accurately. Fund raising expenditures are reported in Part II of IRS Form 990. Interest income is reported in Part VII. Tax-exempt income is reported on IRS Form 990, Parts I and VII.*

- Have any Research Corporations invested in the stock market or other similar investment funds? If so, identify which Research Corporations, the amount invested and the date each investment was made.

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

Acting Under Secretary for Health: *All corporation funds must be managed in accounts that are backed by the full faith and credit of the US government.*

- What oversight requirements are in place to monitor Research Corporations to prevent and detect fraud, waste, abuse, mismanagement, inappropriate expenditure of funds, and violations of Federal ethics rules and regulations?

Acting Under Secretary for Health: *Each corporation has a board of directors that has responsibility for direct oversight of the nonprofit. In addition, each corporation has a CPA accountant and an external auditor. Further, the Inspector General, the Comptroller General, the IRS and the government of the state in which the corporation is incorporated have the right to examine the records of a corporation at any time.*

VI. In FY 2000 and 2001, how many Research Corporations were required to submit an annual audit as required by § 7366(b)?

Acting Under Secretary for Health: *70 research corporations were required to submit an annual audit for FY 2000.*

- Did every Research Corporation submit an audit?

Acting Under Secretary for Health: *All of the corporations that were required to submit an audit did so.*

- What mechanism does VA have in place to monitor compliance? Please provide a list of all Research Corporations that are required to file.

Acting Under Secretary for Health: *Corporations with revenues over $300,000 are required to undergo and submit to VA an annual audit. Corporations with revenues between $10,000 and $300,000 undergo and submit an audit once every three years. Corporations with revenues less than $10,000 are exempt from the requirement. See attached Annual Report for list.*

VII. Did all Research Corporations submit the required annual ethics certification signed by the executive director on behalf of the directors and employees?

Acting Under Secretary for Health: *Yes.*

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

- How has the VA ensured compliance with the statutory requirements?

Acting Under Secretary for Health: *VA ensures that required statements are signed by Executive Directors and required forms are completed in time for submission to Congress.*

VIII. Expenditures not directly related to research.

- Please list the amount each Research Corporation spent in FYs 2000 and 2001 on the following:

  - Licensure and fees
  - Memberships
  - Vehicles
  - Cell phones
  - IT equipment (laptops, blackberries, etc.)
  - Travel
  - Entertainment, receptions, parties
  - Publishing
  - Salaries of family members
  - Training

Acting Under Secretary for Health: *The corporations are not required to report the above categories of expenditures.*

- Please provide a copy of all guidance VA has published in regard to what expenditures are considered proper versus improper expenditures?

Acting Under Secretary for Health: *Guidance is provided in attached Handbook 1200.17.*

- Please list expenses each research corporation incurs in any given year in the following categories: clerical, office supplies and equipment, telephones, overhead charges, etc.

Acting Under Secretary for Health: *VA does not maintain this data.*

- If external research funds were deposited in and allocated from the General Post Fund, what would be the decreased costs in administrative overhead and compliance monitoring.

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

Acting Under Secretary for Health: *We have no reason to believe there would be a decrease in administrative overhead with deposits going to separate General Post accounts as opposed to non-profit foundations.*

IX. Conflict of interest/advocacy issues:

- Pursuant to an agreement with the National Association of Veterans' Research and Education Foundations (NAVREF), legal services can be provided by certain identified employees of the Office of General Counsel. Reimbursements for services are made by individual Research Corporations through a reimbursement to the General Counsel. Why is this agreement not a conflict of interest since the same attorneys or attorneys in the same office may be responsible for representing the Agency in decisions or actions that the Research Corporation, or an employee of the Research Corporation, violated some aspect of the statute.

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *In 1997, in consultation with NAVREF, the Office of General Counsel devised a process whereby corporations may request legal services of certain field attorneys (not OGC attorneys) and reimburse VA for such services. Recognizing that legal advice on issues involving VA is not readily available in the private sector, the program is designed to provide accurate, timely and consistent advice to NPCs on matters in which VA has an interest.*

The OGC Corporations Panel has only 10 members. Should a conflict of interest occur, any interested persons could be recused and non-panel attorneys could take up the issue.

Response provided by Chairman, OGC Corporations Panel: *I do not believe there is a conflict of interest in the arrangement between the Office of General Counsel (OGC) and the National Association of VA Research and Education Foundations. Rather, the relationship between OGC and the various VA nonprofit research and education corporations (the Corporations) is similar to our representation of the many other parts of VA and the Department's many employees.*

VA Research Corporations may use either VA legal counsel (OGC) or private legal counsel. VHA Handbook 1200.17, para. 6.j. (Dec.17, 2001). Legal services provided by Panel attorneys are part of their official Federal duties.

Panel attorneys do not represent the Corporations, or employees of a Corporation, in decisions or actions where they may violate some aspect of federal law, to include any Federal statute,

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

regulation, or policies. As in all their work, a Panel attorney's client remains the United States, and not a Corporation or its employees who act in conflict with Federal law.

The Panel is a group of attorneys in OGC who have a developing expertise in this fast-growing and challenging area of law. That expertise is the result of Panel conferences, training, group email sites, library costs, travel, administrative overhead, and other costs.

Panel attorneys assist Corporations and their employees in understanding and following applicable federal law and regulations, and other VA authorities. Panel attorneys provide the Corporations advice on corporate powers, fund raising, contracting, negotiations with private sector donors, intellectual property concerns, unique conflict of interest issues, explaining Federal matters to non-federal employees, and a growing list of other issues.

Panel attorneys do not serve as a representative or advocate on behalf of a Corporation in matters before the Federal government. As is generally true of all Federal lawyers, we in General Counsel, to include those of us on the Panel, have a single client, the United States.

To date, to my knowledge, there has not been a situation where a Corporation violated the statute establishing them. If that arises, OGC could determine if there was a substantial relationship between the matter at issue and the advice of one or more of its attorneys and then assign different attorneys to be involved.

- What percentage of funds for the Research Corporations are spent for advocacy purposes:

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *NAVREF does not collect information on corporation advocacy expenditures.*

However, a small portion of NAVREF's expenditures is related to advocacy. During its last completed fiscal year, NAVREF spent $29,145 on advocacy for the VA research program. This represents about 10% of NAVREF's total expenditures and .01% (or one ten thousandth) of total corporation revenues of $174 million.

- What was the total amount of the membership fees paid to NAVREF in FYs 2000 and 2001?

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *NAVREF is a voluntary membership organization supported by dues. Fiscal Year 2000-2001: $245,200. Fiscal Year 2001-2002: $256,000.*

- How are these fees determined?

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *The NAVREF board of directors establishes membership dues.*

- What services does NAVREF provide the Research Corporations?

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *NAVREF is a 501(c)(3) education organization. NAVREF provides the corporations with the following programs and services:*

- *Two educational conferences each year designed to promote the highest standards of fiscal and operational management of the corporations; focus is on the unique needs of the VA research corporations as well as issues relevant to all nonprofit organizations. See attached program of educational sessions held during the 2002 Annual Conference.*
- *The Best Practices Consultations program under which members invite NAVREF to send a pair of specially selected, experienced executive directors to spend two days on site reviewing all aspects of the corporation's management and suggesting "best practices." NAVREF supports all the costs of each consultation.*
- *A group insurance program that provides the corporations with access to insurance products that are both cost effective and tailored to meet their particular needs.*
- *A "preferred vendor" program that takes advantage of the cumulative purchasing power of the corporations to negotiate discounts on supplies, services and equipment.*
- *A bulletin board that allows members to share questions and solutions among themselves.*
- *Identification of funds management firms that meet the criteria specified by OGC that all corporation funds must be backed by the full faith and credit of the US government at all times.*
- *Frequent electronic newsletters on timely issues.*

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- *A searchable web site with comprehensive information about corporation management.*
- *Staff who serve as a readily available resource for information on corporation operations; turnaround on questions is usually within one day.*
- *Advocacy for the annual appropriation for the VA research program; the corporations are predicated on a successful VA research program and the revenues they generate cannot replace a robust federal appropriation.*

- What benefits have VA Research Corporations realized from NAVREF in the past 3 years.

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *In addition to the ongoing benefits of the NAVREF programs and services listed above, benefits during the last three years include:*

- *Working with OGC to improve Handbook 1200.17.*
- *Negotiating with the Department of Health and Human Services Office of Human Research Protections a template Federal-wide Assurance application for the use of the corporations.*
- *Assisting corporations with implementation of the education authority.*
- *Assisting VAMCs in establishing new corporations*
- *Improving compliance with the annual reporting requirements through education and dissemination of the requirements.*
- *Improving corporation management by supporting and participating in Best Practices Consultations.*
- *Working with members of the OGC Corporations Panel to improve communications and simplify negotiation of research agreements.*
- *Providing resource materials on a variety of operational issues including the Intergovernmental Personnel Act, Federal conduct and ethics requirements, dual compensation, etc.*

- Would these services be needed if Research Corporations were discontinued and funds for research managed through the General Post Fund or one VA-wide Research Corporation?

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

NAVREF: *Training in administration of private sector and non-VA Federal research studies would still be needed. If administered by the General Post Funds or one VA-wide corporation, a tremendous number of new VA and/or private sector personnel would need to be trained to take over central and local administration of the more than 4,600 grants that corporations currently manage. In addition, VA would have to replace the estimated 2,000 corporation research employees whose services are currently donated to VA. As a result, the need for training would remain though it would not be provided by NAVREF.*

- Do all VA Research Corporations belong to NAVREF? If not, identify those corporations that do not?

Acting Under Secretary for Health: *This question is probably best answered by NAVREF, the National Association of Veteran's Research and Educational Foundations.*

NAVREF: *All of the active research corporations belong to NAVREF. Inactive corporations in Huntington, WV; Lexington, KY; and Fresno, CA are not members*

X. <u>Research Corporation funds expended for consultation services and awards</u>.

- Were any Research Corporation Funds expended for consultation services during the period FY 1998 through 2001?
  - For each such expenditure, identify which Research Corporation spent funds for consultation services and identify, who was paid, how much was paid, what services were provided, and how they related to the research.

Acting Under Secretary for Health: *VA does not collect information on consulting fees paid by corporations. However, such fees, if any, are reported to the IRS on Part II of Form 990.*

- For FY 1998 through 2001 were any Research Corporation funds spent on awards, media, or public relations efforts?

Acting Under Secretary for Health: *Some corporations make donations or incur costs associated with facility National VA Research Week activities. Such activities are designed to educate the general public about the benefits of VA research. Members of Congress are often among the invited guests.*

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

- For each award, identify the Research Corporation that made the expenditure, the research fund from which it was made, the amount of each award and identify the recipient of the award and reason for the award.

Acting Under Secretary for Health: *Corporations are not required to report awards made.*

XI. Reimbursement of medical care appropriation

- Please list internal controls that ensure medical care appropriations are appropriately reimbursed for services and resources used to support research protocols?

Acting Under Secretary for Health: *The board of directors and facility management are responsible for ensuring that the medical care appropriation is appropriately reimbursed for services.*

- Please identify these reimbursements made by the Research Corporations in FYs 00 and 01?

Acting Under Secretary for Health: *VA does not maintain data on such reimbursements.*

- Identify the medical centers that were reimbursed and the amount of each reimbursement.

Acting Under Secretary for Health: *VA does not maintain data on such reimbursements.*

XII. Unused research funds

- Please identify research projects terminated/completed in the last five fiscal years, and the reasons for their termination.

Acting Under Secretary for Health: *VA does not maintain this data*

- Of those projects that were completed, how many had remaining or unused funds?

Acting Under Secretary for Health: *VA does not maintain this data.*

- What was the amount of the unused funds for each project?

EXHIBIT 1

COMPILED RESPONSES TO THE QUESTIONS IN THE COMMITTEE'S MARCH 22, 2002 LETTER ON NONPROFIT RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS AFFILIATED WITH VHA FACILITIES

Acting Under Secretary for Health: *VA does not maintain this data.*

- For each project identified, please explain the disposition of all unused funds?

Acting Under Secretary for Health: *Any residual funds are spent on VA research or education in accordance with policies and procedures established by the board of directors.*

XIII. To improve the monitoring of the Research Corporation funds, the 1994 OIG report recommended that VA establish consistent accounting reporting periods for the Research Corporations; consistent record keeping procedures; and, establish cost principles for accounting purposes.

- What has VA done to develop and implement these recommendations?

Acting Under Secretary for Health: *Provisions specifying use of commonly accepted accounting practices and other record keeping guidance were added to Handbook 1200.17. Additionally, corporations must follow record keeping procedures and accounting principles established for nonprofits by the Federal Accounting Standards Board (FASB) and the American Institute of Certified Public Accountants (AICPA) and OMB when applicable.*

- What procedures are in place to ensure compliance?

Acting Under Secretary for Health: *Each corporation has a board of directors that has responsibility for direct oversight of the nonprofit. In addition, each corporation has a CPA accountant and an external auditor. Further, the Inspector General, the Comptroller General, the IRS and the government of the state in which the corporation is incorporated have the right to examine the records of a corporation at any time.*

STATEMENT
OF
JOHN H. MATHER, M.D.,
CHIEF OFFICER,
OFFICE OF RESEARCH COMPLIANCE AND ASSURANCE
DEPARTMENT OF VETERANS AFFAIRS
ON
OVERSIGHT OF RESEARCH AND OTHER ISSUES
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
AND THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

MAY 16, 2002

*****

Mr. Chairman and Members of the Subcommittees, thank you for the opportunity to appear before you to discuss the activities of the Office of Research Compliance and Assurance (ORCA) and, in particular, its role and responsibilities in the protection of human research subjects in the Veterans Health Administration (VHA). Further, this will provide an update on the scope, structure, philosophy, and product lines of ORCA since this committee's oversight hearings of April 21, 1999, and September 28, 2000.

Scope

The scope of ORCA is defined in the Mission statement, which is in accordance with the commitment made to the Congress in 1999:

> The Office of Research Compliance and Assurance (ORCA) serves as the primary VHA component in advising the Under Secretary for Health on all matters affecting the integrity of research in the protection of human subjects and animals, promoting enhancements in the ethical conduct of research in conformance with regulations and policies and investigating any allegations of research improprieties and research misconduct.

ORCA reports directly to and serves as the primary advisor to the Under Secretary for Health on all matters affecting the integrity of VHA research related to compliance and assurance. ORCA advocates and promotes the application of continuous quality improvement to enhance the ongoing protection of human subjects enrolled in research and welfare of animals used in research. Further, in circumstances involving allegations of potential research impropriety and research misconduct, this office conducts the necessary investigations, and prepares recommendations for remedial and corrective actions. This scope of responsibility is codified in VHA Directive 1058, "Responsibilities of the Office of Research Compliance and Assurance," issued May 23, 2001.

Important to ORCA and the VA are the connections made through ongoing collaboration with the various other federal departments and agencies, and non-

governmental organizations that are responsible for the issues under ORCA's purview. ORCA has close working relationships with the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), the Office for Laboratory Animal Welfare (OLAW) and the Office of Research Integrity (ORI), all located in the Department of Health and Human Services. Vitally important relationships with these organizations have helped to ensure that the VA is conducting its activities in a consistent and ethical manner. There is much more that can and will be done to build upon these productive relationships.

Structure

The structure of ORCA includes a central office and five regional offices. The central office is responsible for the overall accomplishment of its mission, while providing direction, guidance and oversight to its five field-based units that routinely perform their delegated operational roles and responsibilities. The central office has eight (8) full time staff; and the four (4) fully activated regional offices are each staffed with four full time staff. Recruitments for the fifth regional office are currently in process.

Each regional office covers a geographical area that encompasses between three and six Veterans Integrated Service Networks (VISNs) and provides support and services on the full scope of ORCA's activities to about 25 VA medical centers (VAMCs) and VA Health care Systems (HCSs). The original four regional offices have been fully staffed since September 2001, and the fifth regional office, which will serve the VAMCs in the three VISNs in the Northeast, will be completely activated by the end of this fiscal year. Each regional office is developing an expertise in a particular area so that it can be an authoritative resource throughout ORCA. For example, in the Southern regional office in Decatur, GA, we have a veterinarian on the staff who collaborates with the VA's chief veterinarian, located at the same VAMC, while the Mid-Atlantic regional office in Washington DC is developing an emphasis in the area of research safety. While the preponderance of ORCA's activities have so far been related to human subject protections, the areas of animal welfare and research safety need to be given greater attention. Also, research misconduct oversight is rapidly evolving as a major issue with the implementation of the new Federal Research Misconduct Policy and the publication in the April 30,2002 Federal Register, that the VA has adopted this policy.

ORCA has established a Field Advisory Committee that meets twice a year to advise on the implementation of its programs. It is composed of VA staff across the full spectrum of operations and research, including representatives from VISNs and VAMCs, such as Associate Chiefs of Staff for Research and Development, Administrative Officers for Research, and Research Compliance Officers.

Philosophy

From the beginning, ORCA has set for itself a course that seeks to promote continuous quality improvement in the responsible conduct of research. Since ORCA is not an entity that has the authority to 'regulate', it is forging a different paradigm.

ORCA's philosophy for oversight has been described as the ACE approach. This balanced approach is embodied in the acronym ACE, which refers to ORCA's need to create a culture of Assurance/Assessment, being a Counselor/Cop, and acting as Educator/Enforcer.

Another key feature has been the interest in developing an emphasis on preventative measures rather than a reliance on the after-the-fact investigation of research improprieties. Research improprieties are violations of the regulations, which the VA has adopted, that govern the responsible conduct of research. These include the "Common Rule" (Title 38 CFR Part 16), various FDA regulations, and certain State regulations for the protection of human subjects enrolled in research. There are also a number of federal regulations that pertain to the welfare of animals, research safety, and the recently promulgated research misconduct policy.

The ongoing intent of ORCA is to continue to shift the philosophy of compliance from a reactive to a proactive mode, wherever possible. ORCA's reactive mode of retrospectively conducting inquiries into allegations of research improprieties will continue as post hoc "for cause" reviews, very similar to those of the Office of the Medical Inspector in its review of allegations of improprieties in clinical situations. Nonetheless, ORCA seeks to emphasize a prospective approach to oversight and surveillance that increasingly relies on prevention of regulatory non-compliance. This requires continuing education that logically will result in a reduced need for remedial education and training.

Product Lines

In accordance with ORCA's scope and derived from its philosophy of proactive operations, ORCA has four primary and four secondary product lines.

The four primary product lines are: 1) Administration of the Assurances Program, 2) Prospective Compliance, 3) Reactive Compliance, and 4) the Training, Education and Development (TED) activity.

The four secondary product lines are: 1) Management of the Adverse Event-Serious Adverse Event processes, 2) Promotion of the Research Compliance Officer (RCO) concept, 3) Liaison with the VA National Ethics Center, and 4) Liaison with the VA Office of Research and Development regarding management of the Human Research Protection Program (HRPP) accreditation contract with the National Committee for Quality Assurance (NCQA).

Primary Product Lines

In March 2000 ORCA assumed responsibility from the Office of Research and Development for the VA Multiple Project Assurance (MPA) contracts for the protection of human subjects. This contract, required by the "Common Rule" is a written document that a VA facility prepares so that it commits itself to fulfill all of the requirements of the federal regulations and VA operational policies and procedures in the protection of human subjects. Today, 111 VAMCs have these "Assurances". At about 40 sites, of

the 111, the VAMC, or HCS, rely on the academic affiliate's Institutional Review Board (IRB) to review research protocols to ensure compliance with the provisions of the "Common Rule" and other pertinent regulations.

Since early in 2001, ORCA has worked closely with OHRP to implement a new Federal-Wide Assurance (FWA) program, which is designed to simplify the assurance process. This collaboration with OHRP has worked well, and we have almost completed the conversion of the VA MPA contracts to this new FWA process. Further, ORCA, under this overall FWA schema, has developed and issued guidance for two sorts of Memoranda of Understanding (MOU). The first set of MOUs allows VAMCs with relatively small research programs to partner with VAMCs having much larger programs and a mature Human Research Protections Program (HRPP). This will enable these smaller programs to capitalize on some economies of scale. Additionally, ORCA has provided VAMCs with guidance and a template for a second MOU between a VAMC and its Academic affiliate, where the VAMC relies upon the affiliate's IRB. These MOUs are important for VAMCs to complete, as they are required by the standards for the accreditation of a HRPP sponsored by the NCQA.

ORCA created and then initiated the prospective compliance product line in September 2001. An ORCA working group, the members drawn from staff at VAMC research programs, has guided the preparation of a Multi Assessment Program or MAP. This MAP has two components: 1) a Self Assessment instrument, and 2) an On-Site review process. The MAP Self-Assessment instrument incorporates checklists for the full scope of ORCA's four areas of responsibility. This instrument includes an introduction to Self Assessment and provides a full list of websites that VAMCs can access to assist them in completing Self Assessments. ORCA has incorporated and distributed the checklist for the HRPP into compact disc (CDROM) containing a compendium of all of the regulations and guidance pertinent to the protection of human subjects. This compendium, also posted on the ORCA website, has cross-linked references to all of the regulations, checklists and accreditation standards for a HRPP mandated by the VA and other federal agencies, including OHRP and FDA. It contains more than 150 documents and they are completely cross-linked to the regulatory source: clicking the internet hyperlink promptly displays the section of the rule or guidance being cited.

During their site visits ORCA's regional office staff orient each VAMC to the MAP Self Assessment process, and provide a list of NCQA's accreditation standards for an HRPP that go beyond the minimum regulatory requirements. The VAMC is also provided written guidance on how to complete a MAP Self Assessment. Research staffs are encouraged to consult with the staff of the VAMC's Quality Assurance Office to assist in conducting a MAP Self Assessment. The ORCA regional office offers to return to do an On-Site MAP review when the VAMC has completed its MAP Self Assessment or before, if the VAMC invites ORCA to return. This MAP is a voluntary

program and increasingly VAMCs are recognizing its benefit. Wherever possible, the regional office provides training and education on any subject pertinent to ORCA's mission, requested by the VAMC.

The reactive compliance product line has always been a fundamental ORCA activity. Whenever a VAMC reports a potential or actual research impropriety or ORCA receives a notification from other sources, such as OHRP or the FDA, the ORCA regional office is responsible for follow-up and assistance with the resolution of the issue. The inquiry may be handled by telephone or exchange of correspondence; in some instances the regional office conducts a limited fact finding visit, an on-site Focus Review. If there are more serious systematic problems ORCA selects a Special Inquiry Force Team (SIFT) for an on-site review that lasts for several days. The process follows the general methods involved in performing a root cause analysis. The SIFT team conducts its work according to a written charter and files its report and recommendations with ORCA central office. The Under Secretary for Health signs and issues the final report and ORCA monitors Action Plans until all of the recommendations have been fully implemented. ORCA then closes the SIFT review with a written notification to conclude the process and after all of the recommendations have been satisfactorily implemented.

ORCA has conducted ten (10) SIFT reviews, two of which are in active status. Among the eight (8) that have now been closed out, one VAMC was in serious regulatory non-compliance, and ORCA placed restrictions on its "Assurance", that took almost a year to resolve. ORCA confers with OHRP when issuing a restriction on a VAMC's "Assurance". The problems ORCA has identified in the SIFT reviews are comparable to, if not identical to, the problems that have been identified by OHRP.

The fourth primary product line is the training, education and development (TED) activity. ORCA has an ongoing working group for this TED activity and the Under Secretary for Health has annually approved the strategic plan for these TED activities. The TED working group has provided guidance in several basic and developmental activities. ORCA has a web site [www.va.gov/ORCA] that continues to grow in importance as a vehicle for identifying important education and training resources. Copies of all of ORCA's fifty or so Information Letters, the ten ALERTS on critical issues, and the minutes of ORCA's Bimonthly Teleconferences are all posted on the website. The website is regularly updated. Also appearing on the website is a Best Practices guidance document n how a VAMC can prepare a standard operating procedures manual for its IRB. ORCA originally issued this as a CD, and we have had many requests for copies from interested parties beyond the VA. The TED working group has also identified sources for training and education of investigators in human subjects protection as required by VA's Office of Research and Development and National Institutes of Heath (NIH). Through collaborative arrangements with several academic institutions that are involved in a project known as CITI (Collaborative IRB

Training Initiative), we were able to assist in the preparation of a specific module on research protections in the Department of Veterans Affairs. This CITI program is an optional training vehicle for investigators to be certified in human subjects protection. In addition, all VAMC Directors must complete three training modules on their responsibilities under the FWA that they all sign. Recently, ORCA has, in conjunction with OHRP, begun to distribute CDs to VAMCs and training manuals prepared by the main professional association, Public Responsibility in Medicine and Research (PRIM&R). These are intended for use by investigators and other research staff to help them understand the ethical foundations of the regulatory requirements for the responsible and ethical conduct of research involving human subjects.

ORCA has also presented a VA DAY at the Annual PRIM&R meeting for the past two years and will continue to support these annual forums. In partnership with OHRP and the FDA, ORCA is sponsoring joint conferences and seminars on the protection of human subjects, which occur about six times a year. ORCA's regional offices take the lead for the VA on the seminar's planning committees. Further, over the past year, ORCA has worked with the VISN leadership to conduct one-day intensive seminars on the various requirements for the responsible conduct of research. The faculty for these seminars, which are targeted for VA's senior executives routinely include representatives from OHRP and FDA. These seminars have broad representation from the leadership of the VISNs and their VAMCs. These seminars, almost complete now, have been well received and the materials distributed are current.

While TED activities assist VA personnel in understanding the responsible conduct of research within the research enterprise, ORCA has not forgotten the veteran who is or might participate in VA research. ORCA has developed a brochure, "I'm a veteran. Should I participate in research?" which was recently unveiled April 10 by the Under Secretary for Health at the bi-monthly meeting of the Veterans' Services Organizations (VSOs). This brochure will help veterans understand their rights as research volunteers and help them decide if they want to participate in a research protocol. ORCA will widely distribute the brochures this month throughout the VA and to the VSOs. The brochure indicates where veterans can make local contact with those knowledgeable about VA research at a VAMC and what it means to volunteer.

Secondary Product Lines

As regards to the four secondary product lines some particular comments are needed to clarify ORCA's role. Management of the Adverse Event/Serious Adverse Event processes was assigned to ORCA in March 2000. Dr. David Weber, Deputy Chief Officer, ORCA, has taken the lead for administering this process and is continuing to bring some 'common sense' to this difficult and complex issue. He processes all serious and unexpected adverse events reported to ORCA, in accordance with regulations and the additional guidance ORCA has provided in its Information Letters. For the past several months he has participated in a working group, under the aegis of

OHRP with representation from several other departments and agencies. He chairs an ORCA working group that is charged with simplifying the adverse events reporting issues for research. Further, guidance will soon be provided, which will harmonize with the directions taken by OHRP and, in particular, FDA.

ORCA has been promoting the concept of dedicated quality assurance staff for research activities. About five years ago, VISN # 7 established a Research Assurance and Compliance Officer (RACO) for its research product line, and since then other VISNs have established RACOs, and, some VAMCs have established Research Compliance Officers (RCOs). These individuals play a role in quality assurance and quality improvement management, monitoring compliance with regulations for the responsible conduct of research. These individuals have performed a number of functions such as "audits" of research protocols, routine monitoring of the IRB activities and the conduct of education and training activities. ORCA's Field Advisory Committee recently established a subcommittee to document the level of activity within VAMCs and the VISNs and ascertain what ORCA can do to assist in the further development of these RACO and RCO positions.

ORCA, early on in its existence, established a close liaison with the VA National Ethics Center for the purposes of collaborating on matters concerning the ethical conduct of research. A member of ORCA's central office staff serves on the VA's Ethics Advisory Committee, administered by this Center. It has been addressing a number of important issues related to research, especially in regard to clarification of some important definitions of what should be included under the umbrella of human subjects research.

ORCA has a direct liaison with the HRPP accreditation program sponsored by National Committee for Quality Assurance (NCQA) and under contract with the VA, through the Office of Research and Development. Until just recently, ORCA has acted in a general advisory capacity, offering its ideas and suggestions. Now that the contractor for this accreditation program, the NCQA, has begun to notify VAMCs it has surveyed of their accreditation statuses, the level of activity for ORCA has significantly increased. NCQA has made determinations of accreditation status at eleven (11) of the 23 sites it has surveyed and has issued notices of "Not Accredited" at three (3) VAMCs and "Accredited with Conditions" at the other eight VAMCs.

These accreditation determinations have been of great concern. ORCA makes immediate contact with the VAMCs that are "Not Accredited" to make a preliminary assessment of the situation. Within 48 hours a Focus Review team, of one or two ORCA staff, is on-site to make a better assessment as to whether human subjects enrolled in the research protocols are adequately protected and determine, as far as possible, whether there has been any medical harm. Also, an evaluation is made as to whether there is any serious or egregious non-compliance with the regulations that are designed to protect human subjects at the VAMC. If so, ORCA may immediately

suspend or restrict the VAMC's "Assurance". So far, the three completed Focus Review reports are reassuring, but they are insufficient to make a complete determination of the extent and magnitude of possible regulatory non-compliance.

Each of these VAMCs that received notification of "Not Accredited" were surveyed several months ago by NCQA, and all of them have sent NCQA letters of intent to appeal, within 30 day limit. Filing an appeal with NCQA "freezes" the notification until the NCQA's Appeals Panel considers additional information provided by the VAMC and renders a final decision. ORCA needs in depth and current information about the HRPP activities and has created a Systematic Post-Accreditation Review (SP-AR) to address the situations at VAMCs when NCQA gives a "Not Accredited" designation. ORCA conducts a SP-AR review at the VAMC, the week after the VAMC files its appeal documents with NCQA. The charter for a SP-AR defines the purpose for these on-site reviews performed by a team of several ORCA staff and peer research administrators. The SP-AR is expected to assess the full scope and significance of the issues that relate to the performance of the VAMC's HRPP. The SP-AR report, including recommendations, is available two weeks after the team completes its on-site review. The first SP-AR report is due the end of this week.

During the course of the on-site review, serious and egregious non-compliance with the regulations that protect human research subjects may become apparent. If so, ORCA may issue a suspension or restriction on the VAMC's "Assurance". While no SP-AR reports have been completed, ORCA has issued a restriction on the "Assurance" at one VAMC that was "Not Accredited" for serious, but not egregious, non-compliance with several provisions of the "Common Rule". When the SP-AR report is completed ORCA decides on the next steps and elicits an Action Plan from the VAMC that has to substantially address the recommendations. Other notifications will need to be made, as appropriate, to other regulatory agencies such as OHRP and FDA. Eventually, when the Recommendations have all been fully implemented to ORCA's satisfaction, the Office of Research and Development will be notified. This will signal that consideration might be given to a new review of the VAMC's HRPP through the NCQA accreditation program.

Conclusion.

In summary, in the three years since the Under Secretary for Health announced the establishment of this office, ORCA has exerted considerable time, thought and energy to defining its scope, creating its structure, articulating its philosophy, and delineating its product lines. The 'die has been cast' to firmly establish ORCA as the primary office within the VA for oversight of the VA research enterprise in regard to the responsible conduct of research. This role and responsibility has to be fulfilled in collaboration with the other VA offices, the relevant other federal departments and agencies, and non-governmental organizations. Over the next few years the foundation

robust research enterprise where the rights of human subjects will be continuously protected.

Again, I appreciate the invitation to discuss these important issues with you, and I will be pleased to try and answer any questions you might have.

Statement
of
Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
on
Non-profit Research Corporations
and Educational Foundations
and the Department of Veterans Affairs
Human Studies Protection Program
before the
Subcommittee on Health and
the Subcommittee on Oversight and Investigations
of the
Committee on Veterans' Affairs
U.S. House of Representatives

May 16, 2002

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Mr. Chairmen and Members of the Subcommittees:

Thank you for the opportunity to appear before you to discuss non-profit research corporations and educational foundations and the Department of Veterans Affairs (VA) Human Studies Protection Program.

1. Non-profit Research Corporations and Educational Foundations

Establishment

In 1988, Congress authorized VA to establish non-profit research corporations at the medical center level "to provide a flexible funding mechanism for the conduct of approved research" (Title 38, Section 7361). Prior to this measure, VA medical centers had been limited to using the General Post Fund to accept and expend non-appropriated research funds. This new mechanism has helped VA research by increasing flexibility with respect to staffing and handling donated funds and grants. The Veterans Millennium Health Care and Benefits Act of 1999 expanded VA's authority by permitting the establishment of non-profit corporations to accept funds to facilitate research or education (or both). Education includes those activities supporting work-related instruction and training for VA-employed staff, as well as broad instructional and learning experiences directed toward improving and maintaining the health of the veteran patient. The Secretary of Veterans Affairs has delegated to medical center Directors the authority to establish corporations.

As of June 1, 2001, 88 research and/or education corporations had been chartered. Of these, 85 remain active. Recently, two facilities established education corporations that are separate from the research corporations already serving these facilities. The current practice of one research corporation per facility provides the optimum on-site service to investigators, immediate oversight by VA line officials, and helps comply with state and local requirements.

Recent Contributions

In 2000, non-profit corporations received $173.7 million in donations, grants, and interest for both research and education activities. This represents a 17% increase over the previous year and demonstrates that VA clinicians and basic scientists continue to be highly successful in competing for private and public sector research and education funding. Less than 1% of 2000 revenues were received in direct support of education.

Funding generated from private sector sources in 2000 totaled $64.5 million and constituted the single largest source of donations. However, the number of corporations administering NIH grants has increased steadily since 1996, and NIH funding now represents the second largest source of all donations.

Non-profit corporations continued to manage funds very efficiently as evidenced by a low administrative overhead rate averaging 10 percent in contrast to the sector-wide average of 25 percent. As a result, 90 percent of all funds that corporations receive are available for the direct support of VA approved research and education.

In 2000, non-profit corporations supported 4,651 VA-approved projects, an eight percent increase over last year. Most of the projects are medical research clinical trials that focus on conditions prevalent in the veteran population and provide a direct benefit to VA patients. Non-profit corporations also provide salary support for clinical research personnel to monitor even more closely veteran patients enrolled in clinical trials.

Non-profit corporations benefit our veterans by generating funds that permit the acquisition of research equipment and supplies; space renovations; travel to scientific conferences; and salaries for research personnel including technicians, nurses, research coordinators, animal care takers, data clerks and investigators.

Specific examples of corporation support of VA medical centers include:

a. Indianapolis VAMC: Received $52,000 to purchase a confocal microscope and set aside $87,000 to purchase equipment for a newly renovated wet laboratory that will include a new biosafety level 3 lab.
b. Little Rock VAMC: VA investigators received funding for pilot studies, equipment purchases and bridge grants. Received three sets of animal cages at a cost of $75,000 and salary funding salary for a full-time Research Compliance Officer and a half-time Safety Officer for a total cost of $81,000.

Staffing

By statute, the Board of Directors is responsible for the management and operation of the corporation. The board must consist of at least five members, including the statutory Directors, who are: the medical center Director, the Chief of Staff (COS), and the Associate Chief of Staff for Research (ACOS/R&D). The Associate Chief of Staff for Education (ACOS/E) is included for research and education corporations. At least two board members must be persons who are not officers or employees of the Federal Government, and who are familiar with issues involving research or education and training as appropriate for the activities of the corporation.

The medical center Director is authorized to approve all appointments and all changes to the membership of the corporation's Board of Directors serving that VA medical center. The Board of Directors of each corporation has authority to act for the corporation as provided in its articles of incorporation and bylaws. This includes the authority to appoint, subject to the concurrence of the medical center Director, an Executive Director for the general operation of the corporation and to establish the specific duties and responsibilities of the Executive Director.

The corporation may employ individuals to work on VA-approved research projects or education and training activities. Corporation employees assigned to VA to provide research, education, or training services are subject to VA's supervision, direction, and control. All corporation employees, including VA employees who work for the corporation during their non-VA duty hours, who are assigned to VA to work on research projects or education and training activities, must have a Without Compensation (WOC) appointment regardless of whether they receive a corporate salary. All corporation board members, officers, and employees are subject to Federal statutes and regulations applicable to Federal employees with respect to conduct and conflicts of interest. VA employees who, as part of their official responsibilities have any role or function, whether statutory or otherwise, in the affairs or operations of corporations, are required to ensure that the corporations further the best interests of VA.

Management

Ensuring the corporation's assets are used for research is the primary goal in the management of corporate funds. An appropriate official of the corporation must approve all expenditures. That official may be the Executive Director or another person designated by the corporation's Board of Directors. When transferring funds to VA, the corporation must document the transaction. The documentation may consist of the following: a bill for collection, an Intergovernmental Personnel Act (IPA) mobility assignment, or an approved Memorandum of Understanding (MOU), as well as other records.

The corporation must make and preserve records of the organization, including its functions, policies, decisions, procedures, and transactions in accordance with commonly accepted non-profit practices and commonly accepted accounting practices. These records must be: designed to furnish information needed to protect the legal and financial rights of the Federal Government and of persons directly affected by the corporation's activities; and maintained for the benefit of the corporation. All pertinent tax records for purposes of IRS review shall be retained for 6 years. All other non-tax records shall be retained according to Federal and state laws. The creation and maintenance of such records must be consistent with sound accounting principles

The corporations are engaged in business activities that generate tax-exempt revenues. They may not, consistent with their IRS tax-exempt status, engage in

activities that would generate unrelated business income. Fundraising expenditures by the corporations are far below the national norms for nonprofits.

Oversight and Accountability

Corporations, in connection with any audit, inquiry, investigation, or review of corporation activities, must cooperate with and make their records available to the VA Inspector General, the Comptroller General, the IRS, the Secretary of Veterans Affairs, and the State where the corporation is doing business. All corporations must submit a report each year to the Secretary of Veterans Affairs. Corporations with annual revenues between $10,000 and $300,000 must obtain an audit of the corporation at least every three years. Corporations with annual revenues over $300,000 must obtain audits each year. The Executive Director of the corporation is responsible for providing a copy of the auditor's report to the Chief Fiscal Officer or equivalent at the VA medical center which the corporation serves.

By June 1 of each year, corporations must submit an annual report to either the Office of Research and Development (ORD) or the Office of Academic Affiliations in VA Central Office, or to both, as appropriate, detailing corporation funding and expenditures. Expenditures are reviewed for appropriateness by the corporation's Executive Director, board of directors, accountant, and auditor prior to incorporation in financial statements and the IRS Form 990, which is included in the annual report to VA. The annual report is required even if the corporation did not accept or expend funds during the previous year.

Conclusion

Non-profit corporations are dedicated to fulfilling their congressional mandate in a responsible and conscientious manner, serving as a flexible funding mechanism for the conduct of VA-approved research and education. Revenues and expenditures in support of VA research and education programs are increasing, and the expertise of management is improving steadily as evidenced by corporation audit reports.

2. Protections for Human Participants in Research

VHA's Research and Development program is focused upon the high priority health care needs of veterans. A special advantage of the VA research program is that it is nested within a health care system that serves more than six million enrolled veterans, creating a unique opportunity to discover and apply new medical knowledge. Most VA investigators are also clinicians who have responsibility for providing care for our patients and for training future health care providers for the nation. Unlike NIH, VA does not make research grants to colleges and universities, cities or states, or any other non-VA entity. Many advances in health care that benefit veterans and the nation have emerged from VA research – from the first treatments for tuberculosis and some of the first successful organ transplants, to the discovery of a gene for schizophrenia and improved treatments for Post-Traumatic Stress Disorder.

Given the importance of clinical research in VA, it is essential that our research program be committed to protecting the safety of patients and research subjects. VA is one of the 17 federal agencies that are signatories to the Common Rule for the Protection of Human Subjects of Research (38 CFR 16) and also has a separate regulation (38 CFR 17.85) that guarantees needed medical care for any patient injured in a VA research project. All VA scientists are required to abide by stringent ethical principles and rigorous regulatory requirements to ensure the protection of people who participate in their research projects.

The protections offered to human subjects apply to all VA research regardless of sponsor or funding source. Much of the research conducted in VA facilities is also subject to the regulations of other federal agencies. For example, human studies funded by pharmaceutical companies and conducted at VA facilities in support of a new drug or device application are subject to FDA as well as VA regulations and oversight. Similarly, studies funded by NIH and conducted in VA facilities are subject to Department of Health and Human Services as well as VA regulations and oversight. Thus, the framework for a strong human subjects protection program has long been in place in VA.

During the past three years, VHA has taken a number of proactive steps to further enhance and strengthen protections for human subjects of research. In September 2000, the former Under Secretary for Health announced the establishment of the Office of Research Compliance and Assurance (ORCA). This office reports directly to the Under Secretary for Health and, under the direction of its Chief Officer, serves as primary advisor to the Under Secretary for Health on all matters affecting the integrity of VHA research as it relates to compliance and assurance. In addition to its oversight role, ORCA advocates and promotes the application of continuous quality improvement to enhance the ongoing protection of human subjects enrolled in research.

ORCA has launched the Training, Education, and Development (TED) Initiative, a program designed to develop and disseminate information on a wide spectrum of training and education activities, including those offered by public and private agencies, for investigators and research administrators. ORCA is currently developing a strategic plan for education and training for all VHA personnel involved in the protection of human subjects in research.

The Office of Research and Development (ORD) implemented a requirement that all VA investigators must provide documentation that they have participated in educational programs on human subjects protections before their research projects can be approved.

In the wake of VA's suspension of the research program at the Greater Los Angeles Health Care System and the closure of several research programs by other Federal oversight agencies, Dr. Kenneth Kizer, VA's former Under Secretary for Health,

announced in his April 21, 1999, testimony before Congress that VA would become the driving force to establish both an accreditation entity and an accreditation process that will provide the public and our veterans the assurance that VA research programs meet or exceed established quality standards. The purpose of the accreditation program is to provide an independent, external validation that these research programs are functioning properly and effectively and to provide the necessary regulatory and ethical protections for research subjects. A notice was published requesting proposals for the establishment of such an accreditation program shortly after Dr. Kizer's announcement.

In April 2000, VA awarded a five-year contract for $5.8 million dollars to the National Committee for Quality Assurance (NCQA), a private, non-profit accrediting organization dedicated to improving health care quality. NCQA has developed accreditation standards and will survey and determine the accreditation status of all VA facilities conducting human subjects research every three years. Accreditation site surveys began in September 2001.

In April 2001, the Institute of Medicine cited the standards NCQA developed for VA as the strongest basis for accreditation "because they pay specific attention to quality improvement, provide flexibility in achieving performance goals and are explicit in their grounding in current regulations." NCQA's accreditation standards cover six domains: Institutional Responsibilities, Institutional Review Board (IRB) Structure and Operations, Consideration of Risks and Benefits, Recruitment and Subject Selection, Privacy and Confidentiality and Informed Consent.

Since September 2001, 23 VA facilities have undergone NCQA accreditation surveys. As of May 8, 2002, eleven (11) final reports have been issued, with eight facilities being "Accredited with Conditions" and three facilities receiving a preliminary result of "Not Accredited." The latter facilities are currently appealing the preliminary result before NCQA makes a final determination of their accreditation status. An additional 32 sites have been tentatively scheduled for accreditation surveys (with 14 confirmed to date) during fiscal year 2002.

The most common deficiencies involve three main areas:

- the lack of local facility policy and procedures related to IRB structure and operations,
- the lack of policy and procedures related to the Informed Consent process and the content of the informed consent document, and
- the evaluations and determinations the IRB must make and document during the initial review of research projects.

VA Central Office officials are currently assessing the situation to determine if any subjects have been placed at risk, and to implement any necessary safeguards. Once the final accreditation status is determined by NCQA, VACO and the facility will take appropriate corrective actions to ensure the protection of all subjects entered into research programs and compliance with all applicable regulations.

ORD has developed through the Cooperative Studies Program a Site Monitoring and Review Team (SMART). SMART consists of a Good Clinical Practice (GCP) Monitoring Group and a GCP Review Group established in 1998. The mission of SMART is to augment quality improvement activities in research. Reviews are performed at the study site and consist of reviewing the regulatory documents, the files of randomly selected patients and the informed consent process for all patients. The SMART program promotes GCP through four major service elements: (1) education, training, and certification for investigators and study coordinators, (2) site reviews to assess adherence to GCP and reinforce training, (3) GCP tools and guides for organizing files and activities, and (4) evaluation of consent forms.

We found that with these GCP review visits and our educational efforts, adherence to GCP improved significantly. The specific areas that improved were institutional review board interactions, regulatory document management, patient records in investigator file, drug/device accountability, and general site operations. Based on the success of this program, ORD is establishing Accreditation Consulting Teams (ACT). ACT will use VA employees and consultants to help VA field facilities prepare for NCQA accreditation. Team members will be familiar with research, with VA and other federal regulations and policies for the protection of human participants in research, and with NCQA standards and survey procedures.

The Department of Veterans Affairs strives to lead the nation in assuring that its investigators follow the highest standards for assuring respect of the rights, dignity, and safety of research participants. We believe the approach VA is taking, with its continued emphasis on training and education, independent oversight and mandatory external accreditation will result in a system-wide human subjects protections program that will place VA at the forefront of ethical science.

Mr. Chairman, this concludes my statement concerning VA's non-profit corporations and the human studies protection program. My colleagues and I will now be happy to answer any questions that you and other members of the Subcommittees might have.

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Testimony

before the

Subcommittee on Oversight and Investigations

and the

Subcommittee on Health

of the

Committee on Veterans Affairs

Hearing on

The VA-Affiliated Nonprofit Research and

Education Corporations

May 16, 2002

Presented by

Antonio Laracuente

Chairman

National Association of Veterans'

Research and Education Foundations (NAVREF)

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

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

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

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

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

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

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

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

Everyone associated with the nonprofits is acutely sensitive to the possibility that poor management of one corporation has the potential to reflect badly on all the nonprofits. This is the main reason that 14 corporations established NAVREF in 1992. NAVREF is a 501(c)(3) education organization whose primary purpose is to provide a forum for guidance on managing a VA nonprofit. As chairman, I am particularly proud of the spirit of cooperation and sharing that is characteristic of everyone involved in NAVREF.

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

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

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

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

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

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

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

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

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

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

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

Atlanta – Atlanta Research and Education Foundation (AREF)

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

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

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

1. The corporations assist VA in recruiting clinician investigators who in turn provide high quality care for veterans. They support recruitment travel costs and often pay to upgrade a laboratory to suit a new investigator's particular needs.
2. Efficient services provided by the corporations increase principal investigator satisfaction and productivity and help VA retention rates. Prompt personnel hiring, quick turnaround on travel reimbursements, and efficient procurement are just a few of the benefits.
3. Veterans have access to the latest drugs and the extra care that goes along with participation in clinical research, saving VA millions of dollars in pharmaceutical costs and improving patient outcomes.
4. The corporations help make up for inadequate VA travel funding by supporting the costs of attending scientific meetings.

The corporations are gradually implementing the 1999 authority to support VA's education mission. Two facilities have established corporations specifically to administer educational activities, but more commonly, the research corporations are evolving into research **and** education corporations. This is a

gradual process because we have to develop new policies and procedures and inform VA education personnel of the advantages — and limitations — of partnering with the corporations. In a few years, we anticipate that the corporations will be providing VA with access to educational opportunities for staff and patients that currently are not possible due to the lack of VA funding for education. Examples of recent corporation education activities:

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

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

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

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

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

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

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

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

The VA Office of General Counsel (OGC) has long maintained that NPC employees who have VA without compensation (WOC) appointments and work on VA-approved research projects under the supervision of VA employees are afforded protection against medical malpractice liability under the Federal Tort Claims Act and 38 U.S.C. §7316, subject to certification by the Attorney General that the

employee's work is within the scope of government work. However, in an opinion issued in 2000, the Department of Justice (DOJ) cast an unacceptable degree of doubt on the OGC position by stating that NPC employees are not federal employees for purposes of the FTCA.

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

In my testimony, I have described some of the donated goods and services the corporations provide to their VAMCs. At the same time, when it is cost-effective and efficient, VAMC research and education programs would benefit from agreements that would allow the corporations to provide additional services over and above what they can afford to donate. However, to date, OGC has considered a VA payment for a service provided by a corporation to be a prohibited transfer of VA-appropriated funds. As a result of this interpretation of §7361(a), the NPCs' ability to facilitate VA research and education has been curtailed.

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

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

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

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

Attachment 1

Selected Additional Examples of Research Corporation Contributions to VA Facilities

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

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

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

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

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

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

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

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

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

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

Buffalo Institute for Medical Research (BIMR):

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

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

Salem Research Institute:

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

Midwest Biomedical Research Foundation:

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

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

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

Statement for the Record
of the
Subcommittee on Oversight and Investigations
and the
Subcommittee on Health
of the
Committee on Veterans Affairs
Hearing on
The VA-Affiliated Nonprofit Research and
Education Corporations

May 16, 2002

Submitted by Franklin J. Zieve, M.D., Ph.D.

- **Background and Biography: Franklin J. Zieve, M.D.,Ph.D.**

For 25 years I have been ACOS for Research at McGuire VA Medical Center in Richmond. More importantly, I am Director of the Diabetes Health Center at McGuire, which recently was designated as one of two VA Centers of Excellence in Diabetes. I served as Acting Associate Chief Medical Director for Research in VA Central Office for 5 months in 1991 and have served on VA committees developing clinical guidelines for management of diabetes and lipid disorders. I have also twice been an inpatient at McGuire VA Medical Center, and I have been and am now a subject in clinical research studies. My VA connection goes back much further; when I was growing up I lived on the grounds of the Minneapolis VA Hospital. I now have over 30 years of federal service and am 58 years old, so economically it would make sense for me to retire today. I have no intention of doing so because I don't think I could find another position this rewarding. Today, however, I am on annual leave and testifying as a private citizen and as Chairman of the Board of McGuire Research Institute. I should stress that my testimony is not endorsed by either VHA or the National Association of Veterans' Research and Education Foundations.

My testimony focuses on the history of the IRB and Human Research Protection Program at Richmond VAMC. Our IRB was set up on an emergency basis because it had become clear that a research shutdown at our university affiliate was imminent. Because our program has been fully funded by our nonprofit, McGuire Research Institute ("MRI"), I start with a brief description of MRI.

- **History of McGuire Research Institute**

McGuire Research Institute ("MRI") was established in November, 1989, to administer external research funds at McGuire VA Medical Center. 98% of the research administered by MRI is human research, and about 80% is FDA-regulated studies of new drugs and devices. For Calendar Year 2001, MRI had revenues of $4.2 million and expenditures of $4.0 million. In contrast, VA Appropriated research funds in Richmond were $2.2 million. Of MRI's $4.0 million in expenditures, 47% was for salaries, 20% for vendor services, 15% for supplies, 7% for travel and 3% for payment to research subjects. Thus, MRI is not a small add-on, but rather represents 2/3 of all research funding at McGuire VAMC. MRI has 82 employees, while the VA Research appropriation has 41 employees.

From the beginning the fiscal management of MRI has been very conservative; we have held administrative expenses to a bare-bones minimum, accumulating funds for a rainy day. Thus, we had resources available in 1999, when we suddenly had to make a large investment in our Human Research Protection Program.

Over 95% of the funds which flowed into MRI in its first years replaced funds kept at the affiliated medical school, Virginia Commonwealth University ("VCU"). When this movement of funds to MRI started, we found some research studies which had been going on at McGuire without any VA knowledge. The money was at VCU; the drugs were dispensed from the VCU pharmacy, brought to the VA in paper bags and administered to our patients without any record in their VA charts. In addition to being contrary to regulation, this was dangerous; when a veteran comes to the Emergency Room, it is important for the doctor to know all the medications he is taking, including study drugs.

- **Richmond's IRB and Human Research Protection Program**

Until August, 1999, McGuire VAMC used the IRB at the affiliated Virginia Commonwealth University ("VCU"). We were dissatisfied with the VCU IRB, but we underestimated the depth and importance of its deficiencies. After the research shutdowns at West Los Angeles and Duke, we immersed ourselves in the Human Subjects Protection regulations and policy guidance and concluded that the VCU IRB was so grossly deficient that we would have to split from them and establish our own

independent IRB. When VCU received an FDA Warning Letter in August, 1999, it was apparent that a shutdown was imminent, and drastic action was indicated. The McGuire IRB held its first meeting on September 7, 1999, and has met weekly ever since. By the time VCU's human research studies were shut down by FDA and OPRR, we were sufficiently established and had enough of our protocols reviewed to avoid the shutdown.

Since the summer of 1999, we have continued to devote major MRI resources to our Human Research Protection Program ("HRPP"), which we feel is the most important current use for our funds. While our program is far from perfect, it has been successful enough to receive some recognition by others:

- A full FDA audit Oct 30 – Nov 3, 2000, found us in compliance.
- ORCA chose us to serve as the designated temporary IRB for a VAMC whose Assurance had been restricted.
- We received a Special Contribution Award from the Undersecretary for Health for our IRB-related activities.
- We have twice been invited to present at VA Day at PRIM&R.
- We were Accredited with Conditions by NCQA after being surveyed Oct. 9-10, 2001; we hope to be the first VAMC to receive Full Accreditation.
- The MIRB database, whose development we funded, has been installed at 19 VA Medical Centers.

Our IRB and HRPP are fully funded by MRI. In the first year of its existence, HRPP expenditures were $474,000, as shown in the table below.

McGUIRE HRPP: SOURCES AND USES OF FUNDS
9/1/99 through 8/31/00

SOURCES OF FUNDS	
IRB Fees From Sponsors	$17,700.00
TOTAL INCOME	**$17,700.00**
USES OF FUNDS	
Bonuses (for passing ACRP exam)	$9,000.00
Business Meals	$872.42
Conferences (food for IRB meetings and training sessions)	$3,702.97
Equipment Purchased	$47,669.85
Office Supplies & Furniture	$25,457.62
Payroll: IRB Members	$106,360.33
Payroll: IRB Staff	$180,272.49
Postage and Shipping	$134.31
Printing and Publications (including copier page charges)	$12,118.97
Registration Fees (ACRP training course; IRB member training)	$22,507.00
Telephone	$1,287.56
Travel	$11,995.63
Vendor Services (database development; courier service)	$52,389.10
TOTAL EXPENDITURES	**$474,288.25**

Recurring expenses have remained significant; in Calendar Year 2001 total HRPP expenses were $571,000 ($391,000 for the IRB, $147,000 for the Investigational Pharmacy, $33,000 for training). Total IRB fees collected were $170,000, so the ongoing MRI investment in the program is about $400,000 per year.

The ATTACHMENT shows the organizational chart of our HRPP and an excerpt from our HRPP Plan, summarizing the roles of the four key entities. Some noteworthy aspects of our HRPP are the training program, the Investigational Pharmacy, the

monthly coordinator meeting, the payment of IRB members, the database, and Research Day. I would like briefly to discuss a few of these to demonstrate the scope of investment we have found necessary.

Training and Education – We have invested heavily in Human Research training and education. The focus on human subjects protection has hugely intensified in the past 3 years; the bar has – appropriately – been raised. Hence, an intensive training program was indicated. MRI has funded the following efforts:

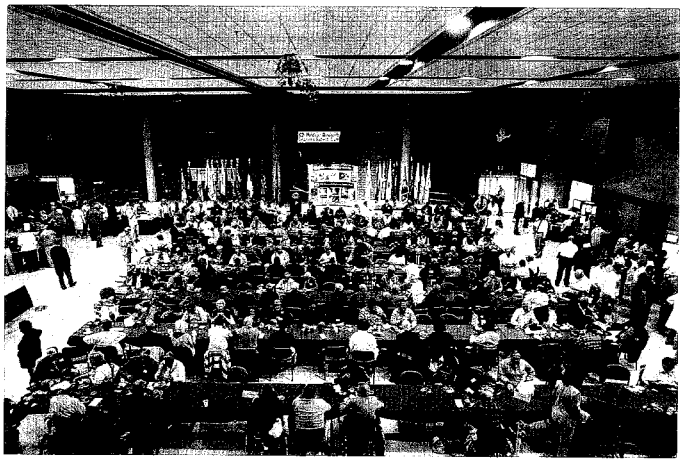
- We have sent all our IRB members to nationally recognized training sessions (PRIM&R's "IRB 101" or equivalent).
- We have sent specific IRB members to meetings on Vulnerable Populations, Financial Conflict of Interest, and Genetic Studies.
- We send multiple IRB members to each year's PRIM&R meeting.
- We contracted with the Association of Clinical Research Professionals to put on a special one day course for our research coordinators. Subsequently we paid for all coordinators to take the ACRP certifying exam and offered a $500 bonus to everyone who became certified as a Clinical Research Coordinator ("CCRC"). At present there are 20 CCRC's at McGuire.
- We sponsor a monthly coordinators' meeting entirely devoted to human research issues.
- We provide all our investigators with the book, Protecting Study Volunteers in Research; before they can submit a protocol to the IRB they must score at least 85% on the book's test. All investigators also receive copies of the monthly Human Research Reports.

This may seem excessive, but we feel it is critically important that everybody at all levels be fully attuned to the nuances of human subjects protection. Certification for investigators does not yet exist, but it will shortly, and when it does MRI will require it of all our investigators. I will be surprised if within 3 years certification is not required for all human research investigators and study coordinators in this country.

Investigational Pharmacy – Another entity fully funded by MRI is our Investigational Pharmacy. Rather than reimbursing the VAMC pharmacy for filling research prescriptions, we have set up an independent VA Investigational Pharmacy which reports directly to the ACOS for Research. Since 80% of our studies involve investigational drugs, this provides critical and important controls. The investigational pharmacist will not fill a prescription unless (a) she has all the relevant drug and protocol information; (b) she has in hand a signed consent form; (c) the Electronic Patient Record contains a Clinical Warning describing the study and the study drug. This level of monitoring is difficult to achieve in a busy hospital pharmacy in which study drugs are less than 1% of all prescriptions; it is much easier with a dedicated investigational pharmacist whose sole duty is to maintain proper controls on investigational drugs. Having an independent VA Investigational Pharmacy is more expensive than reimbursing the VAMC pharmacy, but we feel the extra expense is well worth it.

Compensation of IRB Members -- IRB work is unique in its volume and intensity and in vesting critical responsibilities in a committee rather than an individual. Scientific and ethical review of about one thousand pages of material per week is significant work that cannot reliably be completed during an employee's normal tour of duty. To assure that IRB review is serious and thoughtful rather than merely pro forma, IRB members are compensated by MRI, and IRB meetings are held outside their VA tours of duty. The IRB meets every Tuesday night, and meetings average three hours in length.

Research Day



Research Day – April 12, 2002

For the past 6 years, MRI has sponsored a Research Day Luncheon for veteran volunteers in research studies at McGuire VAMC. The picture was taken at this year's Research Day, which was attended by over 500 veterans. We believe this is the largest number of veteran research volunteers ever assembled in one place at one time. Research Day has been attended by visitors from Office of Research and Development, Office of Research Compliance and Assurance, and the General Accounting Office. The letter inviting veterans to Research Day solicits any complaints or concerns they may have about research or their participation. This represents real human subjects feedback – if you feel good about your research, you should be ready to spend some time listening to your volunteers.

In all the publicity about VA research, the veteran volunteer gets far too little credit. MRI regards its annual investment in this special Research Day as money well spent.

- **Conclusions from the Richmond Experience**

-- The fundamental concept underlying the Richmond HRPP has been that human subjects protection is more important than any other use of corporate funds. Having an uncompromising program requires major investments of time, effort and money. For this to work, the program must utilize a significant fraction of the effort of some of the best people in the hospital.

-- Without the resources of MRI, the Richmond HRPP would not exist in its present form. Only the availability of MRI funding saved us from being shut down along with VCU.

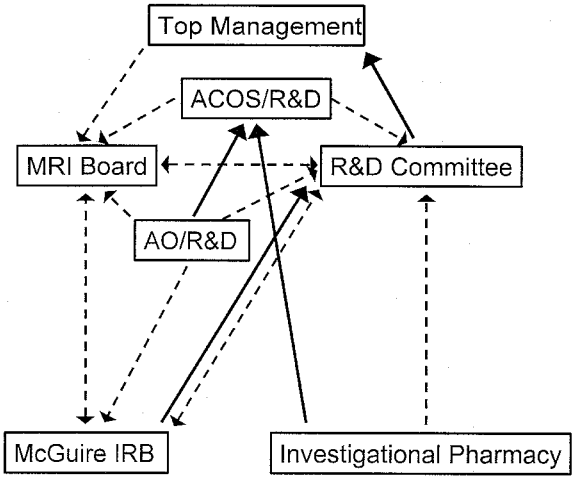
-- The complexity of human subjects-related regulations and paper flow makes an integrated IRB/HRPP database a prerequisite for success. Since no such program existed in early 2000, MRI contracted for and invested heavily in the development of the MIRB database, which has benefited 19 other VAMC's.

-- The NCQA accreditation standards are reasonable and achievable. The NCQA review process is new and presently imperfect, but by going through it, we have improved our HRPP and our IRB.

-- Having a minimal, pro forma program which fills out checklists, goes through motions and meets minimum requirements is neither difficult nor expensive. Having a substantive program which uncompromisingly protects veterans is very expensive.

-- The recent history of human research protection – everywhere, not just VA – has been one of failure to commit resources. Everybody wants a good program, but nobody is willing to pay for it – until they find themselves in the newspaper headlines (Duke, Johns Hopkins, Oklahoma, etc.). At that point these academic institutions have had to spend a fortune. This has not been enough to abolish completely the public perception that they are mistreating research subjects. It is very important that VA not go down this track.

ATTACHMENT
McGuire IRB/HRPP: Operating Relationships



V. Organizational Structure

The operating relationships of the HRPP are shown in the above chart. The key individuals are the Director, Chief of Staff, Associate Chief of Staff for Research ("ACOS/R&D"), Investigational Pharmacist, and the Chairpeople of the Research and Development Committee and the McGuire Institutional Review Board. The key entities are the Board of Directors of McGuire Research Institute, the Research and Development Committee, the McGuire Institutional Review Board, and the Investigational Pharmacy. The policymaking process occurs through deliberations of the McGuire Research Institute Board, the Research and Development Committee, and the McGuire Institutional Review Board. Interaction among these entities is facilitated by cross-membership among the three bodies.

A. McGuire Research Institute ("MRI") provides primary funding and administrative support for the HRPP. The governing body of MRI is the Board of Directors, of which the Director, Chief of Staff and ACOS/R&D are permanent members. The ACOS/R&D is the Chairman of the Board, and the Administrative Officer ("AO/R&D") is the Executive Director and Chief Operating Officer of MRI.

B. The Research and Development Committee ("R&D Committee") oversees all research activities at McGuire VAMC. The Committee selects IRB members with appropriate scientific and non-scientific skills and delegates full authority and responsibility to the IRB for scientific and ethical review for all human research projects.

C. The McGuire Institutional Review Board ("IRB") serves as the human subjects subcommittee of the R&D Committee. The IRB reviews and approves, requires modifications in (to secure approval), or disapproves all human research activities in order to assure that the rights and welfare of individuals involved as research subjects in research conducted under McGuire VAMC auspices are being protected in accordance with federal regulations.

D. The Investigational Pharmacy plays a central role in the HRPP. Research involving drugs comprises approximately 80% of the human research

protocols reviewed by the IRB and 80% of the human subjects enrolled in research studies and represents our greatest vulnerability. The Investigational Pharmacy is uniquely situated in a gatekeeper position to manage human research risk vulnerability by monitoring the informed consent process, identifying need for improvement, developing corrective action plans, implementing these plans, and monitoring their effectiveness. The Investigational Pharmacist reports directly to the ACOS/R&D. The Investigational Pharmacist is a permanent *ex officio* member of the R&D Committee, and detailed submissions from the Investigational Pharmacist are a prominent part of every Continuing Review of a study involving drugs. Except for a few specialized cases where this is not feasible, the custody and dispensing of drugs involved in protocols approved by the IRB and R&D Committee are via the Investigational Pharmacy.

STATEMENT OF
JAMES FISCHL, DIRECTOR
VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
TO A JOINT HEARING OF THE
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
AND THE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES
ON
VA-AFFILIATED NONPROFIT RESEARCH AND EDUCATION CORPORATIONS

MAY 16, 2002

Mr. Chairmen and Members of the Subcommittees:

The American Legion appreciates the opportunity to submit this statement for the record on the subject of the management and effectiveness of the relationship between Veterans Health Administration (VHA) facilities and their affiliated nonprofit research and educational foundations. The Department of Veterans Affairs (VA) is required to report to Congress on an annual basis the activities of these corporations.

BACKGROUND

The Veterans' Benefits and Services Act of 1988, PL 100-322 (now codified at 38 USC 7361-7368), authorized the establishment of a nonprofit corporation (NPC), at any VA medical center (VAMC), to provide a flexible funding mechanism for the conduct of approved research at the medical center. NPCs are to facilitate and support the VAMC's research program. Any funds received for research at the VAMC, other than VA's appropriated funds, may be transferred to a NPC. NPCs may accept gifts and grants from individuals, public or private entities. NPCs can also enter into contracts with individuals, public or private entities. NPCs are authorized to hire employees. A NPC may not spend funds for a research project unless the project is approved in accordance with procedures prescribed by the Chief Medical Director for research carried out with VA funds. Such procedures shall include a peer review process.

NPCs, established under this law, must comply with the nonprofit corporation laws of the State in which the VAMC is located and, to the extent not inconsistent with any Federal law, are subject to the laws of such State. For the purposes of pertinent sections of the Inspector General Act of 1978, the programs and operations of the corporation are considered to be VA programs and operations with respect to the responsibilities of the VA Inspector General. Further, a NPC is considered an agency for the purposes of section 716 of title 31 (relating to availability of information and inspection of records by the Comptroller General).

As of June 1, 2001, 88 VAMCs had received approval for the formation of NPCs and all had acquired nonprofit organization status under section 501(c)(3) of the Internal Revenue Code. In 2001, 84 NPCs reported previous year revenues totaling nearly $174 million. This represents 20 percent of VA's total research funding from all sources. Individual corporation's revenues ranged from $17,000 to nearly $21 million with 36 foundations reporting income of more than $1 million. Although it was originally anticipated that NPCs would primarily accept clinical research grants from private sector organizations, administration of non-VA federal grants is increasing. Grants from other federal agencies including National Institute for Health (NIH), Department of Energy (DOE), Centers for Disease Control (CDC), Department of Defense (DoD), and National Science Foundation (NSF) amounted to 39 percent of all total NPC revenues in 2000. One NPC in Chicago claims annual revenue in excess of $3 million from a wide range of sources including Abbott Laboratories; Pfizer, Inc.; Genentech, Inc.; Merck & Co., and Smith Kline Beecham and Boehringer Mannheim Corporation.

MANAGEMENT AND EFFECTIVENESS

In the nearly 15 years since the authorization of the establishment of NPCs, many have grown both in size and sophistication beyond what was envisioned by the enabling legislation. We commend their success in becoming such a tremendous asset to VA and to the veteran population.

The American Legion continues to support legislation that clarifies that VAMCs may enter into contracts or other forms of agreements with NPCs to provide services to facilitate VA research and education. The American Legion believes research and education for the betterment of veterans and their families are key elements of VA's overall mission. The American Legion remains a strong advocate for the VA research program and the dollars needed to support it. The American Legion supports the proposed change relating to contracts between VAMCs and NPCs. The legislation would further clarify that research corporation employees are covered under the Federal Tort Claims Act (FTCA). It is critical that these employees of VA-affiliated research corporations be protected under FTCA while carrying out their duties under a VA appointment. If they are not, alternatives NPCs would have to consider may not be acceptable. Two of these possible alternatives would be to either use funds normally devoted to supporting research to buy an expensive blanket insurance policy or to close down the entire operation. Neither option is acceptable to The American Legion.

HUMAN RESEARCH SUBJECT PROTECTIONS

As federal entities conducting medical, clinical, and prosthetic device research involving human subjects, NPCs are subject to Federal regulations governing human experimentation and informed consent. The Department of Health and Human Services' Office for Human Research Protections (OHRP) (previously known as the Office for Protection from Research Risks) established these Federal regulations in 38 CFR Part 16.

The regulatory body responsible for a given clinical trial depends on the type of trial that is being conducted. FDA regulates clinical trials involving experimental drugs and devices, while trials for other therapies, such as surgery or bone marrow transplants, are subject to HHS regulation. However, FDA and HHS themselves do not review research proposals. Instead, federal regulations delegate authority for the review, approval, and monitoring of biomedical research studies to Institutional Review Boards (IRBs), which are committees designated by individual institutions. Therefore, the protection of the rights and welfare of human subjects are left primarily to local peer review committees that are not themselves governmental entities. However, this satisfies peer review requirements of 38 U.S.C. 7364(b).

Federal regulations mandate that each IRB have at least five members, with "at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas." At least one member of each IRB must be a person "who is not otherwise affiliated with the [research] institution[,]" but all others may be staff members and individuals who are, themselves, conducting clinical trials at the research facility. According to OHRP, 86 percent of IRB members in 1995 were affiliated with academic research institutions. Members included people that served as full-time faculty (56 percent), clinical and research staff (18 percent), and administrators (6 percent). Academic institutions do not compensate their IRB members for their work; therefore, these individuals must volunteer their time without receiving payment or relief from other work duties.

IRBs must review all research activities that are covered by regulations and must approve each proposed study prior to its commencement. Regulations provide detailed criteria that are required for approval of research. Initial IRB review can filter out clinical trials that are obviously unsound or pose excessive risks for participants, but effective periodic monitoring by IRBs during the actual course of a study is essential to the protection of human subjects. FDA and HHS, however, provide little guidance for IRBs concerning continuing reviews. Regulations state merely that "[a]n IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to

the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research."

The regulations further provide that the IRB may "suspend or terminate approval of" any clinical trial that does not comply with its requirements or has caused subjects to suffer "unexpected serious harm."

The VA Office of Research Compliance and Assurance (ORCA) is responsible for:

- advising the Under Secretary for Health on all matters affecting the integrity of research in the protection of human subjects and animals,
- promoting enhancements in the ethical conduct of research in conformance with regulations and policies, and
- investigating any allegations of research improprieties and research misconduct.

ORCA identifies five functional "product lines" as its primary mission:

- *Product Line One*: Comprehensive Inspection -- Annual comprehensive inspections of research integrity using a standardized Mini-Assessment Program (MAP), and periodic unannounced site visits.
- *Product Line Two*: External Accreditation -- Participant/Observers on external accreditation site visits for human subjects and animal welfare, conducted tri-annually.
- *Product Line Three*: Investigation -- Investigations of allegations of research improprieties:
  - ❖ Types of review:
    1. Special Inquiry Force Team (SIFT).
    2. Comprehensive Research Integrity Program (CRIP). Investigations of allegations of scientific misconduct (Level 2).
- *Product Line Four*: Training, Education and Development -- Conduct training, education and development [TED approach]. Work with Veterans Integrated Services Networks (VISNs) and VA medical center "Compliance Officers". Collaborate with other federal agencies and academic affiliates.
- *Product Line Five*: Academic Affiliations – Develop and maintain specific area of emphasis and expertise. Establish academic affiliation arrangements. Advance "state of the art" of research assurance and compliance activities.

ORCA has five geographic regions each overseeing a number of VISNS to which it assigns ORCA/VISN liaisons. Each VISN has a Research Assurance and Compliance Officer (RACO) and each VAMC has a Research Compliance Officer (RCO).

The American Legion has previously reported on the problems encountered in the protection of human research subjects at the West Los Angeles (WLA) division of the Greater Los Angeles Healthcare System (VAGLAHCS). In 1994, the Office of Protection from Research Risks (OPRR) restricted WLA's Multiple Project Assurance (MPA) because of reporting discrepancies and defects in informed consent procedures. Over the next five years, an increasingly contentious relationship between OPRR and VAGLAHCS/WLA ensued eventually resulting in OPRR's deactivation of WLA's MPA and halted all HHS-funded research projects at that facility. In its 1999 report, The American Legion Research Task Force made the following recommendations:

- ✓ Apprise Veterans Service Organizations (VSOs) of VAGLAHCS progress in implementing its recovery plan and new IRB procedures.
- ✓ Establish Data Safety Monitor Boards for VAGLAHCS and all VA institutions conducting research on vulnerable populations.
- ✓ Create a national IRB to review approved research and to assist in the process of settling disputes between and differences of opinion among multiple IRBs.
- ✓ Educate and train all IRB Chairs, members, VA investigators, R&D committees, and support staff.
- ✓ Establish a minimum and maximum work load that a single IRB can administer.
- ✓ Reimburse VA 15 percent for NIH and other non-VA funded federal research administered by a VA IRB and using VA assets. Similar arrangements should be negotiated with private funders of research.
- ✓ Fund OPRR (now OHRP) to increased staffing.
- ✓ Eliminate studies having little or no benefit to the veteran population.

- ✓ Hire a Chief of Staff for the National Ethics Center and require an ethicist to be on both local and National IRBs.
- ✓ Coordinate research involving Post Traumatic Stress Disorder (PTSD) with the National Centers for PTSD.

VA, as a sponsor of research, is limited in its ability to monitor all 88 NPCs. The American Legion believes that a program of annual and occasional unannounced site visits is simply not enough to assure compliance with the myriad of rules and regulations. It is further recommended that ORCA be authorized to use commercial contract research organizations to provide more frequent comprehensive site inspections. This monitoring should be done in accordance with the International Conference on Harmonization (ICH) E6 (efficacy) Good Clinical Practices standards. Clinical Safety Data Management is also classified as an "efficacy" topic concern.

The American Legion believes great progress has been made with the implementation of Federal-wide Assurance (FWA) procedures. Each VA affiliated NPC that administers federal research grants involving human subjects is required to obtain OHRP approval prior to the expiration of its existing assurances, such as Multiple Project Assurances (MPAs). VAMCs were required to complete FWA application process by September 30, 2001. A NPC may not "share" a FWA with a VA medical center or a university. Each NPC must have its own approval; however, underlying FWA, there must be a written document detailing each institution's respective responsibilities in assuring oversight. OHRP maintains that, in the event of an investigation, it will hold an institution responsible only for oversight for which it is legitimately responsible. However, respective responsibilities must be specified in an agreement with the VAMC. FWA replaces the OHRP Multiple Project Assurance (MPA), Single Project Assurance (SPA), Cooperative Project Assurance (CPA), and the VA Multiple Project Assurance (VA MPA). In consultation with the VA Office of General Counsel, the National Association of Veterans' Research and Education Foundation (NAVREF) has negotiated with OHRP revisions to the standard FWA application that address the close relationship between a NPC and its affiliated VAMC. These modifications clarify that a NPC is responsible for aspects of human studies research oversight to the extent allowed by its authorizing statute. It also clarifies that a NPC is responsible for its own employees, not VA employees.

SUMMARY

The American Legion is convinced that VA is the premier research organization leading the nation's efforts to promote the health care of its veterans. In meeting its mission, VA capitalizes on the unique opportunities provided by its integrated health care system. VA continues to strike a balance in research resources among its basic and applied research to achieve a complementary role between the discovery of new knowledge and the application of these new discoveries to medical practice.

VA research is divided into four organizational units:

- Cooperative Studies Program – supports the clinical trials with its own statistical support centers and its own FDA approved pharmacy. The research determines the efficacy and cost effectiveness of new medications and new treatment strategies.
- Health Services Research and Development Service – supports investigator-initiated research projects, the training of clinicians in applied clinical research, centers of excellence devoted to specific aspects of health care delivery, and service directed projects addressing clinical management needs.
- Medical Research Service – supports investigator-initiated research projects, the training of clinicians in basic and clinical research, and centers of excellence devoted to specific diseases.
- Rehabilitation Research and Development Service – investigator-initiated research projects, the training of clinicians and engineers in rehabilitation research, centers of excellence devoted to specific disabilities and technology transfer.

As the immediate stakeholders in VA's medical and prosthetic research, The American Legion continues to lobby Congress annually for additional discretionary funding. This year, National Commander "Ric" Santos urged Congress to provide VA with $420

million in FY 2003. The American Legion believes every dollar spent in VA's research program is a wise investment in a national resource.

Mr. Chairman, that concludes The American Legion's statement.

STATEMENT OF
JOY J. ILEM
ASSISTANT NATIONAL LEGISLATIVE DIRECTOR
OF THE
DISABLED AMERICAN VETERANS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
AND THE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES
MAY 16, 2002

Messrs. Chairman and Members of the Subcommittees:

Thank you for the opportunity to present the views of the Disabled American Veterans (DAV) on the management of Department of Veterans Affairs (VA) affiliated nonprofit research corporations and educational foundations and the effectiveness of the partnership between those corporations and the Veterans Health Administration (VHA). As an organization of more than one million service-connected disabled veterans, DAV is especially concerned about maintaining a veterans' health care system that can meet its primary mission of providing quality medical care to our Nation's veterans and effectively carry out all its other missions, including research.

The VA Medical and Prosthetic Research Program has been a hallmark of VA excellence. Researchers in VHA research programs have received three Nobel prizes and numerous other distinguished awards. VA research concentrates on health care concerns that are prevalent among veterans and has become a world leader in such research areas as aging, women veterans' health concerns, AIDS, and post-traumatic stress and other mental health disorders. The fiscal year 2003 *Independent Budget* (*IB*), co-authored by the DAV, the Veterans of Foreign Wars, Paralyzed Veterans of America, and AMVETS, rightfully acknowledged VA's Medical and Prosthetic Research Program as a national asset. The *IB* stressed the importance of supporting VA research now and in the future, recognizing that advances in medical treatment and technology developed in VA hospitals and research laboratories have greatly improved not only the quality of life of veterans but all Americans. VA's research program also helps to attract first-rate physicians and keep veterans' health care on the cutting edge. The *IB* noted that, "The atmosphere of medical excellence and ingenuity promotes the advancement of medical science in conjunction with the nation's leading medical schools and ultimately benefits every veteran receiving VA care."

With a clinical focus on improving patient care through evidence-based research, VA has worked hard to be a national leader in health care. And, according to VA, "VHA provides an unparalled setting for its researchers to see their results rapidly and directly applied to better patient care and shared with the medical and scientific community in general." VA's research and development contributions include: discovery of a potential new therapy for chronic pain; identification of genes associated with Alzheimer's disease and schizophrenia; development of lighter better-fitting artificial limbs; pioneer of early treatment for spinal cord injury; performance of the first successful liver transplant; and demonstration of the fact that aspirin reduced rates of death and heart attacks for angina patients. VA also developed its own Quality Enhancement Research Initiative to translate research discoveries into better patient care and systems improvement.

In 1988, Congress passed legislation that allowed VA medical centers to establish nonprofit research corporations (NPCs), broadening VA's ability to accept private and non-VA public funds to support VA's research program. Subsequently, Congress expanded the authority of the NPCs to include supporting VA's patient and staff education, and training missions as well. Section 7361 of title 38, United States Code, authorizes the establishment of a nonprofit corporation at any VA medical center to provide a flexible funding mechanism for approved research and education. Congress allowed VA to develop appropriate regulations for the VA NPCs, which are specified in the VHA Research and Development Manual. There have also been several General Counsel opinions issued in response to specific concerns of operating a VA NPC. Additionally, NPCs are required to comply with local, state, and federal requirements.

The National Association of Veterans' Research and Education Foundations (NAVREF) is a membership organization of the VA-affiliated nonprofit research foundations. NAVREF's mission is to promote the interests of the VA affiliated NPCs and to provide a forum for guidance on managing a VA NPC. NAVREF's stated goals include promoting the highest standards of fiscal and operational management; assuring appropriate, but not overly burdensome, oversight and regulation of the corporations; education of the general public and Congress about VA research; and advocating improved federal support for the program.

From DAV's perspective, the partnership between VHA and NPCs is a successful and highly effective one. We certainly want to ensure that continued oversight is maintained and that VA research programs are properly managed. We believe sufficient compliance standards are in place to ensure proper management and regulation of research funds. It is clear that the affiliated NPCs are an integral component of VA research initiatives and greatly enhance VA's research program in a number of ways. NAVREF reports that: 1) NPCs bring additional resources to VA that ultimately benefit veterans' medical care; 2) research involving clinical drug trials increases veterans' access to the latest drugs and technology; 3) NPCs provide opportunities that attract first-rate physicians to careers in VA; and 4) administrative overhead is significantly reduced by NPCs to ensure more resources may be available for research or retained for the benefit of the affiliated VA medical center.

NAVREF testified before the Subcommittee on Health of the House Veterans' Affairs on behalf of the Friends of VA Medical Care and Health Research (FOVA) on April 24, 2002, and stated that NPCs and researchers are faced with many challenges as a result of VA funding shortfalls. We acknowledge the concerns brought to light during that hearing regarding the serious need for infrastructure renovations and improvements at many VA research facilities. We concur that VHA's research infrastructure in many locations is desperately in need of repair and improvement. Significant investment in VA's research infrastructure is essential to maintain the viability of the program. Adequate funds are necessary to upgrade research infrastructure to current standards to ensure the safety of patients, researchers, and their staff. DAV believes it is an investment worth making. If VA research facilities are allowed to fall into further disrepair and decline, VHA's opportunities for leveraging its research funds will likely be compromised. VA's research laboratories must be able to accommodate modern science. If facilities are inadequate for research purposes, VA becomes a less attractive research partner. NAVREF testified that, "[l]ess than state-of-the-art research facilities also impact on medical centers' ability to attract investigators to VA, particularly clinician investigators, those who have the most direct impact on the quality of care provided to veterans." The IB recommends that VHA should allocate research infrastructure improvement funds independently of the Veterans Equitable Resource Allocation System (VERA).

Regardless of the overall challenges pertaining to VA research and affiliated partnerships, the *IB* strongly supports a constantly expanding research program focused on veterans' health concerns, particularly aging and disability. VA should not have to choose between meeting veterans' basic clinical needs and continuing its high standards for research, given the direct impact of VA research on veteran patients' overall health and well-being.

We thank the Subcommittees for holding this hearing today and providing DAV the opportunity to express our views on the management of VA-affiliated nonprofit research corporations and educational foundations.

STATEMENT FOR THE RECORD

PRESENTED BY

RICHARD B. FULLER

NATIONAL LEGISLATIVE DIRECTOR

PARALYZED VETERANS OF AMERICA

REGARDING

VA NON-PROFIT RESEARCH CORPORATIONS

BEFORE THE

SUBCOMMITTEE ON HEALTH AND

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

HOUSE COMMITTEE ON VETERANS' AFFAIRS

MAY 16, 2002

Mr. Chairman, on behalf of the members of Paralyzed Veterans of America (PVA) I would like to present our views on the status and effectiveness of the VA's Non-Profit Research and Education Corporations. Established by law in 1988, these entities have proven extremely effective in advancing the state of health care research, attracting hundreds of millions of private and non-VA public sector dollars to support the VA research enterprise, and improving the state of veterans health care through the provision of resources to support additional patient care activities, personnel, and medical equipment.

In 2001, non-profit corporations at 84 VA medical centers reported previous year revenues of nearly $174 million. These are revenues that never would have been available to VA without the mechanism the corporations afford as conduit, but also as administrators of these funds. Legislation authorizing the

corporations was first sponsored by then Chairman of the House Committee on Veterans' Affairs G.V. (Sonny) Montgomery to help solve a serious problem. A private entity, such as a pharmaceutical company, wishing to have access to VA researchers to provide grants to sponsor research in the unique atmosphere of VA medicine had very limited ways to achieve that goal. First, it could channel the grant through the books of the VA-affiliated teaching hospital, which, for its effort, would take its share of the indirect cost directly off the top for managing the grant. Second, it could provide the grant money through the cumbersome vehicle of the VA medical center's "Post Fund" which is totally ill equipped to handle potential sums of this magnitude designated for this purpose. In both cases, VA had little oversight into the direct operation and management of these funds. The corporations serve as a magnate for research dollars, but also, as established by law, an administrating entity for those grants with multiple layers of accountability to ensure those dollars are spent appropriately.

As non-profit entities the corporations are subject to numerous reporting criteria at the state level and with the Internal Revenue Service. Corporations with incomes in excess of $300,000 per year are subject to annual audits, those under $300,000, audits every three years. Each medical center director, chief-of-staff and assistant chief-of-staff for research serve on the boards of directors of the corporations at their facilities. A corporation's statutory affiliation with the VA affords an even greater level of scrutiny from the VA and the Federal Government. The corporations are required to submit their annual reports to VA and subsequently to the Congress. They are subject to Inspector General oversight and General Counsel's office review going all the way up the chain of command to the Secretary of Veterans Affairs.

PVA has a long affiliation with the health care research enterprise in the United States. In the past 25 years, our Spinal Cord Research Foundation has awarded more than $30 million for basic science, clinical and technological research of spinal cord injury and disease. Since 1986, our Education and Training

Foundation has awarded more than $4 million in grants to expand health care professionals' knowledge and experience in care for veterans and all Americans who have incurred these injuries and diseases and to advance consumer education. PVA's foundations have maintained a close relationship with VA researchers and with VA research and education programs. VA is a recognized national leader in these fields of inquiry. We clearly understand how partnerships, both within the VA and external to the VA, can work closely together to maximize research potential. One example is the PVA, EPVA Center for Neuroscience and Regeneration Research. The center was constructed and is supported with funding from PVA and Eastern Paralyzed Veterans Association (EPVA) on the grounds of the West Haven VA Medical Center. Its staff and activities are led by Stephen Waxman, M.D., Ph.D., Chief of Neurology at the Yale Medical School, and Chief of Neurology at West Haven VA. In similar fashion, our Spinal Cord Research Foundation has made grants to other investigators at other VA facilities using the on-site VA non-profit research corporations to administer those funds. We have found the non-profit corporations to be an effective and efficient means to direct funds to VA investigators, ensuring the proper utilization of those funds to the maximum research benefit. At this time of limited VA research appropriations, the non-profit corporations provide an excellent avenue for VA to leverage its resource opportunities with other private and public research interests to enhance the care of veterans and improve medical science for all Americans.

This concludes my statement. I would be happy to respond in writing to any questions the Subcommittees might have.

STATEMENT OF

PAUL A. HAYDEN, DEPUTY DIRECTOR
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

SUBMITTED TO

THE SUBCOMMITTEE ON HEALTH AND
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

WITH RESPECT TO

THE DEPARTMENT OF VETERANS AFFAIRS' AFFILIATED NONPROFIT
RESEARCH CORPORATIONS AND EDUCATION FOUNDATIONS

WASHINGTON, DC MAY 16, 2002

MESSRS. CHAIRMEN AND MEMBERS OF THE SUBCOMMITTEES:

On behalf of the 2.7 million members of the Veterans of Foreign Wars of the United States (VFW) and our Ladies Auxiliary, I would like to thank you for the opportunity to present our views on this issue that is of vital importance to improved medical care not only for veterans but for all people.

The *Independent Budget* (IB), of which the VFW is proud to coauthor along with AMVETS, Disabled American Veterans and Paralyzed Veterans of America, subscribes to a guiding principle that the Department of Veterans Affairs' (VA) "mission to conduct medical and prosthetics research… is critical to the integrity of the veterans health-care system and to the advancement of American medicine."

Undeniably, the VA has established itself as a world leader in medical and prosthetic research. Along with its Nobel prize-winning research, VA has developed special centers nationwide that focus on rehabilitation, environmental hazards, aging, and mental illnesses such as Post-traumatic Stress Disorder, to list a few. In 1988, Congress passed the *Veterans' Benefits and Services Act*, which expanded the VA research program by granting the Veterans Health Administration (VHA) the right to establish nonprofit corporations (NPCs) in order to compete for non-appropriated research funds, primarily from the National Institutes of Health and other foundations, combined with supporting funds from pharmaceutical companies. Congress expanded the NPC role in 1999 to include education in addition to research.

The VFW believes that the partnership between VHA and NPCs is effective and has played an instrumental role in attracting hundreds of millions of non-appropriated

dollars that have served to directly impact the state of VHA research programs. Dollars, that otherwise would never have been available had it not been for the existence of NPCs. Currently there are 85 active corporations who attracted nearly $174 million in funds in fiscal year (FY) 2001.

Therefore, it is clear to the VFW that NPCs are accomplishing their mission of providing a flexible funding mechanism for VA research. Past and current investigations, however, by the VA Office of Inspector General reported the need to improve accountability and oversight related to the administration of NPC funds to ensure they are used for research. Currently, NPCs, as state-chartered tax-exempt corporations, must comply with all federal, state and local reporting requirements. In addition to independent annual auditing for corporations with revenues exceeding $300,000 per year they are subject to the scrutiny of the Internal Revenue Service (IRS), the Department of Labor, VHA guidelines, VA Inspector General and General Counsel, a Board of Directors, and of course, Congress.

In addition to official oversight, the mission of the National Association of Veterans' Research and Education Foundations (NAVREF), a membership organization of VA affiliated nonprofit research and education foundations, was established to promote the highest standards of fiscal and operational management; assure appropriate, but not overly burdensome, oversight and regulation; and educate the general public and Congress about VA research and advocating improved federal support for the program.

Given the numerous organizations that directly or indirectly impact the operation of NPCs, it is our contention that significant oversight authority currently exists. Further, we believe that the result of having so many layers of regulations and oversight has improved the management and accountability of NPCs. This oversight should continue and NPCs should strive to implement oversight recommendations that progress their ability to prove that research funds are used as intended.

This concludes my statement and I would be happy to respond to any questions the Subcommittees may have.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

CHAIRMAN BUYER TO MICHAEL SLACHTA, JR., ASSISTANT INSPECTOR GENERAL

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington DC 20420

June 21, 2002

Mr. Arthur K. Wu
Staff Director
Subcommittee on Oversight and Investigations
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Wu:

This letter is in response to your June 7, 2002 request to answer specific questions on the Department of Veterans' Affairs (VA) research and research corporations and educational foundations. Per your request, we have provided our responses to the Subcommittee's questions in the Enclosure. We have also requested more detailed responses to Chairman Stephen Buyer's questionnaire and we are proceeding with conducting the additional work the Subcommittee requested in our May 30, 2002 meeting. If you have any questions, please contact me at (202) 565-4625, or Linda Halliday at (202) 565-4501.

Sincerely,

MICHAEL SLACHTA, JR.
Assistant Inspector General
for Auditing

Enclosure

ENCLOSURE

1. You stated in your testimony that in your 1994 OIG report, some foundation funds were spent on non-research related items such as conferences, entertainment and travel. After your discovery, were any efforts made to replace the funds in the foundation that were improperly spent?

Based on our 1994 review of VA nonprofit research corporations (VANPCs), OIG Report No. 4R2-A09-078 dated June 14, 1994, we reviewed $1,025,008 of $3,641,811 spent at three VANRCs during the period July 1989 to October 1992. We performed a review and selected accounts for review in categories that allowed latitude for discretionary use. We concluded that $624,370 was spent on activities not directly related to research, such as general operating expenses of VA Medical Centers (VAMCs), entertainment, and expenses of VA researchers and others. This occurred because the Veterans Health Administration (VHA) policy and procedural guidance did not clearly describe the types of activities VANPCs could support.

Existing policy guidelines did not specifically identify restrictions or limitations to be applied in establishing whether obligations and expenditures were allowable and reasonable. VHA and the Office of General Counsel (OGC) took action to incorporate our recommendations in a draft VHA policy directive chapter on VANRCs. The process culminated in a new VA policy chapter governing nonprofit research corporations, issued May 1994. No effort was made to replace the funds expended by the corporations that were identified in our report. We focused our efforts on ensuring there would be adequate guidance applicable the future VANRCs activities to prevent actual or even the appearance of inappropriate activities or personal benefits in the conduct of future VANRCs activities.

At the time of the review, we asked both VA and the OGC to define what type of expenditures would be appropriate and what expenditures and/or fund use would be considered inappropriate for VANPCs. The new guidance identified some examples of the types of expenditures that would be appropriate to expend corporation funds on. The guidance indicated that corporate funds could be used to pay for professional memberships, publications, and travel expenses directly related to an approved research or educational activity and travel to conduct corporation business. The guidance prohibited VA corporations from paying for professional licenses for VA employees, however it did not adequately address funds used for entertainment purposes.

One concern we had in 1994 and continue to have focuses on VA's response to the Committee's question regarding what are the criteria for considering an expenditure a research expenditure. The Acting Secretary for Health's response to the Committee noted " If an expenditure is related to research, it is considered to be a research expenditure." We believe that VA's response provides discretionary latitude that is far too broad to provide an effective yardstick to measure what is research related and/or necessary.

During our 1994 review, auditors identified smaller operating funds being administered by VA Medical Center Directors through VANPC financial accounts, where fund use appeared highly discretionary. For example, VA corporation funds could be used to send a colleague or researcher to educational activities, however management controls and VA oversight was not adequate to ensure that the related expenditures were not necessary and added reasonable value to direct VA research activities. In addition, we saw that such potentially questionable expenditures may not be apparent to independent auditors conducting financial statement audits. As a result, better assurance and management controls including improved oversight and visibility over VA nonprofit corporate funds is needed to ensure VA research corporations expenditures and activities are necessary, reasonable, allowable, and allocable to enhance VA research as intended by the 1988 legislation granting VHA authority to establish these corporations.

2. How were these specific research corporations held accountable for that loss?

The three VA nonprofit corporations reviewed in 1994 were not held accountable for any "loss". At that time, VHA guidance that did exist was issued so not to restrict VANRC management with regulatory requirements and to promote the legislative intent for flexible administration of non-VA research funding. Given the absence of appropriate guidance it would be difficult to hold specific individuals accountable for such expenditures. In addition, no evidence was identified to support that the expenditures we identified were spent inappropriately for personal gain. Generally we reported that the expenditures were for general administrative funds needed to operate the VA corporations, but certain expenditures appeared unrelated to VA research and/or unnecessary.

3. Based on your review of VA's non-profit corporations, what should Congress do to raise the level of monitoring of these functions? Do we need legislation or does the hearing we held on May 16, 2002 and others we may hold in the future suffice for this purpose?

Our prior review of VA nonprofit corporations occurred several years ago in 1994. The current review effort based on the Committee's request shows that the significance of the total revenues reported by the VA's 85 active corporations in FY 2000 averages slightly less than $2 million annually per corporate entity. We have also observed that the mix of funding received by VANPCs has increased to include more grant awards from other Federal Agencies. In most of the larger corporations (based on reported annual revenues), VA is no longer the cognizant Federal agency. We confirmed that all 15 of the VANPCs reporting they had expended $300,000 or more in Federal awards in FY 2000 had also met the requirements of the Single Audit Act. Audits were submitted to VA consistent with the provisions set forth in U.S. Office of Management and Budget (OMB) Circular A-133, *Audits of States, Local Governments and Non-Profit Organizations*. These audits add an additional level of oversight over Federal funds to ensure entities are maintaining internal controls over Federal programs and complying with laws, regulations and the provisions of contract and grant agreements. Compliance requirements considered in every audit conducted under OMB Circular A-133 include

reviews of allowable costs and cost principles, as prescribed by A-122, *Cost Principles for Non-Profit Organizations*.

Our review also found that 7 of the 15 VA research corporations required to comply with OMB Circular A-133 requirements have Indirect Cost Rate Agreements established with the Department of Health and Human Resources (HHS), the Federal agency designated as the individual non-profit organization's cognizant Federal agency for the negotiation and approval of indirect cost rates. Two additional corporations were in the process of negotiating their indirect cost proposals with HHS.

OMB Circular A-122 guidance requires Federal agencies to accept the terms of rate agreements negotiated by cognizant Federal agencies. The review process that cognizant Federal agencies follow to negotiate and approve indirect cost agreements represents an additional level of oversight and monitoring over non-profit organizations receiving Federal awards and generally entails a review to determine whether organizations have procedures for determining the allowability of costs to Federal awards according to the applicable cost principles and other terms of awards.

In consideration of our recent review and preliminary findings, we believe that efforts to strengthen management controls over VANPC activities should be focused on improving visibility and accountability over the use of private donations administered by VA research corporations. Our concerns persist that without adequate guidance and VA oversight some VA corporation's expenditures will fail the test of being necessary and be made without adequate consideration of VA research program's mission, strategic goals, and program objectives.

4. Do you believe the financial reporting requirements now in the law are sufficient, or do these need strengthening and if so, how would you suggest they be improved?

In 1994 we concluded that VHA visibility over VANRC activities was generally limited to information provided in the annual reports VANPCs submit to the Secretary. We found that these reports were inconsistent in scope, depth and timing of the information provided and did not provide comprehensive information to identify non research activity. Additionally, we were informed that VHA did not substantially review the annual reports to validate compliance.

VANPC financial reporting could be enhanced by requiring a uniform financial management system be used at each VANPC corporation. We also believe there is an opportunity to redirect more funds to direct support of research by consolidating and reducing the number of corporations thus reducing the overall administrative costs associated with managing the corporations.

In our May 16, 2002 testimony, we recommended that annual reporting by the VANPCs could be improved to provide the Congress improved visibility over the use of funds to ensure funds are used as intended by the Congress if VA's annual report to Congress provided detailed expenditure reporting of VANPC activities.

5. 15USC 3710d(b) states that for the purposes of specified section *" Federal employees include special Government employees as defined in section 202 of title 18, Unites States Code" i.e., "an officer or employee of the executive or legislative branch of the United States or the District of Columbia, who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed one hundred and thirty days during any period of three hundred and sixty-five consecutive days, temporary duties either on a full-time or intermittent basis,...* Given this, are not VANRC researchers, who are not specifically employed by the VA, subject to the same oversight and accountability as " Federal employees"? Does the OIG take this into account in the formulation of its annual audit planning process?

VANRC researchers, who are not specifically employed by the VA, are not subject to the same oversight and accountability as " Federal employees". They are not Federal employees, but they are subject to same ethics rules as Federal employees. VHA's guidance requires that at the time the relationship or employment is initiated, each corporation board member, officer, and employee must sign a statement certifying awareness of and compliance with Federal conduct and conflict of interest laws and regulations. Annually, each VANPC Executive Director must certify that such a statement is on file for each board member, officer, and employee.

OIG has not specifically examined VA nonprofit research corporations since our 1994 review. However, our annual audit planning process does assess the significance of the total revenues reported by the VA's 85 active corporations in its annual audit planning process in conjunction with identifying significant program risks and vulnerabilities. Previous audit planning decisions were made that prioritized higher risk programs and operations within other areas and functions of VA.

6. When IG audits research and educational foundations, do audits typically include a review of all expenditures of the foundation? Please describe for the Committees a typical audit of a research foundation.

Past IG performance audits and reviews of research and educational foundations have all begun with objectives that determined the type of audit to be conducted and the audit or inspection standards to be followed. Our previous work focused on management and operations, effectiveness of oversight activities, and reliability and accuracy of accounting information of VANRCs. Audits focusing on performance and evaluating management operations typically assess operational economy and efficiency and generally review the extent to which the desired results or benefits established by the legislature are being achieved, evaluate internal management and program controls, and assess and ensure entities have an adequate system for measuring and reporting performance.

Audits do not typically include a review of all expenditures of a research foundation, since such efforts would require significant resources and many expenditures made by the corporations may not be significant. Audits are planned to consider materiality and

significance before audit teams select the methodology and design audit tests and procedures. One criteria considered in determining materiality is the monetary value of an item, such as an asset, revenue, or expenditure.

Our 1994 review of VA nonprofit research corporations evaluated the management and operation of VANRCs and the effectiveness of VA oversight activities. This review included conducting: (i) a review of applicable law and pertinent VA policies, (ii) in-depth reviews of operations at three non-profit corporations, (iii) limited reviews of operations and selected information at several other corporations, (iv) review of accounting records, bank records, project files, pertinent financial and administrative records, and reports of independent auditors. Our review was conducted in accordance with Quality Standards for Inspections published by the President's Council on Integrity and Efficiency.

The scope of a VANRC financial audit would generally determine whether the financial statements of a corporate entity present fairly the financial position, results of operations and cash flows or changes in financial position in accordance with generally accepted accounting principles and whether the corporation has complied with laws and regulations for those transactions and events that may have a material effect on the financial statements. Most VANRC financial audits are conducted by independent certified accounting firms.

CONGRESSWOMAN CARSON TO DR. ROBERT ROSWELL, UNDER SECRETARY FOR HEALTH, AND DR. JOHN FEUSSNER, CHIEF RESEARCH AND DEVELOPMENT OFFICER

DEPARTMENT OF VETERANS AFFAIRS
UNDER SECRETARY FOR HEALTH
WASHINGTON DC 20420

JUL 0 5 2002

The Honorable Julia Carson
Ranking Democratic Member
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515

Dear Congresswoman Carson:

Enclosed are the Department of Veterans Affairs' responses to the 37 post-hearing questions addressed to Dr. John Feussner, Chief Research and Development Officer and me. There were also 4 post-hearing questions addressed to Dr. John Mather, Chief Research Compliance and Assurance Officer. The responses to all 41 questions are enclosed and relate to the joint hearing on VA Research, Research Corporations, and Educational Foundations held on May 16, 2002. A complete set of responses has been provided to each co-signer of your letter.

If you have further questions, or need additional information, please have a member of your staff contact Doug Dembling, in the Office of Congressional and Legislative Affairs. He may be reached at 202-273-5615.

Sincerely,

Robert H. Roswell

Enclosure

House Veterans Affairs Committee
Subcommittee on Health
Subcommittee on Oversight and Investigations
Hearing on VA Research, Research Corporations,
And Educational Foundations
May 16, 2002

Follow-up Questions

Questions for Dr. Robert H. Roswell, Under Secretary for Health, and Dr. John Feussner, Chief Research and Development Officer

1. This Committee recently asked VHA to answer a series of questions relating to VA's research programs. When asked several questions related to funding in the research corporations, VHA's response was "*The corporations are not required to report....*" If this is the case, then how is the Inspector General able to obtain expenditures on non-research related conferences and entertainment? Is this kind of information not available to VHA officials?

Response: The statute does not require the corporations to include these details in their annual reports. Consequently, this information is not routinely provided to Department officials in Central Office. However, more specific information about the corporations funding sources and expenditures is available upon request. Moreover, under the terms of the authorizing statute, local VA officials, i.e., the facility Director, Chief of Staff and ACOS for Research/Education, serve as ex-officio members on the VA non-profit's Board of Directors. In this role they have access, input, and oversight responsibility for corporation operations. The information on corporation expenditures reported by the Inspector General is based primarily on data collected during three site visits, which occurred over 5 years. It does not reflect the current status or practice among the VA non-profits.

2. What actions are taken in the Department to review the annual report submitted by the corporations as required by law? Who reviews the information and determines if documentation is in order and accurate? If something is found out of order, what action does VA take?

Response: The law requires that each corporation report annually to the Secretary details concerning its operations, activities, and accomplishments during that year. Corporations are required to include their most recent audit with their annual report. Under regulations prescribed by the Under Secretary for Health, corporations must list all research and educational activities supported by the corporation during the previous year. The report also lists revenues from Government and private sources; tracks research and education donations and expenditures separately; identifies employees and payees; and lists expenditures for the salaries, administrative support, and travel.

The Corporation Board of Directors, which includes the facility Director, Chief of Staff and ACOS for Research/Education, is responsible for ensuring that the information in the annual report is accurate and complete. The Office of Research and Development in VHA collects the reports from individual corporations, reviews the reports for completeness, and compiles the data in an annual report to Congress. That report is circulated for review and concurrence by the offices of the General Counsel, Congressional and Legislative Affairs, and Academic Affiliations. Central Office officials review the annual report to Congress to ensure compliance with the requirements of 38 U.S.C. § 7366 and Department regulations. Shortcomings in the report identified during this process, e.g., incomplete data or late submissions, are reported through VHA to local VA and corporation officials who immediately provide the corrected or missing data.

3. Your testimony indicated that NCQA has determined that one of the most common deficiencies in VA's research programs is in the area of policy and procedures related to informed consent. Do you agree with NCQA that informed consent is still a challenge after several years of intense activity to improve it?

Response: We agree with NCQA. While the regulatory requirements are very specific, issues related to informed consent will continue to be an ongoing challenge. There are a number of factors involved, including: a) the increasing complexity of clinical trials; b) the evolving understanding of ethical issues related to certain aspects of clinical trials including the use of placebos and the enrollment of decisionally impaired research participants; and c) science's increasing ability to develop better means of testing within studies, as with the use of gene array technology. The use of this technology has resulted in fewer subjects being entered into some studies but a tremendous increase in the amount of genetic information obtained from one sample and thus increasing the risks to subjects. To compound these evolving challenges there is also a paucity of research regarding how best to construct an informed consent and how to word the information within the consent form.

VA has initiated research in how to improve the quality of the informed consent and the consenting process. The project entitled "Enhancing Quality of Informed Consent" (EQUIC) will attempt to determine the success and validity of the informed consent process by interviewing subjects immediately after they have given informed consent for a study. The information gained through these studies will be used to improve the informed consent and the informed consent process.

4. In your written statement you point out that prior to establishment of the research and educations corporations, VA medical centers were limited to using the General Post funds to accept and expend non-appropriated funds for research purposes. Is the General Post fund used for any purpose associated with research now, and if so, for what purpose?

Response: Facilities may still use, at their discretion, the General Post fund to accept and expend non-appropriated funds for research purposes even though research

corporations provide a more effective and flexible spending mechanism. VHA does not require facilities to report such usages.

5. Dr. Roswell, a recent speech by Secretary Principi indicated that VA Medical Care Appropriation provides about $400 million in support of research. How do VERA funds support VA research? Are such funds actually received by the medical center, and in the research laboratory, and how do you know this to be the case? What monitors do you use to ensure these funds are allocated to research?

Response: The actual amount of Medical Care funding (VERA) in support of VA research was $356 million in FY 2001 and is estimated at $386 million for FY 2002. Per a directive signed by the Under Secretary for Health, these funds are required to reach the medical centers. VERA funds are intended to cover facility and administrative costs and clinical investigator salaries. The Office of Research and Development (ORD) has proposed to the Under Secretary for Health a cost accounting system to monitor the allocation of these funds.

6. We have held hearings in 2001 as well as during this year about research capital infrastructure and its unmet needs. Is the Department prepared to pay more attention to research facilities to ensure they are safe and up to the task of supporting VA's world-renowned work?

Response: The Department will continue to ensure that infrastructure needs for all its programs are identified. The Capital Asset review process will be utilized to evaluate each project to determine a relative ranking. Which projects are ultimately presented to Congress for authorization and appropriation is dependent on budget considerations that must strike a balance between provision of medical care with infrastructure needs as well as other factors.

7. I understand that the backlogged research facility infrastructure needs total more than $100 million, but the research-related construction projects never appear on the VA's top twenty priorities submitted to Congress. It has been many years since a research project was listed in VA's budget request for major medical facility authorization or appropriation. Please provide a plan to deal with these unmet needs.

Response: The VHA process for identification of major construction needs begins at the facility level. Projects are then reviewed at the network level and submitted to VACO for prioritization in budget formulation. Higher priority is given to health care facilities. In fiscal years 2001, 2002, and 2003 combined, approximately 44 individual major construction projects were considered of which 4 were research related. VHA will continue to plan for all major construction needs; however, VA has had to focus priority funding in the areas of patient safety and medical services delivery.

8. If Medical Care support funds actually reach the research facility, can these be used to improve facilities (for minor construction or maintenance and repair, etc.), or are they restricted from such uses?

Response: Research support funds from the Medical Care budget are used to fund salary costs for the portion of time Medical Care employees spend working on research projects and the cost of administrative support (i.e. Fiscal, Engineering, Acquisition and Materiel Management, etc.), including maintenance and repair, provided to the Research Program. Minor construction projects would be funded from the Minor Construction appropriation.

9. Do you believe VA's research volunteers are generally fully informed as required by the Common Rule, HHS and VA policy? What is the basis for your response?

Response: In a recent quality improvement survey conducted by ORD, 97 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."

During the past 3 years ORD has placed more emphasis on both the written informed consent and the consenting process through quality improvement efforts that include the ongoing EQUIC study that surveys research participants after they have consent to participate in a clinical trial; the development of Focus Groups composed of Veterans that assist in the review; development of informed consents; presentations by ORD staff to national and regional conferences; and the State of the Art conference on informed consent held March 7-9, 2001.

ORCA has recently issued a brochure for veterans entitled, "I'm a Veteran. Should I participate in Research?" This brochure will further educate veterans on what they need to know before deciding to participate in research.

10. If VA has a "documentation problem," could it be solved if VA invested more funds to support Institutional Review Boards, or would some other remedy be necessary to improve the situation?

Response: In March 2002, the Acting Under Secretary for Health asked that a plan be developed to identify resource needs for human studies protection and determine a more equitable funding from research than from the medical care appropriation. VA has devoted many resources in administrative support of VA research. This includes direct ORD funding of $85 million over the past three years. On-going initiatives that will further improve effective human research protections documentation include:

- increasing staffing;
- increasing resources such as computers, and computer software to allow better tracking and more complete record keeping;
- education through such mechanisms as the Research and Development Accreditation Consulting Team (ReDACT), and national and regional conferences;
- consultative services;

- guidance documents; and
- increasing networking among facilities to disseminate best practices and model documents.

11. Please explain the mechanisms of joint patents filed by VA with its academic partners. Specifically, how are respective "contributing shares" determined? Assuming the subsequent licensing of those patents, how are royalty distributions between partners determined? Are royalty distributions, received by the VA under those circumstances, in force over the life of the patent, or are VA's royalties received in one lump sum?

Response: Although VA can assert an ownership right in inventions made by our employees under Executive Order 10096, "Providing for a Uniform Patent Policy for the Government with Respect to Inventions Made by Government Employees and for the Administration of Such Policy", and its implementing regulations, VA 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 the universities may have an interest in an invention made at a VA facility, leading to joint ownership. In July 2001, the Department of Commerce issued a statement supporting the existence of joint ownership under these circumstances.

To further enhance our unique relationship and the cooperation between our research affiliates and VA, and to facilitate the technology transfer process, VHA's Technology Transfer Program developed a Cooperative Technology Transfer Agreement (CTTA). This legal agreement outlines relevant definitions, terms, and conditions for handling intellectual property between both organizations. The CTTA allows ownership to remain with VA while providing the university unimpeded access and authority to patent and market the intellectual property in question.

Royalty distributions are based on an inventor's employee status; that is, whether the inventor is a full-time VA employee, full-time affiliate, or holds a dual appointment (DAP) at both institutions. If three employees jointly develop intellectual property where two are full-time VA employees and one is a full-time affiliate, the royalty split would be two-thirds VA and one-third affiliate. If, however, two employees are full-time affiliate and one is DAP the royalty split would be five-sixth affiliate and one-sixth VA. All relevant conditions concerning royalty distribution are defined in the CTTA. The distribution of royalty income is also outlined in the CTTA, and is paid yearly over the term of subsequent license agreement.

12. Relative to the National Institutes of Health's (NIH) concern regarding VA's ability to track and manage its finances, as first raised in 1989, has VA significantly improved its cost accounting to fully account for its expenditures in all VA facilities, particularly subsequent to requirements for joint consolidated audits of VA's financial statements?

Response: VHA has made vast improvements in its cost accounting methodologies and practices for managing facility and central office funds. VHA compiles its costs by,

but not limited to, medical care, medical education, medical research, compensation and pension, and operating costs. These costs are further broken down by production costs, public costs, non-production costs, and non-VA program costs. All costs are captured and presented on the consolidated financial statements as part of the Statement of Net Cost.

VHA has made additional improvements in tracking project and work-flow costs. Technology costs will be tracked according to the line item in OMB's budget information. VHA is able to determine patient and other medical costs to improve the management of available and future funds.

The Decision Support System (DSS) has been designated as VHA's cost and workload accounting system and is fully deployed. It is a derived database and provides information to conduct Activities Based Costing (ABC) and clinical productivity analysis. Costs may be broken down, by category, as fixed, variable, direct, or indirect. Data can be used for modeling, formulating business strategy, assisting in budget distribution and execution, and forecasting. Additionally, costs can be broken down by production unit, intermediate product, inpatient, outpatient, or by Social Security number for specific patients. Information is available for individual or groups of patients, trend identification, patterns of care, and cost or comparative case costs.

DSS has capability to provide the following:

1) Costs of tests and procedures
2) Costs of patient encounters
3) Clinical care information
4) Standard workload classifications for building budgets
5) Costs of episodes of care for rate setting and financial analysis
6) Patient specific costs for resource allocation
7) Data for audit accomplishment
8) Data to assist in the assessment of process and efficiency of care as well as adherence to clinical care guidelines

The system has been designed to closely mirror cost and workload systems currently used in the private health care sector. That is, the system incorporates the use of diagnostic related groups (DRGs), resource utilization groups (RUGs), Centers for Medicare and Medicaid Services' ambulatory classifications, and other clinical and business information recognized as standard to the health care industry.

13. Has VA obtained an unqualified audit opinion on its consolidated financial statements in recent years? Please specify and elaborate on the material weaknesses disclosed in the most recent audit, particularly as related to R&D and associated research. Are VA facilities included in VA's consolidated financial statement? If not, are separate audits of VA facility consolidated financial statements conducted?

Response: VA has received an unqualified opinion on its consolidated financial statements for the past three years.

The following items were identified as material weaknesses during the audit of the FY 2001 Financial Statements. None of these is related to research.

- Reliance on Independent Specialists: VA relies on the use of actuarial consultants and other specialists for various financial statement assertions. Specialist work was not always reviewed.

  VA created an Actuarial Officer position, which is responsible for oversight of actuarial and expert contracts and for reviewing and certifying the results produced.

- Management Legal Representations: VA management did not provide adequate legal representation on pending litigation and contingent liabilities. In addition, the case descriptions were not provided with sufficient detail.

  VA management established new procedures to address this issue.

- Lack of Integrated Financial Management System: VA has difficulty in the preparation, processing, and analysis of financial information to support the effective and efficient preparation of VA's consolidated financial statements.

  VA is implementing a new core financial management system. With the completion of this project, the accuracy and validity of data will improve. The new system will improve the flow of data and other information, and therefore improve the reconciliation and reporting processes.

- Loan Guaranty Application Systems: Control weaknesses exist in critical loan guaranty systems applications security and process controls due to a lack of accountability and definition of responsibilities for security administration standards and reconciliation procedures.

  VBA has implemented a remediation plan to correct each of these items.

- Information Technology Security Controls: VA's program and financial data are at risk due to serious weaknesses in the Department's control and oversight over access to its information systems.

  VA created the Office of Cyber Security to address this issue and ensure that the confidentiality, integrity, and availability of data is maintained. This office has developed a plan to address information technology security controls.

- Management Ownership of Financial Data: Instances were noted whereby VBA management provided insufficient review of accounting data and transactions.

  VBA has established and implemented new procedures to ensure data provided in support of the audit is timely and accurate.

VA has furnished OMB with the Department's remediation plan that also details milestones and the status for each of the material weaknesses identified above. Senior VA officials review the plan monthly.

VA facilities are included in the consolidated financial statements. The financial and programmatic data is transferred to VA Central Office (VACO) and the VA general ledger for reporting purposes. Stations are audited, with the results provided to the stations and VACO for comment. Stations do not develop their own financial statements for audit purposes.

14. From 1996 through 1998 (inclusive) VA applied for three patents. During the same period, the Department of Energy applied for over 2,000 patents. Can VA estimate the number of lost opportunities and provide a reason the Department did not apply for more patents? How many VA collaborative discoveries were patented by research affiliates during this period?

Response: Although the requirement for disclosure of inventions has been in effect since 1956, systematic handling and pursuit of VA IP rights did not begin in earnest until February 2000. Exact figures for the years requested are not available. However, based on FY 1998 actual data, we estimate the following:

- total number of disclosures processed; 150
- total where VA retains ownership rights; 24
- total where VA was sole owner. 3

At a minimum, lost opportunities for the time period in question would be 126 inventions. Prior to February 2000, there was no dedicated VA Technology Transfer Program or staff in place to pursue and protect VA intellectual property. More important, there was no collaborative partnership between VA's Office of General Counsel and Office of Research and Development to address this important endeavor.

15. The Office of Research Compliance and Assurance (ORCA) reports directly to and serves as the primary advisor to VHA research on safety and compliance matters. Considering its proactive and reactive role in oversight and investigation of human subjects and animal safety, and the fact that ORCA staff may work with and for persons they may need to investigate, is ORCA independent enough to accomplish its mission?

Answer: The Office of Research Compliance and Assurance reports directly to the Under Secretary for Health, not to the Office of Research and Development. The Under Secretary for Health fully supports the independence of ORCA in both its proactive and reactive compliance and assurance activities. Various reports, such as those from the Special Inquiry Force Team (SIFT) and the Systematic Post-Accreditation Review (SP-AR), are prepared for the Under Secretary's signature, and in every instance, the Under Secretary has endorsed the reports without revision. When ORCA has issued a letter restricting the "Assurance" at a VA medical center, the Under Secretary is kept informed and has supported the decisions made independently by ORCA. Further,

when reports and letters are sent to a VA medical center, suitable copies are provided to other key offices after they have been issued. The present reporting relationships facilitate rather than compromise ORCA's independence.

16. At the hearing, Dr. Wendy Baldwin of the National Institutes of Health Extramural Research Office that "the door was open," implying that NIH was willing to negotiate with the VA regarding the reinstitution of the 15% add-on indirect-cost allowance for NIH research grants performed in VA laboratories. Has follow-up contact been made with NIH to discuss this matter? Please provide a report to the Subcommittees concerning the next steps to be taken to assure these negotiations are successful.

Response: Former Under Secretaries Kizer and Garthwaite both attempted to negotiate indirect cost allowances with NIH. However, NIH rejected reimbursement of indirect costs in 2001 despite a 21-year precedent (1968-89) during which time VA received such payments from NIH. Under Secretary Roswell has since written to the NIH director (with a copy to Dr. Baldwin) proposing that the two organizations negotiate indirect cost allowances. VHA has not yet received a formal response but will again contact NIH leadership this month.

17. The VA's policies for the protection of human subjects are contained in VA Manual M-3 Chapter 4. The GAO, in its 2000 report, pointed out that these policies were issued 10 to 15 years ago. In Dr. Feussner's testimony before the Subcommittee on Oversight and Investigations in September 2000, he made a commitment to update these policies in a handbook by December 2000. Has this handbook been issued?

Response: VA's policies for the protection of human subjects in research are contained in M-3, Part 1, Chapter 9, and were issued October 30, 1992. The Handbook on Human Subjects Protection is currently in the final concurrence process. It was also sent to VA and non-VA experts in the field of human subjects protection for review and comment. Based on comments received the Handbook is being revised and will be finalized in FY 2002. Although the Handbook on Protections of Human Subjects has not been issued, VA field facilities have received human studies protection training and materials from both ORD and ORCA.

18. Assuming a new human protections handbook has not be issued, how much time and effort will be needed by VAMCs to implement the provisions of the new handbook when it is issued? Will you provide a grace period for implementation? Will the Office of Research and Development provide education and training in the use of the new handbook?

Response: Virtually no additional time and effort will be needed by the VAMCs. Many of the requirements in the new handbook are good clinical practices, and the field has begun to adopt them (for example, IRBs requiring more complete information for continuing review and wording in the consent form on research-related injuries). 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. The provisions of the new handbook have been available in draft form for a year and a half; therefore, a grace period will not be necessary.

19. Does ORCA need additional resources to fulfill its role in light of its new need to evaluate the VAMCs that have been "not accredited?"

Response: The Chief Officer, ORCA, and the Under Secretary for Health agreed to the staffing for ORCA and the number of ORCA Regional Offices in the summer 1999. This commitment is represented the first two columns in the chart below. Since then there has been a steady augmentation to the staff and activation of the ORCA Regional Offices. In April 2002, the present Under Secretary for Health approved in principle the expansion of ORCA Central Office and the ORCA Regional Office staffing to level shown in the chart for FY 2003 for five Regional Offices. The resources for the full activation of five ORCA Regional Offices have been approved, while the proposal for the additional two FTE for Central Office is in process.

	Original Plan		**Current**	**Current Needs**	
Resources	**FY 2000**	**FY 2001**	**FY 2002/03**	**FY 2002**	**FY 2003**
VACO FTE	8	12	8	9	10
ORCA Regional Offices (RO)	5	6	5	5	5
ORCA RO FTE	30	36	20	25	30

The FY 2003 level of staffing for Central Office (10 FTE) and for five ORCA Regional Offices (30 FTE) should be sufficient, although the situation will remain under continuing review.

20. The rate of VAMCs receiving "not accredited" status is about 25% of those that have received a final notification. Please identify these facilities and review the actions being taken to improve their performance.

Response: The three VAMCs that have been notified of an initial "Not Accredited" status are the Northern California HCS, Pittsburgh (HD) HCS and the Providence VAMC. All have appealed and are awaiting a final determination of their accreditation status from NCQA.

When NCQA provides a preliminary notification of "Not Accredited" to a VAMC on its HRPP, the Office of Research and Development (ORD) and ORCA in Central Office simultaneously receive these reports that indicate the reasons for the designations. Since early April 2002, ORCA has followed up according to standard procedures. ORCA immediately sends a Focus Review team of one to two persons to ascertain, as best as possible, if any subjects in the research have been medically harmed or if the

policies and procedures in place are so flawed as to present immediate risk to subjects. If necessary, the Chief Officer, ORCA, will restrict the Assurance document that was negotiated with ORCA immediately so that research may be curtailed or suspended until corrective actions can be taken. The general procedure would be to follow up the Focus Review with a Systematic Post-Accreditation Review, consisting of a larger team performing a more comprehensive review.

The ORCA reviews are performance based and they take place some time after the visit of the NCQA surveyors due to the length of time between NCQA's accreditation review and visit and issuance of its findings. In that interim, the facilities may devote more attention to the research programs so that the ORCA observes an improved HRPP at the time of its visits. The research receives comprehensive attention by ORCA site visitors and the follow-up SP-AR to ascertain the safety of research subjects and to ensure that any problems or deficiencies (especially non-compliance with the regulations for the protection of human subjects) in the program are corrected. The VAMC is required to submit an Action Plan to ORCA on the SP-AR recommendations for review and approval and subsequent implementation.

When each VAMC has fulfilled the agreed upon Action Plan, ORCA will provide the VAMC with a written communication that the deficiencies have been corrected. The removal of the restriction on any Assurance will also have to have been completed. Then ORCA will notify ORD, which then will decide when to ask for a further NCQA survey.

ORCA has completed Focus Reviews and SP-ARs at all of the three VAMC/HCSs NCQA has designated as "Not Accredited." The Under Secretary for Health has issued all the SP-ARs for the Northern California VAHCS, Pittsburgh (HD) VAMC, and the Providence SP-AR. The Northern California HCS SP-AR had 23 recommendations and a Restriction on its Assurance. The Pittsburgh and Providence VAMCs received Status of Federal-wide Assurance letters that described required follow up. Pittsburgh VAMC SP-AR had five recommendations, and Providence VAMC had three. All VAMCs have to provide ORCA with Action Plans in response to the SP-AR reports. ORCA reviews and tracks these until completion by the VAMC/VAHCS.

21. In your testimony, you indicate you have taken a leadership role in mandating accreditation of VA's human research protection programs by awarding a contract to the National Committee on Quality Assurance (NCQA). How would you assess the performance of NCQA under this contract? What will be changed to make the accreditation program more responsive to the needs of the VA? If there are substantial changes in the program, will VA require NCQA to reevaluate the accreditation status awarded to the VAMCs so far? If there are changes, would it not be fair to completely reassess the accreditation of these twenty or so VAMCs? Why was the NCQA accreditation program delayed?

Response: The contract requires NCQA to develop accreditation standards (the first such standards to be developed in this country), to survey all VA facilities conducting

human subjects research every 3 years, and to determine the accreditation status for the Human Research Protection Program (HRPP) of each facility. NCQA is fulfilling the tasks identified in this contract. NCQA initiated work on this contract August 30, 2000, posted draft standards in March 2001, and conducted pilot site surveys during the spring of 2001. The first official accreditation standards were promulgated on August 1, 2001, with formal accreditation surveys beginning in September 2001. In April 2001 the Institute of Medicine (IOM) issued their report "*Preserving Public Trust: Accreditation and Human Research Participant Protection Programs.*" IOM recommended the draft NCQA standards as the strongest basis for accreditation "because they pay specific attention to quality improvement, provide flexibility in achieving performance goals and are explicit in their grounding in current regulations."

The process established by VA and NCQA to address concerns of the field will remain in place. There is a VA Advisory Committee with representatives from ORD (most with field experience), ORCA, the Ethics Office, and an Associate Chief of Staff for R&D. This Advisory Group reviews NCQA's policies, procedures and the accreditation standards. VA is adding two VISN directors to this group.

The standards will be reviewed annually to address changes in Federal regulations or to address field needs. Facilities that have accreditation with conditions will be re-reviewed within a 12-month period. The review will be based on the revised standards. Programs that have a "not accredited" status will be evaluated on the revised standards after they are directed to submit their reapplication for accreditation to NCQA.

The revised standards will not change the substance of the human protections program. The current draft revisions are designed to provide greater opportunity for "partial credit" on file review elements and other elements (so that compliance is evaluated on a more continuous scale), to streamline the standards, reduce redundancy, and reduce the total number of standards; to make the scoring and decisions about accreditation outcomes clearer and easier to understand and predict; to clarify standards through the addition of explanations and examples. The reassessment of facilities that have been accredited with conditions will come within a year of the issuance of the final revised standards.

As a part of the accreditation process, NCQA conducted quality improvement (CQI) interviews and collected CQI comments and suggestions from VAMC personnel, site surveyors and staff from NCQA and MCMC at each significant step in the development of the accreditation process. A number of themes emerged, suggesting the need for refinement of accreditation policy, sampling approaches, scoring, reporting, and specific aspects of operations. The purpose of delaying surveys scheduled for May, June, and July is to concentrate efforts on making the process refinements identified through the CQI process.

22. Before the recent notification of the first VAMC to be "not accredited" at the end of March this year, what plans did the VA have in place to bring facilities back into compliance?

Response: The responsibility for ensuring compliance with human subjects protection rests with the Facility Director. ORCA has the responsibility to address sites that are not in compliance with Federal regulations associated with the protection of human research subjects and animals. Depending on the scope and magnitude of problems found during an ORCA inspection, ORD may place a hold on funding for new research programs or projects and may also place on hold funding for existing research projects involving human subjects.

23. If a VAMC files an appeal and NCQA confirms it is still "not accredited," should the VAMC's research on human subjects continue? Under what circumstances can we be assured that veterans involved in the research are protected?

Response: The National Committee for Quality Assurance (NCQA), under contract to the VA to accredit the Human Research Protection Programs (HRPPs), has completed 23 surveys this year. The 12 VAMCs with final reports include 9 that have been notified of "Accredited with Conditions" status and three that have been notified of "Not Accredited" status. All with an initial "Not Accredited" designation have appealed the designations and are awaiting a final determination of their accreditation status from NCQA.

When NCQA provides a final notification of accreditation to a VAMC on its HRPP, ORD and ORCA in Central Office simultaneously receive NCQA final reports that indicate the reasons for the designations. ORCA reviews all of these final reports and is particularly concerned about VAMCs that receive a "Not Accredited" notification of their HRPPs. Since early April 2002, ORCA has followed up according to standard procedures. ORCA immediately sends a Focus Review team of one to two persons to ascertain as best as possible if any subjects in the research have been medically harmed or if the policies and procedures in place are so flawed as to present immediate risk to subjects. If necessary, the Chief Officer, ORCA, will restrict the Assurance document that was negotiated with ORCA immediately so that research may be curtailed or suspended until corrective actions can be taken. The general procedure would be to follow up the Focus Review with a Systematic Post-Accreditation Review (SP-AR), consisting of a larger team performing a more comprehensive review.

ORCA has performed Focus Review and SP-ARs at the three facilities on "not accredited" status so far. In one case, ORCA restricted the Assurance after the SP-AR visit such that new recruitment was suspended and other corrective requirements were imposed before the restriction could be lifted. At the other two facilities, ORCA required corrections to the program, but research was not suspended or limited.

The ORCA reviews are performance-based and take place some time after the visit of the NCQA surveyors due to the length of time between NCQA's accreditation review and visit and issuance of its findings. In that interim, the facilities may correct problems in their research programs, so that ORCA often observes an improved HRPP at the time of its visits.

Research is, therefore, not automatically suspended at VA facilities that NCQA designates as Not-Accredited. However, such NCQA findings result in immediate and comprehensive review by ORCA site visitors and follow-up to ensure the safety of research subjects and to ensure that any problems or deficiencies in the program are corrected.

24. Approximately 40 VAMCs that have a Federal-wide assurance for protecting human research subjects rely upon and already have a Memorandum of Understanding (MOU) with their academic affiliates' IRBs. The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is another organization that carries out research accreditation. If AAHRPP accredits the academic affiliate's HRPP, and therefore, its IRB, will the VA recognize and allow for reciprocity? Will the VA permit the NCQA to recognize the academic affiliate's IRB, already accredited by AAHRPP, thus avoiding a duplicate review?

Response: Yes. The Under Secretary for Health has made the determination to recognize AAHRPP's accreditation. This will permit VHA to recognize the academic affiliate's IRB provided the academic affiliate's human research protection program has had AAHRPP review and received its accreditation notice.

25. Would VA modify its contract with NCQA to allow for allowing NCQA to adopt the AAHRPP's accreditation of the academic affiliate's HRPP and IRB, if used by the VAMC? If not, why?

Response: Yes. VA has discussed a modification with NCQA to work with other accrediting organizations, to include AAHRPP, to develop one set of standards in order to avoid multiple sets of accreditation standards.

26. Are there any substantial differences between NCQA's and AAHRPP's accreditation standards, how might the VA help resolve these?

Response: The differences in the accreditation standards are significant enough that VA, as mentioned in our response to question 25, has discussed with NCQA a modification to its contract so that NCQA would work with other accrediting organizations, including AAHRPP, to develop one set of accreditation standards, thus avoiding multiple sets standards. A single set of standards, we believe, will resolve the existing differences and enhance protection of human participants in research.

27. In its 2000 report, the GAO identified the need to make resources available to VAMCs to support your human subjects research programs and other administrative functions needed to conduct a safe and effective research program. Your testimony indicates that you are now beginning this effort. Why has it taken the VA nearly two years to address this issue?

Response: ORD's efforts to provide resources to VAMC research programs and to help them identify additional streams of revenue have been ongoing for almost two

years. These efforts include a) efforts to ensure adequate funding of IRB and human studies protection activities from VA's appropriation; b) assisting VAMCs in leveraging private funds in support of research from such organizations as the pharmaceutical companies; c) efforts to recover costs from private sponsors of research for those activities generated by their sponsored research; and d) negotiating with NIH in an attempt to facilitate the VAMC research programs receiving indirect costs directly from NIH rather then the indirect costs going to either the university affiliate or the nonprofit corporations. In April 2002, through a request for proposals, ORD announced a program to assist facilities in obtaining additional resources. VA facilities with active research programs were invited to apply for one time, non-renewable funding of up to $50,000 to support their human and animal subject compliance programs. The proposals will be evaluated through a quality review process and those found to be of sufficient merit will be funded. It is estimated that funding for the programs will begin this fiscal year.

28. What has been done in the VA to identify the total resources needed by a VAMC to ensure the responsible and ethical conduct of its research programs? If and when this is known, how will you designate funds from Medical Research and Prosthetics appropriation?

Response: The Office of the Under Secretary for Health has asked for a strategic plan and an action plan from the Office of Research and Development for appropriate resourcing of human studies protection programs.

There are also some extramural funds available to research programs from such sources as overhead from non-NIH funded protocols and from recovery of cost by IRBs to review non-VA funded protocols.

Currently, the Health Economics Resource Center is analyzing the results of a study designed to estimate the total cost of operating biomedical IRBs within VA. This study assessed both IRBs run by VA only, and those based at academic affiliates that reviewed VA protocols. The study will be complete and available later this fiscal year. ORD is also attempting an ambitious improvement to the distribution methodology. This has the potential for a significant financial impact on the research programs at each VA facility. As a first step, all VA facilities conducting research have been asked to answer specific questions regarding their program. It is hoped that by mid to late summer a draft methodology will be completed and assessment of this model begun.

29. Why should the Medical and Prosthetics Research appropriation be used at all to support the administrative resources needed to conduct a VAMC's research program?

Response: Although administrative resources at VAMCs support both patient care and research activities, research funds should be used to fund administrative requirements that are solely associated with a VAMC's research program, such as, IRB review of research protocols. ORD is currently conducting a study of IRB staffing that will be complete and available later this fiscal year. The findings should enable VAMCs to

accurately assess IRB costs to be reimbursed out of the research appropriation. Use of research funds for this purpose is necessary to ensure that the medical care appropriation is available to support the primary VHA mission of providing patient care.

30. Should a VAMC rely on the non-profit research corporations to support administrative costs of VA research?

Response: Yes. VA non-profit research corporations should and do contribute to meeting the costs of the administrative functions directly related to research conducted at the hosting VAMC. VA non-profit research corporations were created for the explicit purpose of providing a flexible funding mechanism to support VA research. To that end, research corporations are available to support all facets of VA research to include providing funds for personnel, administrative support, equipment, facilities and infrastructure.

31. Kenneth Kizer, M.D., then Under Secretary for Health, in his testimony before the Subcommittee on Health and the Subcommittee on Oversight and Investigations on April 21, 1999, stated that ORCA would organizationally report directly to the Under Secretary for Health. Dr. Garthwaite confirmed this reporting arrangement in his September 28, 2000, testimony before the Oversight Subcommittee. In the VHA organizational chart, however, ORCA does not report directly to the Under Secretary. Has your policy changed and why?

Response: The Chief Officer, ORCA, has always reported to the Under Secretary for Health and, for regular monthly reports on the activities of ORCA, to the Deputy Under Secretary for Health. The most recent organizational chart may give the impression that there is a departure from this arrangement, but this is not the case. The Under Secretary for Health is always available to the Chief Officer, ORCA, to be briefed directly on various issues. The activities of ORCA are a priority concern for the Under Secretary, who has encouraged the Chief Officer to provide direct input as needed.

32. Is it true that NCQA formally requested on April 17, 2002, a suspension of its conduct of surveys of Human Research Protection Programs (HRPPs) at VAMCs? If true, please provide a copy of the request. What is VA's position on this request?

Response: Yes (see attachment). VA concurs with the request. At the further request of NCQA, the Office of Research and Development has recently extended the date for resumption of the surveyor site visits to August 26, 2002.

33. The West Los Angeles VA Medical Center's human research program was suspended in March 1999. In order to achieve its present level of recovery it has provided the needed resources and funding from its own Medical Care funds. What additional funds have been allocated to all the VA medical centers that conduct human subject research by the Office of Research and Development, or from any other source of appropriated funds, over the past three years?

Response: Over the past three years, the VA Research Office has distributed $85 million in additional administrative funds. This amount comes to about $435,000 per year per site with significant research activities.

34. What is the Office of Research and Development allocating to the field in recurring funds nationwide to cover IRB expenses? How much did this increase after the West LA suspension?

Response: Historically, the source of funding for facility and IRB costs is the VERA medical care funds in support of VA research. As indicated above, ORD is also currently providing over $30 million per year in administrative support funding. In the past three years ORD has provided over $3 million to fund NCQA. In addition, ORD is making up to $10 million in non-recurring funds available over two years for IRB related proposals and will develop an action plan that identifies the appropriate funding sources for the administration of human studies protections programs.

35. What is the classification of the finances administered by the VA research corporations? In other words, what level of government oversight do these funds require?

Response: The most appropriate way to describe the funds administered by VA non-profit corporations would be private funds that are held for a public purpose. VA non-profits are private state chartered organizations bound by state law and IRS regulations. Under the terms of the authorizing statute, corporations can accept and administer funds from any external source (i.e., non-VA appropriation) but solely to support approved VA research projects and/or education activities. VA non-profit corporations administer donations from private individuals and corporations, grants awarded by other Federal and state institutions, as well as, monies transferred from the General Post Fund. Accordingly, corporations and their operations are subject to substantial oversight. State examiners review corporation operations for compliance with state law. IRS audits and filing requirements verify continuation of the corporation's non-profit status. Federal and state entities that award grant money often have their own audit and reporting requirements that corporations must satisfy. VA officials serving as ex-officio members on the Board of Directors ensure that revenues are expended in accordance with title 38 and VA regulations. Furthermore, the corporations, though private entities, are subject to General Accounting Office (GAO) and Inspector General (IG) investigations. Finally, if a corporation is found to be administering its revenues in a manner inconsistent with the best interest of VA or in violation its statutory purpose, local VA officials, under the authority delegated by the Secretary, may take action to suspend the operations or dissolve the corporation.

36. Does VA believe the sunset date should be extended for the establishment of new research corporations and/or education foundations past the current statutory date of December 31, 2003? Please provide an explanation to justify your answer.

Response: Facilities still possess sufficient opportunity to establish non-profit research corporations. However, facilities may require additional time to establish non-profit education corporations. Both programs have been successful. However, we do not have a cleared position on the extension of this authority past December 31, 2003.

37. The Technology transfer Commercialization Act of 2000 requires each Federal agency which operates or directs one or more Federal laboratories to prepare a report on its technology transfer activities for the preceding year, "including its plans for securing intellectual property rights in laboratory innovations with commercial promise and plans for managing its intellectual property so as to advance the agency's mission and benefit the competitiveness of the United States industry;..." In concert with this requirement, please provide the following information, as specified in the attached table, regarding VA's R&D and associated technology transfer activities for the past three fiscal years (i.e., FY 1999, 2000, and 2001).

Response: Please see the attached spreadsheet.

Attachment to Question 32. Note: This request was handled strictly through electronic mail.

April 17, 2002

Ms. Brenda Hebert
Project Officer, Contract No. V101(93)P-1696
Department of Veterans Affairs
Research and Development Office
810 Vermont Avenue, NW
Washington, DC 20420

Dear Ms. Hebert:

The VAHRPAP is now fully operational. Over the past eight months, NCQA has conducted 21 surveys, and we have delivered accreditation decisions to nine VA Medical Centers and draft reports to two additional centers. We have conducted quality improvement (CQI) interviews and collected CQI comments and suggestions from VAMC personnel, site surveyors and staff from NCQA and MCMC at each significant step in the process. A number of themes have emerged,

suggesting the need for refinement of accreditation policy, sampling approaches, scoring, reporting, and specific aspects of operations. The purpose of this letter is to request permission to delay surveys currently scheduled for May and June, so that we may concentrate our efforts on making these refinements. We would resume surveys again beginning July 11. There would be no cost impact to this change in the schedule. The following details our plan.

Survey schedule
We propose to proceed with site surveys of Biloxi and Dallas, scheduled for April 25. We will continue to process survey reports and conduct PAC decisions for sites that have already been surveyed, or that will have been surveyed when the pause goes into effect. The following sites whose survey dates have been confirmed would be affected by this change in schedule: Northport, NY; White River Junction, VT; Memphis, TN; Fargo, ND; Hines, IL; Fresno, CA; Temple, TX; Leavenworth, KS; Kansas City, MO; Tuscaloosa, AL; Marion IN (which notified us today that their research program was to be closed); Leavenworth, KS; Danville, IL; Des Moines, IA; Marion, IL; Louisville, KY; Ann Arbor, MI and Asheville, NC. We propose to shift the entire schedule by 10 weeks, with minor changes as needed to accommodate holidays. No site surveys have been confirmed beyond August 2.

Activities and Deliverables during Revision Period
During the pause in surveys, NCQA proposes to conduct the following activities, and to produce the following deliverables:

1. Develop a proposal for an alternate approach to scoring file reviews, that is statistically defensible, and that meets the "reasonable person" test. This proposal will be vetted with the Program Standards Committee. These alternative approaches could include any of the following: Scoring factors as distinct elements; offering "partial credit" for elements in which the majority

of factors are present; offering partial credit for elements in which the majority of files meet the requirements.

2. Develop a proposed point system for scoring the standards, and vet it with the Program Standards Committee. This system would distribute 100 points across all the elements, and it would include threshold scores for all accreditation outcomes. We are open to developing this system for either the current version (1.1) of the standards or for the proposed new (version 1.2) standards.

3. Refine a data collection process based on the results of tests to be performed in Biloxi and Dallas, that would promote more interaction with VAMC personnel, and that would provide them with more complete information throughout the evaluation process, about their performance. Specifically, refine a data collection tool currently in draft, for the file review portion of the survey.

4. Revise the accreditation report format, based on feedback received, and to be solicited. Develop and test alternative report mock-ups with VAMCs that have already been surveyed and have received reports.

We propose to deliver all four revisions to ORD by June 15. We would expect a brief period of review, and then we would need to discuss how and when to implement the changes. NCQA proposes to implement changes to scoring, data collection procedures three weeks after ORD sign-off. We can negotiate when the new reporting formats would be effective.

Consideration for VAMCs surveyed through April, 2002
If NCQA is to consider applying scoring changes retroactively to sites surveyed through April 2002, we will need to extend the period for appealing accreditation decisions for two sites that have indicated their intent to appeal. Such a re-scoring could be most easily addressed through the appeals process for sites whose accreditation decisions are currently under appeal. For VAMCs that have not appealed accreditation decisions, NCQA could offer new scores and, if applicable, accreditation outcomes.

In summary, we are requesting approval to substitute policy development and revision based on our CQI findings, for survey activity currently scheduled for May and June. We would deliver proposed revisions to ORD by June 15 for immediate implementation, and we would resume surveys again beginning July 11. If a contract modification is required to effect this change, we will expedite its execution on our end, but we will need to know immediately, in order to manage the logistics of continuing or stopping current survey operations. We look forward to hearing from you soon.

Sincerely,

Jessica Briefer French
Assistant Vice President, Product Development

cc: Bill Judy
James Burris, M.D.

Congresswoman Carson to Dr. John Mather, Chief Research Compliance and Assurance Officer

Questions for Dr. John Mather, Chief Research Compliance and Assurance Officer

1. Your written testimony stated that research misconduct oversight is rapidly evolving as a major issue, and that the new federal research misconduct policy has been implemented. How does this policy work in conjunction with the NCQA organization in its contract to review VA research?

Answer: During the deliberations on the implementation of the Scope of Work under the NCQA contract, a decision was made to exclude work that might involve review of research misconduct procedures and processes. The focus for the accreditation program is on the protection of human subjects. Consequently, there is no NCQA standard for review of research misconduct issues.

2. Who in the VA is responsible for determining that research at a given site will be suspended? What happens to the funding for research projects in facilities that do not meet accreditation standards, or where you observe the safety of VA patients is at risk?

Answer: The usual way in which research has been, and would be suspended is when ORCA restricts the Assurance negotiated with ORCA to comply with the regulations and policies for the protection of human subjects. The restriction is based on information determined from the Focus Review visits, Systematic Post-Accreditation Review (SP-AR) visits, or Special Inquiry Force Team (SIFT) visits, or other compelling and convincing information that subjects are at risk because of flawed processes in a VA facility's Human Research Protections Program (HRPP). ORCA initiates the Focus Reviews and SP-ARs when there is a designation of "Not Accredited," so that immediate and additional facts can be ascertained about safety of subjects enrolled in research and the integrity of the HRPP. ORCA does not automatically restrict the Assurance on the basis of a designation of "Not-Accredited," but takes immediate steps to obtain current and detailed information at a facility. The restriction might result in suspension or research and/or required corrections for other part of the system until the Assurance restriction can be lifted. VA may place a hold on funds for protocols involving human subjects when a facility does not meet NCQA accreditation standards or when the safety of VA patients is believed to be at risk.

3. ORCA reports directly to and serves as the primary advisor to the Under Secretary for Health on research on safety and compliance. Considering its proactive and reactive role in oversight and investigation of human subject research and animal safety, and the fact that ORCA staff may work with and for persons they may need to investigate, is ORCA independent enough to accomplish its mission?

Answer: The Under Secretary for Health fully supports the independence of ORCA in both its proactive and reactive compliance and assurance activities. Various reports, such as those from the SIFT and the SP-AR, are prepared for the Under Secretary's signature, and in every instance, the Under Secretary has endorsed the reports without revision. When ORCA, has issued a letter restricting the "Assurance" at a VA medical center, the Under Secretary is kept informed and has supported the decisions made

independently by ORCA. Further, when reports and letters are sent to a VA medical center, suitable copies are provided to other key offices after they have been issued. The present reporting relationships facilitate rather than compromise ORCA's independence.

4. ORCA does not appear to report directly to the Under Secretary for Health, based on VHA's most recent organizational chart. Can you provide the Committees any insight into why this is the case?

Answer: The Chief Officer, ORCA, has always reported to the Under Secretary for Health and, for regular monthly reports on the activities of ORCA, to the Deputy Under Secretary for Health. The most recent organizational chart may give the impression that there is a departure from this arrangement, but this is not the case. The Under Secretary for Health is always available to the Chief Officer, ORCA, to be briefed directly on various issues. The activities of ORCA are a priority concern for the Under Secretary, who has encouraged the Chief Officer to provide direct input as needed.

FY 1999 - Total Expenditure Ranking Report

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22	664 - San Diego, CA	$9,025,638.00	$39,269,397.00	$48,295,035.00	University of California, San Diego School of Medicine	YES	5	4			2			
21	662 - San Francisco, CA	$7,581,154.00	$30,404,736.00	$37,985,890.00	University of California, San Francisco School of Medicine	YES	5	3			40			
21	640 - Palo Alto, CA	$12,429,674.00	$25,440,291.00	$37,869,965.00	Stanford University School of Medicine	YES	1	1						
05	512 - Baltimore, MD	$12,333,749.00	$15,997,896.00	$28,331,645.00	University of Maryland School of Medicine	YES								
14	584 - Iowa City, IA	$7,239,351.00	$21,058,343.00	$28,297,694.00	University of Iowa College of Medicine	YES	1	1			2			
22	691 - West Los Angeles, CA	$9,871,088.00	$17,577,608.00	$27,448,696.00	University of California, Los Angeles School of Medicine	YES	2	1						
01	689 - West Haven, CT	$10,359,321.00	$14,592,607.00	$24,951,928.00										
20	663 - Seattle, WA	$10,980,405.00	$12,324,410.00	$23,304,815.00										
01	523 - Boston, MA	$10,640,012.00	$8,916,955.00	$19,556,967.00										
11	506 - Ann Arbor, MI	$6,405,563.00	$12,627,458.00	$19,033,021.00										
20	648 - Portland, OR	$8,202,149.00	$9,952,214.00	$18,154,363.00	Oregon Health Sciences University	YES	1							
04	642 - Philadelphia, PA	$3,110,775.00	$12,554,860.00	$15,665,635.00										
17	671 - San Antonio, TX	$5,370,876.00	$10,155,111.00	$15,525,987.00	University of Texas Medical School at San Antonio	YES								
10	541 - Cleveland, OH	$6,984,190.00	$8,465,222.00	$15,449,412.00										
06	558 - Durham, NC	$9,353,067.00	$6,066,611.00	$15,419,678.00			1		1					
07	508 - Decatur, GA	$8,012,138.00	$7,323,375.00	$15,335,513.00			4	2	2					
13	618 - Minneapolis, MN	$6,209,572.00	$8,985,422.00	$15,194,994.00	University of Minnesota Medical School	YES	2	1	2		1			
07	534 - Charleston, SC	$3,470,313.00	$11,036,003.00	$14,506,316.00	Medical University of South Carolina College of Medicine	YES								
16	598 - Little Rock, AR	$4,674,285.00	$9,819,908.00	$14,494,193.00										

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12	578 - Hines, IL	$9,779,347.00	$4,712,401.00	$14,491,748.00	Medical College of Wisconsin	YES	1							
16	580 - Houston, TX	$6,510,805.00	$6,407,916.00	$12,918,721.00	Baylor College of Medicine	YES	1							
12	537 - Chicago, IL	$4,714,605.00	$7,553,006.00	$12,267,611.00			1							
19	554 - Denver, CO	$4,511,680.00	$7,685,517.00	$12,197,197.00	University of Colorado School of Medicine	YES								
12	695 - Milwaukee, WI	$3,559,845.00	$8,437,529.00	$11,997,374.00	Medical College of Wisconsin	YES								
					University of Wisconsin Medical School	YES								
22	665 - Sepulveda, CA	$5,135,130.00	$6,645,176.00	$11,780,306.00	University of California, Los Angeles School of Medicine	YES								
10	539 - Cincinnati, OH	$3,132,462.00	$8,557,629.00	$11,690,091.00										
04	646 - Pittsburgh, PA	$3,758,890.00	$7,864,969.00	$11,623,859.00			1							
09	626 - Nashville, TN	$6,175,234.00	$4,409,886.00	$10,585,120.00										
11	583 - Indianapolis, IN	$3,126,262.00	$6,799,431.00	$9,925,693.00										
18	501 - Albuquerque, NM	$6,084,086.00	$3,752,415.00	$9,836,501.00										
03	526 - Bronx, NY	$1,841,084.00	$7,860,691.00	$9,701,775.00			1							
22	600 - Long Beach, CA	$3,378,084.00	$6,240,245.00	$9,618,329.00	University of California, Irvine	YES								
08	546 - Miami, FL	$5,024,657.00	$4,269,104.00	$9,293,761.00										
01	525 - Brockton, MA	$4,033,611.00	$5,136,352.00	$9,169,963.00										
21	612 - Martinez, CA	$1,526,635.00	$7,343,444.00	$8,870,079.00	University of California, Davis School of Medicine	YES								
17	549 - Dallas, TX	$3,606,139.00	$4,646,293.00	$8,252,432.00	University of Texas Southwestern Medical School at Dallas	YES								
19	660 - Salt Lake City, UT	$3,185,161.00	$4,804,038.00	$7,989,199.00	University of Utah School of Medicine	YES								
07	521 - Birmingham, AL	$4,269,332.00	$3,495,820.00	$7,765,152.00										

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09	614 - Memphis, TN	$3,101,765.00	$4,647,123.00	$7,748,888.00	University of Tennessee College of Medicine	YES	1	1			2			
05	688 - Washington, DC	$2,415,461.00	$5,014,868.00	$7,430,329.00										
14	636 - Omaha, NE	$3,476,076.00	$3,738,900.00	$7,214,976.00										
01	518 - Bedford, MA	$5,616,585.00	$1,567,499.00	$7,184,084.00										
06	652 - Richmond, VA	$3,051,140.00	$4,131,315.00	$7,182,455.00										
12	607 - Madison, WI	$2,056,802.00	$4,876,708.00	$6,933,510.00	Medical College of Wisconsin	YES	1	1						
					University of Wisconsin Medical School	YES								
15	657 - St. Louis, MO	$2,356,041.00	$4,350,995.00	$6,707,036.00	St. Louis University School of Medicine	YES								
03	630 - New York, NY	$4,296,452.00	$2,020,714.00	$6,317,166.00										
08	573 - Gainesville, FL	$2,865,805.00	$3,076,652.00	$5,942,457.00	University of Florida College of Medicine	YES	2	1			1			
22	605 - Loma Linda, CA	$975,680.00	$4,637,964.00	$5,613,644.00			1							
09	596 - Lexington, KY	$2,171,516.00	$3,167,905.00	$5,339,421.00										
03	561 - East Orange, NJ	$3,300,035.00	$2,018,074.00	$5,318,109.00										
01	405 - White River Junction, VT	$2,718,428.00	$2,510,562.00	$5,228,990.00										
16	635 - Oklahoma City, OK	$1,744,689.00	$3,285,455.00	$5,030,144.00	University of Oklahoma College of Medicine	YES								
18	678 - Tucson, AZ	$1,850,329.00	$2,848,921.00	$4,699,250.00	University of Arizona College of Medicine	YES								
16	629 - New Orleans, LA	$2,051,819.00	$2,564,744.00	$4,616,563.00	Tulane University School of Medicine	YES	1	1			1			
					Louisiana State University School of Medicine in New orleans	YES								
02	528 - Buffalo, NY	$1,568,543.00	$2,576,093.00	$4,144,636.00										
08	673 - Tampa, FL	$2,237,192.00	$1,618,441.00	$3,855,633.00										
11	553 - Detroit, MI	$2,395,974.00	$1,249,880.00	$3,645,854.00			1	1	3					
02	500 - Albany, NY	$1,785,847.00	$1,714,997.00	$3,500,844.00										

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03	632 - Northport, NY	$1,280,674.00	$1,832,817.00	$3,113,491.00										
15	543 - Columbia, MO	$1,437,201.00	$1,671,562.00	$3,108,763.00										
15	589 - Kansas City, MO	$1,691,758.00	$1,120,744.00	$2,812,502.00										
07	509 - Augusta, GA	$1,415,955.00	$1,266,573.00	$2,682,528.00										
01	650 - Providence, RI	$1,209,854.00	$1,457,279.00	$2,667,133.00			5							
02	670 - Syracuse, NY	$1,482,806.00	$941,799.00	$2,424,605.00										
09	603 - Louisville, KY	$1,777,590.00	$608,017.00	$2,385,607.00	University of Louisville School of Medicine	YES								
08	516 - Bay Pines, FL	$1,317,006.00	$1,023,210.00	$2,340,216.00			9							
16	586 - Jackson, MS	$1,037,370.00	$791,455.00	$1,828,825.00										
21	654 - Reno, NV	$537,096.00	$1,194,673.00	$1,731,769.00										
10	552 - Dayton, OH	$466,046.00	$969,447.00	$1,435,493.00										
09	621 - Mountain Home, TN	$644,310.00	$588,685.00	$1,232,995.00										
21	459 - Honolulu, HI	$106,331.00	$1,125,750.00	$1,232,081.00										
20	531 - Boise, ID	$1,054,987.00	$148,112.00	$1,203,099.00										
03	527 - Brooklyn, NY	$757,655.00	$422,792.00	$1,180,447.00			2							
01	608 - Manchester, NH	$643,130.00	$406,224.00	$1,049,354.00										
18	644 - Phoenix, AZ	$256,829.00	$652,831.00	$909,660.00	University of Arizona College of Medicine	YES								
07	544 - Columbia, SC	$773,991.00	$129,437.00	$903,428.00										
08	672 - San Juan, PR	$350,285.00	$382,166.00	$732,451.00										
16	667 - Shreveport, LA	$455,694.00	$179,604.00	$635,298.00	Louisiana State University School of Medicine in Shreveport	YES								
					Louisiana Tech University*	YES								
04	595 - Lebanon, PA	$123,087.00	$485,211.00	$608,298.00										
17	674 - Temple, TX	$171,951.00	$341,766.00	$513,717.00										
04	542 - Coatesville, PA	$178,527.00	$217,538.00	$396,065.00										
18	504 - Amarillo, TX	$114,427.00	$268,458.00	$382,885.00			1							
09	581 - Huntington, WV	$146,678.00	$211,204.00	$357,882.00										
15	452 - Wichita, KS	$161,686.00	$195,246.00	$356,932.00										

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13	438 - Sioux Falls, SD	$81,298.00	$244,159.00	$325,457.00										
21	570 - Fresno, CA	$64,346.00	$228,601.00	$292,947.00	University of California, San Francisco School of Medicine	YES								
06	590 - Hampton, VA	$283,162.00	$0.00	$283,162.00										
07	679 - Tuscaloosa, AL	$76,998.00	$156,504.00	$233,502.00										
13	437 - Fargo, ND	$69,289.00	$158,462.00	$227,751.00										
06	658 - Salem, VA	$48,609.00	$71,697.00	$120,306.00										
03	620 - Montrose, NY	$37,732.00	$76,848.00	$114,580.00										
06	637 - Asheville, NC	$64,909.00	$40,410.00	$105,319.00										
07	619 - Montgomery, AL	$97,445.00	$0.00	$97,445.00										
06	659 - Salisbury, NC	$62,029.00	$31,007.00	$93,036.00										
15	677 - Topeka, KS	$71,075.00	$6,779.00	$77,854.00										
11	550 - Danville, IL	$0.00	$52,394.00	$52,394.00										
15	609 - Marion, IL	$0.00	$51,301.00	$51,301.00										
11	610 - Marion, IN	$27,600.00	$0.00	$27,600.00	St. Louis University School of Medicine	YES								
22	593 - Las Vegas, NV	$0.00	$24,827.00	$24,827.00										
02	514 - Bath, NY	$20,047.00	$0.00	$20,047.00										
13	568 - Fort Meade, SD	$0.00	$12,288.00	$12,288.00										
08	548 - West Palm Beach, FL	$0.00	$9,803.00	$9,803.00										
04	540 - Clarksburg, WV	$9,197.00	$0.00	$9,197.00										
07	557 - Dublin, GA	$0.00	$5,862.00	$5,862.00										
11	515 - Battle Creek, MI	$0.00	$1,136.00	$1,136.00										
16	520 - Biloxi, MS	$904.00	$0.00	$904.00	Tulane University School of Medicine	YES								
01	402 - Togus, ME	$0.00	$0.00	$0.00										

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01	631 - Northampton, MA	$0.00	$0.00	$0.00										
02	532 - Canandaigua, NY	$0.00	$0.00	$0.00										
03	533 - Castle Point, NY	$0.00	$0.00	$0.00										
04	460 - Wilmington, DE	$0.00	$0.00	$0.00	University of Maryland School of Medicine	YES								
04	503 - Altoona, PA	$0.00	$0.00	$0.00										
04	529 - Butler, PA	$0.00	$0.00	$0.00										
04	562 - Erie, PA	$0.00	$0.00	$0.00										
04	693 - Wilkes-Barre, PA	$0.00	$0.00	$0.00										
05	613 - Martinsburg, WV	$0.00	$0.00	$0.00										
06	517 - Beckley, WV	$0.00	$0.00	$0.00										
06	565 - Fayetteville, NC	$0.00	$0.00	$0.00										
09	622 - Murfreesboro, TN	$0.00	$0.00	$0.00										
10	538 - Chillicothe, OH	$0.00	$0.00	$0.00										
10	757 - Columbus, OPC, OH	$0.00	$0.00	$0.00										
11	655 - Saginaw, MI	$0.00	$0.00	$0.00										
12	585 - Iron Mountain, MI	$0.00	$0.00	$0.00	University of Wisconsin Medical School	YES								
					Medical College of Wisconsin	YES								
12	676 - Tomah, WI	$0.00	$0.00	$0.00	University of Wisconsin Medical School	YES								
					Medical College of Wisconsin	YES								
13	656 - St. Cloud, MN	$0.00	$0.00	$0.00										
14	555 - Des Moines, IA	$0.00	$0.00	$0.00	University of Iowa College of Medicine	YES								

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14	574 - Grand Island, NE	$0.00	$0.00	$0.00										
14	592 - Knoxville, IA	$0.00	$0.00	$0.00										
14	597 - Lincoln, NE	$0.00	$0.00	$0.00										
15	647 - Poplar Bluff, MO	$0.00	$0.00	$0.00										
16	502 - Alexandria, LA	$0.00	$0.00	$0.00	Tulane University School of Medicine	YES								
16	564 - Fayetteville, AR	$0.00	$0.00	$0.00										
16	623 - Muskogee, OK	$0.00	$0.00	$0.00	University of Oklahoma College of Medicine	YES								
17	522 - Bonham, TX	$0.00	$0.00	$0.00										
18	519 - Big Spring, TX	$0.00	$0.00	$0.00										
18	649 - Prescott, AZ	$0.00	$0.00	$0.00										
18	756 - El Paso, TX	$0.00	$0.00	$0.00										
19	436 - Fort Harrison, MT	$0.00	$0.00	$0.00	University of Utah School of Medicine	YES								
19	442 - Cheyenne, WY	$0.00	$0.00	$0.00										
19	567 - Fort Lyon, CO	$0.00	$0.00	$0.00										
19	575 - Grand Junction, CO	$0.00	$0.00	$0.00										
19	666 - Sheridan, WY	$0.00	$0.00	$0.00										
20	653 - Roseburg, OR	$0.00	$0.00	$0.00										
20	668 - Spokane, WA	$0.00	$0.00	$0.00										
20	687 - Walla Walla, WA	$0.00	$0.00	$0.00										
20	692 - White City, OR	$0.00	$0.00	$0.00										
TOTAL		$308,250,112.00	$480,612,777.00	$788,862,889.00										

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22	664 - San Diego, CA	$9,410,744.00	$42,638,876.00	$52,049,620.00	University of California, San Diego School of Medicine	YES	11	3			7			
21	662 - San Francisco, CA	$9,841,756.00	$35,048,298.00	$44,890,054.00	University of California, San Francisco School of Medicine	YES	6	2			3			
21	640 - Palo Alto, CA	$12,482,155.00	$19,399,877.00	$31,882,032.00	Stanford University School of Medicine	YES	2	1						
14	584 - Iowa City, IA	$7,241,283.00	$22,241,344.00	$29,482,627.00	University of Iowa College of Medicine	YES	1	1			1			
22	691 - West Los Angeles, CA	$10,349,696.00	$16,080,305.00	$26,430,001.00	University of California, Los Angeles School of Medicine	YES	14	9	2		7			
20	663 - Seattle, WA	$9,547,267.00	$16,393,779.00	$25,941,046.00										
05	512 - Baltimore, MD	$11,354,968.00	$14,061,406.00	$25,416,374.00	University of Maryland School of Medicine	YES	1	1	2					
01	689 - West Haven, CT	$11,020,019.00	$14,211,453.00	$25,231,472.00			2	1	1					
11	506 - Ann Arbor, MI	$7,197,710.00	$16,549,456.00	$23,747,166.00										
20	648 - Portland, OR	$8,626,325.00	$14,760,736.00	$23,387,061.00	Oregon Health Sciences University	YES	4	4			1			
17	671 - San Antonio, TX	$6,298,947.00	$16,050,654.00	$22,349,601.00	University of Texas Medical School at San Antonio	YES	2							
06	558 - Durham, NC	$11,911,223.00	$6,650,365.00	$18,561,588.00			3							
07	508 - Decatur, GA	$6,604,615.00	$10,832,931.00	$17,437,546.00			1	1						
10	541 - Cleveland, OH	$7,331,893.00	$10,061,122.00	$17,393,015.00										
01	523 - Boston, MA	$9,903,130.00	$6,961,071.00	$16,864,201.00			2	2	3		1			
04	642 - Philadelphia, PA	$3,581,638.00	$13,125,843.00	$16,707,481.00										
13	618 - Minneapolis, MN	$6,128,209.00	$10,168,179.00	$16,296,388.00	University of Minnesota Medical School	YES	1	1						
16	598 - Little Rock, AR	$5,143,614.00	$11,144,567.00	$16,288,181.00										
07	534 - Charleston, SC	$3,412,518.00	$10,851,926.00	$14,264,444.00	Medical University of South Carolina College of Medicine	YES								

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FY 2000 - Total Expenditure Ranking Report

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12	578 - Hines, IL	$9,306,344.00	$4,771,877.00	$14,078,221.00	Medical College of Wisconsin	YES	1	1	1					
16	580 - Houston, TX	$7,647,699.00	$6,289,140.00	$13,936,839.00	Baylor College of Medicine	YES	5	4			2			
04	646 - Pittsburgh, PA	$3,956,505.00	$9,021,667.00	$12,978,172.00										
10	539 - Cincinnati, OH	$3,672,407.00	$8,610,199.00	$12,282,606.00			1	1	1					
03	526 - Bronx, NY	$2,466,184.00	$9,485,290.00	$11,951,474.00										
12	695 - Milwaukee, WI	$3,809,932.00	$7,974,008.00	$11,783,940.00	Medical College of Wisconsin	YES								
					University of Wisconsin Medical School	YES								
22	665 - Sepulveda, CA	$4,663,778.00	$6,936,428.00	$11,600,206.00	University of California, Los Angeles School of Medicine	YES								
19	554 - Denver, CO	$5,151,255.00	$6,284,718.00	$11,435,973.00	University of Colorado School of Medicine	YES	3	2	1					
09	614 - Memphis, TN	$3,746,502.00	$7,395,476.00	$11,141,978.00	University of Tennessee College of Medicine	YES								
12	537 - Chicago, IL	$5,915,453.00	$4,579,634.00	$10,495,087.00										
08	546 - Miami, FL	$4,903,435.00	$4,714,346.00	$9,617,781.00										
01	525 - Brockton, MA	$3,588,050.00	$5,913,074.00	$9,501,124.00										
09	626 - Nashville, TN	$5,769,583.00	$3,562,685.00	$9,332,268.00			2	1			1			
22	600 - Long Beach, CA	$3,266,803.00	$5,762,529.00	$9,029,332.00	University of California, Irvine	YES								
17	549 - Dallas, TX	$3,197,421.00	$5,262,120.00	$8,459,541.00	University of Texas Southwestern Medical School at Dallas	YES	1	1						
18	501 - Albuquerque, NM	$5,800,154.00	$2,256,372.00	$8,056,526.00										
11	583 - Indianapolis, IN	$3,023,269.00	$5,016,270.00	$8,039,539.00			4							
01	518 - Bedford, MA	$6,093,329.00	$1,943,448.00	$8,036,777.00										
21	612 - Martinez, CA	$1,715,917.00	$6,316,935.00	$8,032,852.00	University of California, Davis School of Medicine	YES								

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08	573 - Gainesville, FL	$2,729,822.00	$5,115,888.00	$7,845,710.00	University of Florida College of Medicine	YES	1							
05	688 - Washington, DC	$2,340,855.00	$5,260,453.00	$7,601,308.00										
06	652 - Richmond, VA	$2,431,681.00	$4,958,762.00	$7,390,443.00										
19	660 - Salt Lake City, UT	$3,055,487.00	$4,076,435.00	$7,131,922.00	University of Utah School of Medicine	YES								
22	605 - Loma Linda, CA	$901,154.00	$5,876,508.00	$6,777,662.00			3	3						
14	636 - Omaha, NE	$3,289,256.00	$3,403,575.00	$6,692,831.00										
12	607 - Madison, WI	$2,083,735.00	$4,266,653.00	$6,350,388.00	Medical College of Wisconsin	YES								
					University of Wisconsin Medical School	YES								
03	630 - New York, NY	$2,575,697.00	$3,679,533.00	$6,255,230.00										
03	561 - East Orange, NJ	$3,564,774.00	$2,266,696.00	$5,831,470.00										
09	596 - Lexington, KY	$2,464,707.00	$3,247,709.00	$5,712,416.00										
01	405 - White River Junction, VT	$2,875,470.00	$2,798,611.00	$5,674,081.00										
07	521 - Birmingham, AL	$3,848,621.00	$1,806,876.00	$5,655,497.00										
18	678 - Tucson, AZ *	$1,858,558.00	$3,573,954.00	$5,432,512.00	University of Arizona College of Medicine	YES	1	1						
16	629 - New Orleans, LA	$2,115,452.00	$2,861,266.00	$4,976,718.00	Tulane University School of Medicine	YES	4	4	1		2			
					Louisiana State University School of Medicine in New orleans	YES								
11	553 - Detroit, MI	$2,428,995.00	$2,280,181.00	$4,709,176.00										
16	635 - Oklahoma City, OK	$1,771,570.00	$2,931,031.00	$4,702,601.00	University of Oklahoma College of Medicine	YES	1					1,000 k (?%)		
15	657 - St. Louis, MO	$1,657,908.00	$2,581,728.00	$4,239,636.00	St. Louis University School of Medicine	YES								
01	650 - Providence, RI	$1,057,881.00	$2,975,273.00	$4,033,154.00										
08	673 - Tampa, FL	$2,450,491.00	$1,461,220.00	$3,911,711.00			3							

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02	528 - Buffalo, NY	$1,420,015.00	$2,302,655.00	$3,722,670.00										
02	670 - Syracuse, NY	$1,564,233.00	$1,656,340.00	$3,220,573.00										
15	589 - Kansas City, MO	$1,462,262.00	$1,402,237.00	$2,864,499.00										
07	509 - Augusta, GA	$1,375,806.00	$1,423,688.00	$2,799,494.00										
09	603 - Louisville, KY	$1,897,830.00	$788,829.00	$2,686,659.00	University of Louisville School of Medicine	YES								
02	500 - Albany, NY	$1,741,043.00	$944,925.00	$2,685,968.00			1							
15	543 - Columbia, MO	$1,071,011.00	$1,483,266.00	$2,554,277.00										
03	632 - Northport, NY	$1,850,841.00	$656,702.00	$2,507,543.00										
08	516 - Bay Pines, FL	$1,242,660.00	$1,022,680.00	$2,265,340.00										
16	586 - Jackson, MS	$1,379,603.00	$881,443.00	$2,261,046.00										
21	459 - Honolulu, HI	$392,087.00	$1,242,310.00	$1,634,397.00										
21	654 - Reno, NV	$358,554.00	$1,237,460.00	$1,596,014.00										
03	527 - Brooklyn, NY	$1,011,488.00	$388,402.00	$1,399,890.00										
20	531 - Boise, ID	$1,174,604.00	$195,116.00	$1,369,720.00			1							
18	644 - Phoenix, AZ	$393,494.00	$818,134.00	$1,211,628.00	University of Arizona College of Medicine	YES								
09	621 - Mountain Home, TN	$619,093.00	$404,640.00	$1,023,733.00										
18	504 - Amarillo, TX	$73,616.00	$878,625.00	$952,241.00										
01	608 - Manchester, NH	$499,505.00	$363,683.00	$863,188.00										
07	544 - Columbia, SC	$635,289.00	$139,465.00	$774,754.00										
08	672 - San Juan, PR	$367,778.00	$405,775.00	$773,553.00										
10	552 - Dayton, OH	$561,072.00	$170,395.00	$731,467.00			1							
16	667 - Shreveport, LA	$518,160.00	$160,701.00	$678,861.00	Louisiana State University School of Medicine in Shreveport	YES								
					Louisiana Tech University*	YES								
17	674 - Temple, TX	$194,291.00	$471,724.00	$666,015.00			1							
04	542 - Coatesville, PA	$114,902.00	$473,258.00	$588,160.00										
04	595 - Lebanon, PA	$125,894.00	$363,261.00	$489,155.00										
13	438 - Sioux Falls, SD	$29,189.00	$445,535.00	$474,724.00										

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09	581 - Huntington, WV	$66,193.00	$322,792.00	$388,985.00										
07	679 - Tuscaloosa, AL	$102,510.00	$233,310.00	$335,820.00										
21	570 - Fresno, CA	$169,940.00	$112,409.00	$282,349.00	University of California, San Francisco School of Medicine	YES								
15	452 - Wichita, KS	$171,499.00	$109,173.00	$280,672.00										
06	590 - Hampton, VA	$266,472.00	$233.00	$266,705.00										
06	658 - Salem, VA	$68,895.00	$170,690.00	$239,585.00										
13	437 - Fargo, ND	$151,132.00	$47,703.00	$198,835.00										
03	620 - Montrose, NY	$40,685.00	$118,634.00	$159,319.00										
22	593 - Las Vegas, NV	$0.00	$158,679.00	$158,679.00										
06	659 - Salisbury, NC	$103,235.00	$16,865.00	$120,100.00										
06	637 - Asheville, NC	$53,600.00	$18,157.00	$71,757.00										
15	677 - Topeka, KS	$40,000.00	$27,593.00	$67,593.00										
15	609 - Marion, IL	$0.00	$67,334.00	$67,334.00	St. Louis University School of Medicine	YES								
14	555 - Des Moines, IA	$0.00	$63,700.00	$63,700.00	University of Iowa College of Medicine	YES								
11	550 - Danville, IL	$8,822.00	$53,891.00	$62,713.00										
04	540 - Clarksburg, WV	$39,612.00	$10,500.00	$50,112.00										
16	623 - Muskogee, OK	$0.00	$34,981.00	$34,981.00	University of Oklahoma College of Medicine	YES								
11	610 - Marion, IN	$23,135.00	$0.00	$23,135.00										
08	548 - West Palm Beach, FL	$2,410.00	$15,826.00	$18,236.00										
16	520 - Biloxi, MS	$847.00	$11,067.00	$11,914.00	Tulane University School of Medicine	YES								
TOTAL		**$313,967,151.00**	**$507,065,542.00**	**$821,032,693.00**										

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21	662 - San Francisco, CA	$9,500,941.00	$46,854,966.00	$56,355,907.00	University of California, San Francisco School of Medicine	YES	11	2			2			
22	664 - San Diego, CA	$9,581,100.00	$46,440,946.00	$56,022,046.00	University of California, San Diego School of Medicine	YES	17	8			11			
21	640 - Palo Alto, CA	$16,380,957.00	$34,419,111.00	$50,800,068.00	Stanford University School of Medicine	YES	5	5			20	37,561 (28%)		
05	512 - Baltimore, MD	$12,214,719.00	$24,956,362.00	$37,171,081.00	University of Maryland School of Medicine	YES	2							
14	584 - Iowa City, IA	$6,925,380.00	$24,326,344.00	$31,251,724.00	University of Iowa College of Medicine	YES	4	3			5			
22	691 - West Los Angeles, CA	$11,996,805.00	$19,085,076.00	$31,081,881.00	University of California, Los Angeles School of Medicine	YES	6	6			4			
01	689 - West Haven, CT	$10,494,467.00	$20,277,423.00	$30,771,890.00			4	3	1					
17	671 - San Antonio, TX	$6,764,370.00	$22,686,990.00	$29,451,360.00	University of Texas Medical School at San Antonio	YES	2	1			1			
11	506 - Ann Arbor, MI	$7,941,020.00	$18,596,300.00	$26,537,320.00			2							
20	663 - Seattle, WA	$11,866,288.00	$14,446,969.00	$26,313,257.00			1	1						
20	648 - Portland, OR	$9,039,700.00	$15,564,914.00	$24,604,614.00	Oregon Health Sciences University	YES	4	2			1			
13	618 - Minneapolis, MN	$6,706,618.00	$12,893,899.00	$19,600,517.00	University of Minnesota Medical School	YES	3	1			1			
16	598 - Little Rock, AR	$4,368,121.00	$14,861,634.00	$19,229,755.00			1							
07	508 - Decatur, GA	$7,519,147.00	$11,493,031.00	$19,012,178.00			2	1						
06	558 - Durham, NC	$11,995,401.00	$6,445,028.00	$18,440,429.00			2	1						
08	573 - Gainesville, FL	$3,611,505.00	$13,191,860.00	$16,803,365.00	University of Florida College of Medicine	YES	1	1						
16	580 - Houston, TX	$8,646,896.00	$7,971,890.00	$16,618,786.00	Baylor College of Medicine	YES	4	4			2			
04	642 - Philadelphia, PA	$4,607,198.00	$11,950,348.00	$16,557,546.00										

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10	541 - Cleveland, OH	$7,423,031.00	$9,128,850.00	$16,551,881.00			9	6	3					
04	646 - Pittsburgh, PA	$5,834,458.00	$10,681,487.00	$16,515,945.00			4	1	1					
12	578 - Hines, IL	$9,459,658.00	$6,178,218.00	$15,637,876.00	Medical College of Wisconsin	YES	4	4	4					
12	537 - Chicago, IL	$6,423,579.00	$8,295,830.00	$14,719,409.00			1	1	2					
01	523 - Boston, MA	$9,406,725.00	$4,695,350.00	$14,102,075.00										
10	539 - Cincinnati, OH	$3,735,599.00	$10,247,036.00	$13,982,635.00										
12	695 - Milwaukee, WI	$3,805,698.00	$10,035,587.00	$13,841,285.00	Medical College of Wisconsin	YES	1	1			1			
					University of Wisconsin Medical School	YES								
09	626 - Nashville, TN	$5,724,484.00	$6,641,678.00	$12,366,162.00			1	1						
18	501 - Albuquerque, NM	$9,124,021.00	$2,816,002.00	$11,940,023.00										
03	526 - Bronx, NY	$1,911,481.00	$9,844,231.00	$11,755,712.00										
07	534 - Charleston, SC	$4,005,888.00	$7,654,324.00	$11,660,212.00	Medical University of South Carolina College of Medicine	YES								
22	665 - Sepulveda, CA	$5,379,777.00	$6,007,611.00	$11,387,388.00	University of California, Los Angeles School of Medicine	YES								
09	614 - Memphis, TN	$3,507,128.00	$7,609,264.00	$11,116,392.00	University of Tennessee College of Medicine	YES	1	1			1			
11	583 - Indianapolis, IN	$2,587,379.00	$7,776,109.00	$10,363,488.00			2							
14	636 - Omaha, NE	$3,907,669.00	$5,496,414.00	$9,404,083.00			1	1						
08	546 - Miami, FL	$5,316,844.00	$3,992,600.00	$9,309,444.00										
01	518 - Bedford, MA	$6,945,393.00	$2,330,326.00	$9,275,719.00										
19	554 - Denver, CO	$5,579,216.00	$3,430,027.00	$9,009,243.00	University of Colorado School of Medicine	YES								
17	549 - Dallas, TX	$2,942,295.00	$5,869,962.00	$8,812,257.00	University of Texas Southwestern Medical School at Dallas	YES	1	1						
19	660 - Salt Lake City, UT	$3,184,121.00	$5,389,077.00	$8,573,198.00	University of Utah School of Medicine	YES								

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01	525 - Brockton, MA	$3,376,427.00	$4,732,004.00	$8,108,431.00										
21	612 - Martinez, CA	$2,226,716.00	$5,645,712.00	$7,872,428.00	University of California, Davis School of Medicine	YES	2	2	2					
12	607 - Madison, WI	$1,928,161.00	$5,916,698.00	$7,844,859.00	Medical College of Wisconsin	YES	1	1			2			
					University of Wisconsin Medical School	YES								
03	630 - New York, NY	$2,761,483.00	$5,033,535.00	$7,795,018.00										
05	688 - Washington, DC	$2,134,009.00	$5,313,951.00	$7,447,960.00										
06	652 - Richmond, VA	$2,153,095.00	$5,289,369.00	$7,442,464.00										
22	600 - Long Beach, CA	$5,008,480.00	$2,193,346.00	$7,201,826.00	University of California, Irvine	YES								
07	521 - Birmingham, AL	$4,353,114.00	$2,688,477.00	$7,041,591.00			8	4			4			
22	605 - Loma Linda, CA	$832,509.00	$4,788,499.00	$5,621,008.00										
02	528 - Buffalo, NY	$1,304,896.00	$4,271,744.00	$5,576,640.00			1	1			1			
16	629 - New Orleans, LA	$2,107,129.00	$3,267,720.00	$5,374,849.00	Tulane University School of Medicine	YES	4	2	1		1			
					Louisiana State University School of Medicine in New Orleans	YES								
09	596 - Lexington, KY	$2,286,503.00	$3,060,399.00	$5,346,902.00										
16	635 - Oklahoma City, OK	$1,682,896.00	$3,582,624.00	$5,265,520.00	University of Oklahoma College of Medicine	YES	2	1						
11	553 - Detroit, MI	$3,035,020.00	$2,171,394.00	$5,206,414.00			2	2	2					
01	405 - White River Junction, VT	$2,503,515.00	$2,665,088.00	$5,168,603.00			1							
08	673 - Tampa, FL	$2,924,485.00	$1,779,470.00	$4,703,955.00			1							
01	650 - Providence, RI	$986,065.00	$3,471,320.00	$4,457,385.00										
15	657 - St. Louis, MO	$1,589,154.00	$2,750,083.00	$4,339,237.00	St. Louis University School of Medicine	YES								
15	543 - Columbia, MO	$986,650.00	$3,144,015.00	$4,130,665.00			1	1						

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03	561 - East Orange, NJ	$1,840,314.00	$2,268,805.00	$4,109,119.00			1	1						
02	500 - Albany, NY	$1,770,755.00	$1,476,578.00	$3,247,333.00										
09	603 - Louisville, KY	$1,797,051.00	$964,179.00	$2,761,230.00	University of Louisville School of Medicine	YES								
07	509 - Augusta, GA	$1,564,891.00	$1,136,677.00	$2,701,568.00			4	3			2			
15	589 - Kansas City, MO	$1,086,533.00	$1,540,873.00	$2,627,406.00			1	1	1					
08	516 - Bay Pines, FL	$1,322,975.00	$1,074,806.00	$2,397,781.00			1							
03	632 - Northport, NY	$1,674,105.00	$494,280.00	$2,168,385.00			1	1						
16	586 - Jackson, MS	$1,085,596.00	$904,290.00	$1,989,886.00										
18	644 - Phoenix, AZ	$526,629.00	$1,319,379.00	$1,846,008.00	University of Arizona College of Medicine	YES								
21	654 - Reno, NV	$394,536.00	$1,427,827.00	$1,822,363.00										
02	670 - Syracuse, NY	$1,160,223.00	$554,115.00	$1,714,338.00										
20	531 - Boise, ID	$1,090,871.00	$534,940.00	$1,625,811.00										
04	542 - Coatesville, PA	$17,286.00	$1,537,941.00	$1,555,227.00										
21	459 - Honolulu, HI	$517,210.00	$986,664.00	$1,503,874.00										
18	678 - Tucson, AZ	$464,409.00	$884,602.00	$1,349,011.00	University of Arizona College of Medicine	YES	1	1						
03	527 - Brooklyn, NY	$1,124,119.00	$214,260.00	$1,338,379.00										
09	621 - Mountain Home, TN	$880,838.00	$406,642.00	$1,287,480.00										
08	672 - San Juan, PR	$534,887.00	$563,216.00	$1,098,103.00										
18	504 - Amarillo, TX	$9,027.00	$1,081,536.00	$1,090,563.00			1	1	1					
17	674 - Temple, TX	$170,316.00	$831,360.00	$1,001,676.00										
07	544 - Columbia, SC	$681,455.00	$124,395.00	$805,850.00			1							
10	552 - Dayton, OH	$540,315.00	$203,193.00	$743,508.00										
16	667 - Shreveport, LA	$593,907.00	$66,811.00	$660,718.00	Louisiana State University School of Medicine in Shreveport	YES								
					Louisiana Tech University*	YES								

* CTAA executed due to DAP employees but no official medical school affiliation

FY 2001 - Total Expenditure Ranking Report

VISN	MC	VA	ExtraVA	Total	Affiliate	CTAA	# of Invention Disclosures	VA Retained Rights	# of Patents filed by VA	Associated Royalties	# of Patents filed by Affiliate	% VA - CTAA Royalty	# of patents filed where VA declined	Any consideration to VA from patent holder
01	608 - Manchester, NH	$400,977.00	$100,000.00	$500,977.00										
04	595 - Lebanon, PA	$135,398.00	$331,956.00	$467,354.00										
07	679 - Tuscaloosa, AL	$150,370.00	$293,699.00	$444,069.00										
06	659 - Salisbury, NC	$419,443.00	$19,249.00	$438,692.00										
06	658 - Salem, VA	$198,949.00	$207,451.00	$406,400.00										
21	570 - Fresno, CA	$68,671.00	$266,505.00	$335,176.00	University of California, San Francisco School of Medicine	YES								
06	590 - Hampton, VA	$281,005.00	$900.00	$281,905.00										
14	555 - Des Moines, IA	$107,079.00	$124,724.00	$231,803.00	University of Iowa College of Medicine	YES								
13	438 - Sioux Falls, SD	$0.00	$228,695.00	$228,695.00										
09	581 - Huntington, WV	$45,347.00	$99,737.00	$145,084.00										
22	593 - Las Vegas, NV	$0.00	$142,404.00	$142,404.00										
03	620 - Montrose, NY	$40,466.00	$84,683.00	$125,149.00										
13	437 - Fargo, ND	$100,220.00	$24,000.00	$124,220.00										
08	548 - West Palm Beach, FL	$83,670.00	$17,140.00	$100,810.00										
15	609 - Marion, IL	$65,596.00	$25,367.00	$90,963.00	St. Louis University School of Medicine	YES								
06	637 - Asheville, NC	$5,099.00	$50,228.00	$55,327.00										
13	568 - Fort Meade, SD	$12,830.00	$8,250.00	$21,080.00										
07	557 - Dublin, GA	$16,458.00	$0.00	$16,458.00										
05	613 - Martinsburg, WV	$16,170.00	$0.00	$16,170.00										
11	610 - Marion, IN	$10,381.00	$0.00	$10,381.00										
13	656 - St. Cloud, MN	$8,700.00	$0.00	$8,700.00										
16	520 - Biloxi, MS	$2,680.00	$5,326.00	$8,006.00	Tulane University School of Medicine	YES								
16	623 - Muskogee, OK	$1,074.00	$0.00	$1,074.00	University of Oklahoma College of Medicine	YES								

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FY 2001 - Total Expenditure Ranking Report

VISN	MC	VA	ExtraVA	Total	Affiliate	CTAA	# of Invention Disclosures	VA Retained Rights	# of Patents filed by VA	Associated Royalties	# of Patents filed by Affiliate	% VA - CTAA Royalty	# of patents filed where VA declined	Any consideration to VA from patent holder
12	676 - Tomah, WI	$0.00	$0.00	$0.00	University of Wisconsin Medical School	YES								
					Medical College of Wisconsin	YES								
14	574 - Grand Island, NE	$0.00	$0.00	$0.00										
14	592 - Knoxville, IA	$0.00	$0.00	$0.00										
14	597 - Lincoln, NE	$0.00	$0.00	$0.00										
15	452 - Wichita, KS	$0.00	$0.00	$0.00										
15	647 - Poplar Bluff, MO	$0.00	$0.00	$0.00										
15	677 - Topeka, KS	$0.00	$0.00	$0.00										
16	502 - Alexandria, LA	$0.00	$0.00	$0.00	Tulane University School of Medicine	YES								
16	564 - Fayetteville, AR	$0.00	$0.00	$0.00										
17	522 - Bonham, TX	$0.00	$0.00	$0.00										
18	519 - Big Spring, TX	$0.00	$0.00	$0.00										
18	649 - Prescott, AZ	$0.00	$0.00	$0.00										
18	756 - El Paso, TX	$0.00	$0.00	$0.00										
19	436 - Fort Harrison, MT	$0.00	$0.00	$0.00	University of Utah School of Medicine	YES								
19	442 - Cheyenne, WY	$0.00	$0.00	$0.00										
19	567 - Fort Lyon, CO	$0.00	$0.00	$0.00										
19	575 - Grand Junction, CO	$0.00	$0.00	$0.00										
19	666 - Sheridan, WY	$0.00	$0.00	$0.00										
20	653 - Roseburg, OR	$0.00	$0.00	$0.00										
20	668 - Spokane, WA	$0.00	$0.00	$0.00										
20	687 - Walla Walla, WA	$0.00	$0.00	$0.00										
20	692 - White City, OR	$0.00	$0.00	$0.00										
TOTAL		$333,564,215.00	$594,976,205.00	$928,540,420.00										

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FY 2001 - Total Expenditure Ranking Report

VISN	MC	VA	ExtraVA	Total	Affiliate	CTAA	# of Invention Disclosures	VA Retained Rights	# of Patents filed by VA	Associated Royalties	# of Patents filed by Affiliate	% VA - CTAA Royalty	# of patents filed where VA declined	Any consideration to VA from patent holder
01	402 - Togus, ME	$0.00	$0.00	$0.00										
01	631 - Northampton, MA	$0.00	$0.00	$0.00										
02	514 - Bath, NY	$0.00	$0.00	$0.00										
02	532 - Canandaigua, NY	$0.00	$0.00	$0.00										
03	533 - Castle Point, NY	$0.00	$0.00	$0.00										
04	460 - Wilmington, DE	$0.00	$0.00	$0.00	University of Maryland School of Medicine	YES								
04	503 - Altoona, PA	$0.00	$0.00	$0.00										
04	529 - Butler, PA	$0.00	$0.00	$0.00										
04	540 - Clarksburg, WV	$0.00	$0.00	$0.00										
04	562 - Erie, PA	$0.00	$0.00	$0.00										
04	693 - Wilkes-Barre, PA	$0.00	$0.00	$0.00										
06	517 - Beckley, WV	$0.00	$0.00	$0.00										
06	565 - Fayetteville, NC	$0.00	$0.00	$0.00										
07	619 - Montgomery, AL	$0.00	$0.00	$0.00										
09	622 - Murfreesboro, TN	$0.00	$0.00	$0.00										
10	538 - Chillicothe, OH	$0.00	$0.00	$0.00										
10	757 - Columbus, OPC, OH	$0.00	$0.00	$0.00										
11	515 - Battle Creek, MI	$0.00	$0.00	$0.00										
11	550 - Danville, IL	$0.00	$0.00	$0.00										
11	655 - Saginaw, MI	$0.00	$0.00	$0.00										
12	585 - Iron Mountain, MI	$0.00	$0.00	$0.00	University of Wisconsin Medical School	YES								
					Medical College of Wisconsin	YES								

* CTAA executed due to DAP employees but no official medical school affiliation

JUN 26 2002 17:18 FR NAVREF 301 229 0442 TO 2022252034 P.02/20

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

June 28, 2002

The Honorable Steve Buyer
Chairman
The Honorable Julia Carson
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Veterans Affairs
U.S. House of Representatives
Washington, DC 20515

The Honorable Jerry Moran
Chairman
The Honorable Bob Filner
Ranking Minority Member
Subcommittee on Health
Committee on Veterans Affairs
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairmen and Ranking Minority Members:

Thank you for the opportunity to respond to questions regarding the VA-affiliated nonprofit research and education corporations (NPCs). NAVREF's responses and pertinent attachments follow.

NAVREF is committed to promoting high standards of operational and financial management of the NPCs. We welcome the opportunity to work with Congress and any relevant VA organizations toward this purpose.

If you have questions or need additional information, please do not hesitate to contact NAVREF Executive Director Barbara West or me.

Sincerely,

Antonio Laracuente
Chairman

Enclosures
Questions and Answers
2 Attachments
Hard copies of linked documents

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

Questions and Responses

1. **Mr. Laracuente, you mentioned in your testimony that NAVREF is developing a new self-assessment and improvement program that will provide members with the tools to ensure that they are following the "best practices." What standards are being used to determine the "best practices?" Do they comply with the intent of Congress in regard to the administration and the funding?**

In May 2002, NAVREF began developing a Best Practices Program (BPP) that will incorporate dynamic, web-based risk assessment and management resources designed to provide the executive director, board of directors and managerial staff of a VA-affiliated nonprofit research and education corporation (NPC) with tools to work towards implementing "best practices."

BPP standards will be based on federal laws and regulations applicable to all nonprofits as well as guidance contained in VA handbooks and provided by nonprofit organizations such as Board Source (formerly the Center for Nonprofit Boards) and the Center for Nonprofit Risk Management. Because the NPCs are state-chartered, each one will be encouraged to have certain policies and procedures reviewed locally to assure compliance with local and state laws. While much of the information provided in the BPP will pertain to all nonprofits, many items will be customized for the NPCs to ensure compliance with VA requirements as well as the intent of Congress in regard to the administration and funding of the NPCs.

The four fundamental components of the program will be operational management, governance, financial management, and human resources. Each of these will contain detailed guidance on a variety of issues common to all nonprofits. However, much of the information will be customized to reflect the unique relationship between NPCs and their affiliated VA medical centers. A draft outline of the likely content of the BPP is provided as Attachment 1.

To develop and maintain the program, NAVREF has hired a full-time staff member with thirteen years experience with research and education nonprofits including eighteen months with a VA-affiliated NPC. This staff member will work with the NAVREF executive director and the BPP Working Group, which is comprised of four NPC executive directors who will review and comment on each component of the program as it is developed. Upon final approval by the NAVREF board of directors, each best practice and the resources to achieve it will be posted in a dedicated section of the NAVREF web site.

2. On NAVREF's website, there is a memorandum from Executive Director Barbara West, concerning the submission of annual reports to the VA. It states, "Last year, 93% of the reports arrived by the June 1 deadline. However, it is our understanding that a large number of the on time submissions were incomplete (did not contain one or more of the required components), reported financial data that was inconsistent with amounts reported on IRS Form 990, or contained factual errors." What is NAVREF doing to promote a better understanding and impress the importance among its members of their statutory obligation to accurately report their data? As the deadline approached for filing this year, do you see your members doing a better job than last year?

NAVREF has been very proactive in educating its membership about responsible reporting. To address shortcomings in the reports filed in June 2001, NAVREF took the following steps:

- In late 2001, NAVREF convened a small working group to review the Annual Report requirements contained in 38 USC 7361 and in Handbooks 1200.17 and 1400.2 in order to identify the items that appeared to cause confusion and to clarify the intent of each item. Clarifying guidance was provided to our membership.

- The working group finalized an Excel spreadsheet developed by a member to assist NPCs in ensuring that information reported in IRS Form 990 is accurately transferred to the Annual Report format.

- In early 2002, NAVREF sent every member a package containing specific guidance on completing the reports due on June 1. This included a cover letter from NAVREF detailing the necessity of timely filing and links to the Excel spreadsheet and Appendices A and B from Handbook 1200.17. At the same time, all of these materials were posted on the NAVREF web site in a section devoted to the annual reports. Links to these materials: http://www.navref.org/library/Annual_Reports.htm

- During the 2002 NAVREF Annual Conference, NAVREF stressed the importance of timely and accurate reporting of data for the NPC Annual Report during a 50-minute session. The presentation particularly emphasized the need for on-time, accurate submissions. Link to PowerPoint slides: http://www.navref.org/library/Annual_Reports.htm

- NAVREF assisted in development of a checklist (Attachment 2) that is being used this year to provide feedback to executive directors regarding any deficiencies in the reports submitted in June 2002. This is intended to be a learning tool to prevent repetition of similar errors in future reports and to improve communication with individual executive directors.

- In newsletters, NAVREF urged members to submit accurate, complete and timely reports. It also provided tips to ensure that auditors completed the audits, management letters and IRS Form 990 in time for inclusion in the annual report to VA. As the deadline drew near, NAVREF staff was a resource for questions on completing the reports.

It appears that all of these steps resulted in improved compliance in 2002. The following points illustrate improvement in reporting timely and accurate data on the annual reports for 2001 (submitted June 2002):

- **Timeliness.** Eighty-eight research and research and education corporations submitted reports for 2001. Eighty-seven reports were received by June 6. In all, 98.9% of all reports were on time. This represents a significant improvement over last year.

- **Incomplete Reports.** This year, only one incomplete report was submitted. The report was submitted on June 3, but was missing the audit report and management letter and the IRS Form 990. As indicated in the NAVREF March 1, 2002, reminder letter, an incomplete submission is considered a non-submission. This NPC is working with its auditor to complete the audit and IRS Form 990 and expects to submit them before the end of June.

- **Inconsistent Reporting and Factual Errors.** "Inconsistent reporting" and "factual errors" refers to the amounts reported on the Annual Report form being inconsistent with the amounts reported on IRS Form 990. To resolve these inconsistencies, the checklist mentioned above (Attachment 2) was sent to 35 NPC executive directors. The majority of faxes were issued with a request to clarify inconsistencies between amounts on Annual Report Items 4 a-k (Research and Education Revenues and Expenditures) and the financial data on the IRS Form 990. Of the 35 inquiries sent out, 33 (94%) have been resolved to date and 2 (6%) are in the process of resolution.

NAVREF strongly believes that it has acted responsibly by emphasizing how important it is for all NPCs to meet their statutory obligation to report timely, accurate information on their annual reports, and conveying that the information they provide is compiled into a larger report to Congress through VA Headquarters.

3. Based on the testimonies you heard at our hearing, what recommendations would you offer the Committees in enhancing the monitoring of the activities of the research foundations?

As stated in its May 15 testimony, NAVREF feels that the NPCs are already subject to sufficient monitoring by a variety of federal and state agencies. At the same time, NAVREF is strongly committed to local, on-site monitoring of the NPCs. The fundamental principle that each nonprofit board of directors must exercise duty, care and loyalty in the exercise of its responsibilities has been codified by each state. In addition, by mandating that certain VA personnel serve on the board of directors, Congress clearly intends for each NPC board of directors to provide rigorous oversight. As a result, NAVREF feels that increased monitoring at the national level is not necessary.

That said, we have three recommendations:

- It was evident during the May 15 hearing that the Committees do not feel they have an accurate sense of NPC revenues and expenditures. As indicated in NAVREF's May 24 letter, we have no objection to additional reporting requirements. However, we recommend 1) that these be framed explicitly and 2) in a way that is consistent with the pre-existing local, state and federal requirements. Further, the foundations should be given a reasonable time period in which 1) to make the necessary changes in their accounting policies and 2) to accumulate the required data. **We would be pleased to work with Congress to develop additional reporting requirements.**

- As you are aware, section 2 of S. 2132 would allow VAMCs to contract with NPCs for services **subject to federal and VA contracting regulations**. We encourage the Committees to support final approval of this provision in conference to enhance monitoring of interactions between NPCs and VAMCs. Approval of this clause would ensure appropriate oversight of agreements between VAMCs and NPCs and the flow of contributions from NPCs to VAMCs; improve scrutiny for conflicts of interest; and evaluate the cost effectiveness of any transactions. Further, pursuant to section 2, VA contracting personnel who have been specifically trained to manage conflicts of interest, the fundamental principle underlying federal procurement statutes and regulations, would provide such oversight.

- **Finally, we recommend that the Inspector General and any other VA organizations involved in oversight of the NPCs acquire in depth knowledge of statutes and regulations applicable to nonprofits as well as an understanding of nonprofit, board driven culture.** The NPCs are a growing component of the VA research program and it is my understanding that VA may soon request authorization of additional nonprofits to accomplish specific non-research purposes. As a result, we feel that it would be in everyone's best interests for VA personnel to obtain training in the financial and managerial expertise required to understand and appropriately oversee all VA-affiliated nonprofits.

4. You are an advocate for continuance of the research foundations. Do you have any recommendations for improving their functions, based on your experience leading the Atlanta foundation?

We have four recommendations:

- **Encourage VA to Continue the OGC Corporations Panel.** This panel is an invaluable resource to both VA and the NPCs. Established primarily to ensure that VA interests are not compromised in NPC agreements with private sector research sponsors, the existence of the panel has greatly improved the quality, consistency and timeliness of VA work in regard to the NPCs. Panel members provide important technical assistance to NPCs negotiating increasingly complex

transactions, personnel issues and other legal matters. While OGC Group III resources are best allocated to issues of national scope, the panel is best equipped to focus on day-to-day NPC activities at the local level. It is our understanding that questions regarding NPC reimbursement for VA attorney services need to be resolved, but please be assured that the NPCs value the panel's assistance so highly that they are more than willing to provide such reimbursement.

- **Encourage each NPC board of directors to undergo annual training on board responsibilities.** Mandatory service on an NPC board of directors creates an unusual board dynamic. Normally, nonprofit board members are volunteers who are personally committed to the purpose of the nonprofit and often have substantial nonprofit experience. In contrast, statutory NPC board members have no choice about serving on an NPC board and frequently have no nonprofit experience. Board oversight of NPCs could be improved by regular board training. This could be accomplished on-site through materials available from Board Source or presentations by local nonprofit accountants and nonprofit support organizations as well as attendance at national conferences on nonprofit management sponsored by NAVREF or other organizations.

- **Where appropriate, encourage VAMC leaders to work with their university affiliates to allow NPCs to administer NIH and other federal research grants so that VA can benefit from the indirect costs associated with NPC-administered NIH grants.** While we recognize that many NPCs may currently lack the expertise to administer NIH grants, others are more than capable of doing so but are prohibited by domineering affiliates. As Ken Hickman indicated during his brief testimony on May 15, the Brentwood Biomedical Research Institute currently provides about $400,000 a year in research infrastructure support to the West Los Angeles VAMC. However, due to declining private sector grants, BBRI can sustain this level of support for only one more year. If BBRI assumed responsibility for NIH grants awarded to VA investigators that are currently being administered by UCLA but are performed in VA facilities using VA infrastructure support, BBRI could provide a significantly higher level of support to the West Los Angeles VA research program.

- **Encourage VA to foster collaboration and understanding between VAMCs and NPCs.** Because the NPCs operate in the VA environment, NPC personnel must interact daily with VA personnel who often have little understanding of the NPCs. Attending NAVREF conferences, regular board training and local leadership encouragement to cooperate to meet the mutual VA/NPC objective of supporting research and education would be very helpful.

Attachment 1

Draft Outline for the NAVREF Best Practices Program (Short Version)

NAVREF Best Practices Program – Operational Management

I. **Overview**
- A. Title 38 – Subchapter IV – Research and Education Corporations
- B. VHA Handbook 1200.17 – VA Research and Education Corporations Handbook
- C. VHA Handbook 1400.2 – VA Education Corporation Handbook
- D. VA Approval to Establish the Corporation
- E. Approval of Medical Center Director
- F. Responsibility for Another Medical Center
- G. Available VA Assistance
- H. Legal Counsel
- I. Nonprofit Corporation Status with the IRS

II. **Reporting Requirements**
- A. Federal Reporting Requirements
  - 1. IRS Form 990
  - 2. 501(c)(3)
  - 3. Financial Audits
- B. State Reporting Requirements
- C. Annual Report to the VA
- D. RDIS Reports

III. **Federal Technology**
- A. Federal Technology Transfer Act
- B. Bayh-Dole Act
- C. Executive Order 10096
- D. VA Handbook 1200.18

IV. **Insurance**
- A. Directors and Officers Insurance
- B. General Liability Insurance
- C. Business Personal Property Insurance
- D. Worker's Compensation Insurance
- E. Fiduciary Bond (employee dishonesty)
- F. Professional Liability Insurance
- G. Commercial Package Policy

V. **Research Projects Policies and Procedures**
- A. Project Approval by R&D Committee and Appropriate Subcommittees
- B. R&D Approval Letter
- C. Contracts and Budget
- D. VA Impact Statement
- E. Investigators
- F. Transfer of Investigators

VI. **Education Projects Policies and Procedures**
- A. Project Approval by Education Committee

NAVREF Best Practices Program – Governance

I. Board of Directors
- A. Mission and Program
- B. Governing Body
- C. Conduct of Board
- D. Board Expectations
- E. Board Selection, Recruitment, Orientation, Training, and Development
- F. Board Meetings, Attendance and Minutes
- G. Board Self Evaluation
- H. Conflict of Interest
- I. Public Openness
- J. Public Affairs and Public Policy

II. Corporation Policies and Procedures
- A. Articles of Incorporation
- B. By-laws
- C. Policy Manuals (i.e., Operations, Financial and Accounting, Personnel, etc.)
- D. Handbooks (i.e., Personnel, Investigator, etc.)

NAVREF Best Practices Program – Financial Management

I. Accounting Principles and Procedures
- A. Accrual Basis and Fund Accounting
- B. Financial Statements
- C. Revenue, Support and Capital Additions
- D. Donated and Contributed Services
- E. Donated Materials and Facilities
- F. Investment Income
- G. Chart of Accounts or Classification of Expenses
- H. General & Administrative Costs (G&A) or Indirect Cost Rate (IDC)
- I. Tax Allocation
- J. Fixed Assets
- K. Depreciation
- L. Internal Accounting Control System

II. Funds Management
- A. Asset Accounts
- B. Accounts Receivable
  1. Grants and Contracts: Private
  2. Grants and Contracts: Government
  3. Donations and Honorariums
  4. Transfer of General Post Funds
  5. Receipt of Funds
- C. Accounts Payable
  1. Documentation
  2. Expenditure Types
- D. VA Specific Funding Issues and Mechanisms
  1. Intergovernmental Personnel Act (IPA)
  2. Memorandum of Understanding (MOU)
  3. VA Impact Statement and Reimbursing the Medical Center

NAVREF Best Practices Program – Human Resources

I. **Workplace Statutes and Practices**
Applicable laws (ADEA, ADA, COBRA, ERISA, EEO, etc.)

II. **Hiring, Termination, and Clearance**
- A. Hiring Procedures
- B. Resignations and Terminations
- C. Post Employment Clearance

III. **Employment Practices and Benefits**
- A. Workplace Policies and Procedures
- B. Employee Handbook
- C. Job Performance
- D. Discipline and Grievance
- E. Employee Benefits
- F. Unions
- G. Other Policies of Interest
- H. Consultants

IV. **Compliance with NPC Statute and VA Requirements**
- A. VA WOC Appointment
  - 1. WOC Appointments for Non-VA NPC Employees
  - 2. WOC Appointments for VA NPC Employees
    - a. VA Employees working for NPC
    - b. Dual Compensation
- B. VA Policies and Procedures for WOC Employees
  - 1. Applicability of FTCA
  - 2. Intellectual Property Assignment Form
  - 3. Background Checks
  - 4. Drug Testing
  - 5. Annual Renewal of WOC Appointment
  - 6. Training and Access

Attachment 2

VA Non-Profit Research & Education Corporations
2001 Annual Report - Checklist of Deficiencies

Date

To: Medical Center Director
Executive Director

I am in receipt of your 2001 VANPC Annual Report. Upon review of the submitted documentation, the following checked item(s) are either missing or incomplete and require your immediate attention. Please forward all missing or incomplete items to my attention using the address provided below.

MISSING/INCOMPLETE ITEMS

1. Research and Education Corporation name ☐
2. VA Medical Center Name ☐
3. Executive Director Name, telephone, fax & e-mail address ☐
4. Copy of independent audit report and management letter (If required) ☐
5. Copy of Internal Revenue Service (IRS) FORM 990 with schedules ☐
6. Research & Education Revenues and Expenditures ☐
   a. Government funding received for research. ☐
   b. Government funding received for education. ☐
   c. Non-Government funding received for research. ☐
   d. Non-Government funding received for education. ☐
   e. Salary expenditure for research staff. ☐
   f. Salary expenditure for education staff. ☐
   g. Salary expenditure for support staff. ☐
   h. Total expenditure for research. ☐
   i. Total expenditure for education. ☐
   j. Travel expenditure for research. ☐
   k. Travel expenditure for education. ☐
7. Copy of VA non-profit Corporation (VANPC) project list ☐
8. Executive Director Certification Signature (Conflicts of Interest Regulations) ☐
9. Two (2) copies of List of Non-Governmental Funding Sources (Contributions exceeding $25,000) ☐
10. Two (2) copies of Payees List (Payments exceeding $35,000) ☐
11. Other _____ ☐
12. Other _____ ☐

Forward all listed Items to:

Robert Guancial, Administrative Officer R&D
VA Western New York Health Care System
Attn: Administrative Officer/R&D (151)
3495 Bailey Avenue
Bldg., 20, Room 129
Buffalo, NY 14215

Tel: 716-862-6528
Fax: 716-862-6526
Email: robert.guancial@med.va.gov

Selected Linked Documents

ANNUAL REPORTS TO VA

The statute that authorizes the VA affiliated nonprofit research and education corporations (NPCs) requires VA to submit to the House and Senate Committees on Veterans Affairs an annual report regarding the NPCs and their activities. To assemble the necessary information, each NPC must submit by June 1 a report containing information specified in the **statute** and in instructions contained in Appendix A of **Handbook 1200.17** and **Handbook 1400.2**

Information about Compiling the Report Due June 1, 2002

- **NAVREF Reminder Letter**
- Annual Report Format:
  - **Appendix B of Handbook 1200.17** (Research and Education Corporations)
  - **Appendix B of Handbook 1400.2** (Education Only Corporations)
- **NPC Annual Report Excel Spreadsheet** (developed by Mary Thornton)
- **Highlights of 2000 Reports and Tips for 2001** (developed by Bob Guancial)

2000 Annual Reports to VA:

- **Summary of the 2000 Annual Reports (Based on Reports Submitted June 2001)**
- **Financial Data Sorted Alphabetically**
- **Financial Data Sorted by Revenues**

1999 Annual Reports to VA:

- **Summary of the 1999 Annual Reports** (Based on Reports Submitted June 2000)
- **Financial Data Sorted Alphabetically**
- **Financial Data Sorted by Revenues**

last updated: 01/28/02

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navref@navref.org

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MEMORANDUM

March 1, 2002

TO: NPC Chairman of the Board
NAVREF Members
FROM: Barbara West, Executive Director

As you are aware, the deadline for NPC annual reports to VA is approaching. Last year, 93% of the reports arrived by the June 1 deadline. However, it is our understanding that a large number of the on time submissions were incomplete (did not contain one or more of the required components), reported financial data that was inconsistent with amounts reported on IRS Form 990, or contained factual errors.

This year, the Office of Research and Development (ORD) will not send a letter to medical center directors apprising them of the annual report deadline and requesting their assistance in assuring compliance. Consequently, the purpose of this NAVREF memo is to remind those involved with the NPCs of the seriousness of the annual report deadline and to convey the results of discussions between ORD and NAVREF regarding the ORD position on annual report submissions.

1. VHA Handbook 1200.17, Appendix A, details the annual reporting requirements for each VA nonprofit research and education corporation. Annual reports must be submitted to the designated VA point of contact [currently Western New York Healthcare System, Attention Robert Guancial (151)], on or before June 1. NPCs should take immediate steps to ensure timely submission in 2002. The June 1 deadline is mandatory and not negotiable.

2. Every VA nonprofit established under 38 USC 7361 that has completed incorporation by the state in which it is located must submit an annual report regardless of whether the nonprofit has been granted IRS tax exempt status or has received or expended funds during the previous year. The annual report should reflect activity conducted during the nonprofit's last completed fiscal year.

3. An incomplete report is unacceptable to ORD and will be considered by ORD in the same light as a non-submission. The report format is provided in Appendix B of Handbook 1200.17. It should be used to ensure that all required documentation is enclosed and that the financial data is reported accurately. Verify numbers against the IRS Form 990 where appropriate. NAVREF has posted on its web sit an Excel spreadsheet developed by Mary Thornton, grants management officer at the Palo Alto Institute for Research and Education, to provide NPCs with a tool to make sure that their annual reports are complete and accurate. It is posted at http://www.navref.org/library/Annual_Reports.htm.

4. Upon receipt of an annual report that is incomplete, Mr. Guancial will complete a checklist detailing the deficiency(ies) and will forward the checklist to the VA medical center director and the corporation executive director for immediate action. Mr. Guancial will not make follow up calls to solicit information for the compilation of the annual reports. It is each NPC's responsibility to ensure full compliance.

5. Corporations should notify John A. Bradley, ORD Chief Financial Officer (12B) (john.a.bradley@hq.med.va.gov) of any issue that may affect compliance with the reporting deadline together with a corrective plan of action.

6. In the past, some auditors' management letters raised serious issues. Standard nonprofit practices require that audit reports be reviewed by the Boards of Directors. Each board should initiate appropriate corrective measures to ensure that the same deficiencies will not be noted in subsequent management letters.

Please note: During a recent review, it was noted that the reporting requirement contained in Handbook 1200.17, Appendix A, Item 5, was inconsistent with the NPC authorizing statute and provision 9.b.(2)(e)4 of the handbook. To achieve consistency, ORD has asked General Counsel to revise this provision and the one provided in Item 7 of Appendix B. For purposes of the reports due June 1, 2002, ORD supports following this requirement as revised:

Appendix A, 5. A list that identifies each non-governmental funding source whose total contributions for the year exceed $25,000: provide name, location and total dollar amount.

The non-profit research and education corporations play an important role in supporting VA's research mission. Your assistance in addressing the issues raised above will allow VA to meet the reporting requirements established by Congress as well as ensure that the VA non-profit research and education corporations continue to function effectively as a highly valued component of the VA research program.

Enclosure: **VHA Handbook 1200.17, Appendices A and B**

VA NON-PROFIT RESEARCH AND EDUCATION CORPORATIONS
ANNUAL REPORT FORM
(DUE JUNE 1 ANNUALLY)

Corporation: _____
VA medical center: _____
Executive Director: _____
Phone: _____
Fax: _____
Email: _____

This corporation engages in:
____ Research ____ Research & Education

Total Revenue $ 8,428,332
(See VHA Handbook 1200.17, Appendix A to determine audit requirements.)

Revenues and Expenditures

a. Government funding received for research	$ 4,114,380
b. Government funding received for education	$ -
c. Non-Government funding received for research	$ 4,108,061
d. Non-Government funding received for education	$ 12,720
e. Salary expenditure for research staff	$ 4,622,358
f. Salary expenditure for education staff	$ -
g. Salary expenditure for corporate administrative staff	$ 391,022
h. Total expenditure for research	$ 7,191,113
i. Total expenditure for education	$ 300
j. Travel expenditure for research	$ 119,707
k. Travel expenditure for education	$ -

The following required items are included:
____ Copy of independent audit report
____ Copy of auditor's management letter ____ Or no management letter issued
____ Copy of IRS form 990 with schedules
____ Copy of project list
____ Copy of educational activities list (if applicable)
____ 2 Copies of list of non-governmental funding sources >$25,000 (see attached sample)
____ 2 Copies of list of payees >$35,000 (see attached sample)

I have verified that each board member, officer, and employee has certified awareness of and compliance with, Federal laws and regulations with respect to conduct and conflicts of interest in the performance of official functions in the same manner as Federal employees are required to.

_____ _____
Executive Director Signature Date

Revenue

	Research	Education	Total	
Government funding received	$ 4,114,380	$ -	$ 4,114,380	Total equals 990, Part I, Line 1c + Part VII, Line 93g
Non-government funding receive	4,108,061	12,720	4,120,781	Total equals 990, Part I, Line 1a + 1b + 2, Less Part VII, Line 93g
Interest income			193,555	Total equals 990, Part VII, Line 95
Gain (loss) on sale of assets			(384)	Total equals 990, Part VII, Line 100
Total Revenue			$ 8,428,332	Total equals 990, Part I, Line 12

Expenses

	Research	Education	Admin.	Total	
Program salary expenditures	$ 4,622,358	$ -		$ 4,622,358	Equals 990, Part II, Lines 25-29, Column B
Support salary expenditures			391,022	391,022	Equals 990, Part II, Lines 25-29, Column C
Program travel expenditures	119,707	-		119,707	Equals 990, Part II, Lines 39, Column B
Support travel expenditures			14,085	14,085	Equals 990, Part II, Lines 39, Column C
All other program expenditures	2,449,048	300		2,449,348	Equals 990, Part II, Lines 22-24, 30-38, 40-43, Column B
All other support expenditures			195,425	195,425	Equals 990, Part II, Lines 22-24, 30-38, 40-43, Column C
Total program expenditures	$ 7,191,113	$ 300		$ 7,191,413	Equals 990, Part II, Line 44, Column B
Total support expenditures			$ 600,532	$ 600,532	Equals 990, Part II, Line 44, Column C

8.35% Mgmt. Expenses/Program Expenses

2000 VA Non-Profit Research and Education Corporation Annual Report

Robert Guancial
Administrative Officer Research & Development
VA Western New York Healthcare System

What's New

- NAVREF Reminder Letter
- Check List of Deficiencies
- Report Executive Director Salary on IRS form 990
- Revised Handbook 1200.17, Appendix A and Appendix B

2000 Annual Report Highlights

- Total Revenue was $173.7 million
  - ▲ 17% increase from 1999
- Total Expenditures were $157.4 million
  - ▲ 18.5% increase from 1999
- CPA auditors scrutinized 99% of all expenditures

2000 Annual Report Highlights

- VA NPC administered 4,651 VA-approved projects
  - ▲ 8% increase from 1999
- 29 Corporations reported $50.9 million in government revenue
  - ▲ 65% increase from 1999

2000 Annual Report Highlights

Summary of Major Donors

- NIH
  - ▲ 60% increase from 1999
- Private sector donations
  - ▲ 2% increase in from 1999

Problems Compiling 2000 Annual Report

Incomplete Reports

- Audit report and management letter
- IRS Form 990
- Research and Education Revenues and Expenditures Section 4 not included in the report

Problems
Compiling 2000 Annual Report

- Required Components submitted with the Annual Report are marked **YES (Copy Enclosed)** but are not included:
  - Audit report, if required
  - IRS Form 990
  - Copy of VA NPC Project List
  - Executive Director failed to sign Certification Statement

Problems
Compiling 2000 Annual Report

Action Plan

- ✓ Check-List to identify missing components or incomplete information
- ✉ To Medical Center Director and Executive Director

VA Handbook 1200.17
Appendix A

Item 3: A copy of the Corporation's IRS Form 990 for the Corporation's last completed fiscal year

Inconsistent reporting of government revenues

- Line 1 C Government contributions (grants)
- IRS Form 990, Part VII
  - Line 93 Program service revenue:
  - g Fees and contracts from government agencies

Inconsistent reporting of government revenues

Recommendation

- Seek expert guidance from nonprofit accountant
- Defend your reporting position

Inconsistency in reporting pharmaceutical funds

- IRS Form 990, Part I, Line 1a
  - Direct public support
- IRS Form 990, Part VII
  - Line 93 Program service revenue

Inconsistency in reporting pharmaceutical funds

Recommendation

- Seek expert guidance from nonprofit accountant

Uncertainty how to report government sub-grants & subcontracts

- Is federal identity lost?
- How is this revenue reported on IRS Form 990?
- Government or private sector revenue?

Uncertainty how to report government sub-grants & subcontracts

Recommendation

- Seek expert guidance from nonprofit accountant
- Defend your reporting position

VA Handbook 1200.17 Appendix A

Item 4: Although it is not required in the IRS Form 990, the statute that authorizes the Non-profit Corporations (NPCs) requires them to track research and education donations and expenditures

VA Handbook 1200.17 Appendix A

Problem

Information in ***Item 4*** was ***inconsistent*** with information reported on ***IRS Form 990***

Inconsistent Reporting of Government Revenue

Total Government Revenue

- For Research - **Item 4a**
- For Education - **Item 4b**

Inconsistent Reporting of Government Revenue

Total Government Revenue

The total of **Item 4a** + **Item 4b** **must equal (=) IRS Form 990**

➡ **Part I, Line 1c**

Or

➡ **Part VII, Line 93g**

Inconsistent Reporting of Non-Government Revenue

Total Non-Government Revenue

- For Research - **Item 4c**
- For Education - **Item 4d**

Inconsistent Reporting of Non-Government Revenue

Total Non-Government Revenue

The total of **Item 4c** + **Item 4d** **must equal (=) IRS form 990**

➡ **Part I, Lines 1a, 1b and 2**

Minus (-)

➡ **Part VII, Line 93g**

Inconsistent Reporting of Total Salary Expenditures

Total Salary Expenditures

- For Research Staff - **Item 4e**
- For Education Staff - **Item 4f**

Inconsistent Reporting of Total Salary Expenditures

Total Salary Expenditures

The total of **Item 4e** + **Item 4f** **must equal (=)**

➡ **Part II, Lines 25, 26, 27, 28 & 29 Column B**

Inconsistent Reporting of Salary Expenditures

Combined Salary for Support Staff for Education and Research

Item 4g

Inconsistent Reporting of Salary Expenditures

Salary Expenditures

The total of **Item 4a must equal (=)**

➡ **Part II, Lines 25, 26, 27, 28 & 29**
Column C
Management & General

Inconsistent Reporting of Direct Support Expenditures

Direct Support Expenditures

- For Research - **Item 4h**
- For Education - **Item 4i**

Inconsistent Reporting of Direct Support Expenditures

Total Direct Support Expenditures

The total of **Item 4h** + **Item 4i must equal (=)**

➡ **Part II, Line 44 Column B**
Program Services

Inconsistent Reporting of Travel Expenditures

Total Travel Expenditures

- In conjunction with Research - **Item 4j**
- In conjunction with Education - **Item 4k**

Inconsistent Reporting of Travel Expenditures

Total Travel Expenditures

The total of **Item 4j**+ **Item 4k must equal (=)**

➡ **Part II, Line 39 Column B**
Program Services

Help Is Available

- **Excel Spreadsheet**
  - ✓ To be used as an aid in completing Item 4
    Developed by **Mary Thornton**
    Grants Management Office
    Palo Alto Institute for Research and Education, Inc.
  - In handouts & posted on **NAVREF** web site

VHA Handbook 1200.17 Appendix A

Item 5: A list that identifies each donor whose total contributions for the year exceed $25,000; provide name, location and total dollar amount

VHA Handbook 1200.17 Appendix A

- **Problem**:
  Information requested in Item 5 is ***inconsistent*** with the ***statutory requirement*** in Section 7366 (d)(2)(D)
- Interpret "*other sources*" to mean non-government

VHA Handbook 1200.17 Appendix A

Recommend Revision

- Revise Item 5 in Appendix A and Item 7 in Appendix B
- A ***list*** that *identifies* each *non-government funding source* whose total contributions for the year *exceed $25,000; provide name, location and total dollar amount.*

CHAIRMAN BUYER TO DR. FRANKLIN ZIEVE

ANSWERS TO QUESTIONS -- FRANKLIN J. ZIEVE

QUESTION #1 – Dr. Zieve, you mentioned that your annual "Research Day" includes an opportunity for veterans to voice concerns or complaints they may have about VA research and their participation. Please provide additional information on the types of concerns or complaints occasioned at these Research Day events.

(1) Problems after study terminates (by far the commonest complaint, but generally minor)

- Can't continue study drug after study is over.
- No weekly/monthly clinic visits after study is over.
- Get charged for medications when study is over.
- Must deal with waiting times and scheduling hassles in regular clinics.
- Want to be contacted if a new treatment for their condition seems promising.

(2) Problems during study

- When they signed up they did not realize the time commitment required of a study participant.
- Would like to interact more with study doctor.
- When asked if they understood their consent form, several subjects said it was complicated but they "trusted their doctor to take care of them." This feedback has led our IRB to insist on simpler consent forms, while pressure from both VA and external sponsors is consistently in the opposite direction (they want to create a legal document to protect themselves rather than something the volunteer can understand).
- One veteran complained about being charged for medication to treat a study side effect (his upset stomach). We contacted the investigator, who reviewed the subject's case and deemed that due to side effects it was in the patient's best interest to discontinue participation.

(3) Problems in recruitment

- The commonest study-related problem was exclusion from a study – "my friend got to participate in a hip study but I was never asked." Equity of recruitment is a more important issue than we had appreciated, and we have started addressing it formally at the time of IRB review.

QUESTION #2 – I'd like to quote a portion of your written statement: "Over 95% of the funds which flowed into McGuire Research Institute in its first years replaced funds kept at the affiliated medical school. Virginia Commonwealth University ("VCU"). When this movement of funds to MRI started, we found some research studies which had been going on at McGuire without any VA knowledge. The money was at VCU; the drugs were dispensed from the VCU pharmacy,

brought to the VA in paper bags and administered to our patients without any record in their VA charts."

Could you please elaborate on this and explain what kind of research was "conducted without any VA knowledge?" What actions were taken to address the drug dispensing procedure?

The short answer to this question is that we developed our Human Research Protection Program, involving MRI, our IRB, our Investigational Pharmacy, and our training program. The overall process took 10 years (which seems amazing in hindsight, but is consistent with the primitive state of human subject protection in 1990) and is continuing. Here was the sequence:

(1) The Funding. At first virtually all the funds for VA clinical studies were kept at our affiliate, VCU, and we used the VCU IRB. We did not have the resources to fund a separate Investigational Pharmacy, so investigational drugs were kept in our hospital pharmacy, which provided poor service and poor record keeping. After MRI was established we got our first look at the funds associated with clinical research at McGuire VAMC; it was obvious that the number of patients in studies at McGuire was far larger than we had realized. Some VA investigators had large projects which we had thought were small, and some VCU investigators had no approved projects at all, but still wanted to put funds in MRI. The ongoing unapproved studies ran the spectrum from questionnaires to drug studies. Since all of these studies had approval of the VCU IRB, which we used, we simply asked the investigators to submit them to the R&D Committee. When non-VA employees were being used, they were sent to apply for WOC appointments. We only shut down a handful of projects. We instructed all investigators to use the VA Pharmacy for investigational drugs, but at that stage we could not easily get information to enforce this.

(2) The IRB. As we became more sophisticated we were dissatisfied with the VCU IRB, but we were not politically able to set up our own until 1999. With our own IRB, and with the VCU shutdown, we found a few more studies by VCU investigators which used VA patients, giving them investigational drugs from the VCU pharmacy, but had never been through R&D Committee approval. These studies were shut down promptly.

(3) The Investigational Pharmacy. Our Investigational Pharmacy was established for the sole purposes of handling all study drugs at McGuire VAMC and of enforcing all human subject regulations. For the first time we felt we had adequate control: no patient is issued a study drug until a signed consent form is in the Investigational Pharmacy and a clinical warning is on the cover sheet of the electronic patient record. The pharmacy data provides an important base for the IRB's continuing review of each project.

(4) The Training Program. We have invested over $50,000 to train all personnel associated with human research at McGuire VAMC (*e.g.* we currently have 20 Certified Clinical Research Coordinators). This cadre of trained people provides an additional safeguard – if someone brought in a drug in a paper bag today,

someone would be likely to notice him and take action. We feel this is an important additional protection.

In summary, control of human research at a VAMC requires control of the money, the IRB, the drugs, and the personnel. The multiple layers of protection are important; if you only have one tollkeeper, someone can always find a back road to get around him.

QUESTION #3 – You are an advocate for continuation of the research foundations. Do you have any recommendation for improving their functions, based on your experience leading the McGuire Research Institute?

(1) What good are they doing for the VAMC?

- The corporations' fundamental underlying function is to support and improve the VA Medical Center by providing a flexible funding mechanism for the acquisition and administration of additional research resources. However, the annual reporting requirements of corporations do not include evaluation of what they have done to support either the medical care or the research appropriations of the hospital.
- I suggest that each corporation should make an annual report on what it has done to support the hospital (signed by the Medical Center Director) and to support the VA-appropriated research program (signed by the ACOS/R&D). Specific dollar figures and FTE should be specified. This should be part of the corporate annual report to VACO, and it should be reviewed both locally and centrally.
- It is possible to run a VANRC so its effects on the hospital are either major or inconsequential. Our operating and auditing standards should be able to tell the difference, but currently they don't address this point. Changing this is a simple way to increase VA's benefit from the corporations.

(2) Corporations need feedback on their annual reports.

- When Richmond assembled the annual reports from VANRCs, we gave a "public flogging" report each year at the NAVREF meeting. Our reports, which were noted in the 1997 OIG report on the corporations, highlighted questionable practices and specific items subject to improvement.
- More recently, the annual reports have gone to the VACO collection point, but there has been no feedback to the sites. If the annual reports are to be used as an instrument to improve the corporations, somebody should read them, and each station should get feedback.

(3) Corporations should fund the Human Research Protection Program (HRPP).

- Nationwide, most VA human research is administered through VANRCs. Human research protection is a front-burner issue right now, the standard of practice is changing rapidly, and most VAMCs are seriously behind in achieving compliance; if they wait three years for VACO to figure out what to do they will risk a public relations fiasco and, more importantly, inadequate protection of veterans. The corporations should fund the HRPP now. It is in their best

interest, in VA's best interest and most importantly in veteran's best interest for the corporations to take charge of providing for human subject safety in VA research. The issue is too important to wait.

(4) Corporations should develop "rainy day" reserves.

- For its first 10 years McGuire Research Institute was was run on a shoestring so as to accumulate a significant reserve for a rainy day. When the rainstorm came in 1999, we were quickly able to spend an additional $500,000 per year on our human research protection program. If we had not had a substantial reserve, we would have been shut down.
- Most VANRCs are run by career federal employees who are used to spending their entire budget each year. A corporation can help its VAMC most by systematically assembling reserves and preparing to act quickly. This is the most powerful tool the corporation has.

(5) Corporations should be run for the long term.

- VANRCs should develop a "foundation" mentality: build net assets and fund initiatives off the interest rather than the principal. Create an enduring VA research enterprise; don't just live for today.

QUESTION #4 – Based on the testimonies you heard at our hearing, what recommendations would you offer the Committees in enhancing the monitoring of the activities of the research foundations?

(1) Better use of the independent auditors

- Every VANRC with > $300,000 in revenues must be audited annually by an independent auditor. As a result there is a low probability of fraud and embezzlement. It is reasonable to assume that VANRCs are functioning according to generally accepted business practices. MRI's 2001 audit cost $17,291, and it was far more thorough and inclusive than any audit we have undergone by VA-related entities.
- Despite the effort and expense which goes into the audits, the independent auditors have never been given any direction whatsoever by any VA-related entity. Thus, the audits have never asked a VA-specific question, but have been concerned only with observance of standard good business practice.
- The simplest way to enhance monitoring of corporate activities would be for VHA, OIG, or the Committees to give VA-specific auditing criteria or questions for the independent auditors to address. I can think of some obvious areas to look at, but the important thing is the principle that the annual audit could look for compliance, not only with GAAP, but also with the VA Manual.

(2) Evaluation of what corporations directly do for the VAMC (see above)

- Ultimately the corporations exist to support the overall VHA health care enterprise, but I am not aware of any oversight which has addressed the impact of the corporations on the VAMCs. If they are not helping the medical centers, there is little reason for them to exist. In addition to looking for specific actions

which are questionable, the oversight should try to assure that the corporations are doing big things that are good.

(3) Better review of the assembled annual reports

- When Richmond was responsible for collating the corporate annual reports, we noted some corporations which could potentially have been heading for financial trouble (*e.g.* corporations whose revenues consisted of a very small number of large grants, but whose administrative structure was based on the assumption that these would continue indefinitely). While no disasters have occurred thus far, it would be worthwhile to reduce their chances of occurring in the future. This would require a truly knowledgeable review group for the annual reports. *It cannot be done by VACO – nobody in ORD could run a corporation from VACO if his life depended on it!* On the other hand, it cannot be done by NAVREF, an advocacy organization. My suggestion is to appoint a group consisting of 2-3 very experienced VANRC executive directors, one ORD representative, and one private sector auditor to review the annual reports and give feedback to VACO and to the corporations.

A Final Thought. There are a few simple, fundamental questions which we ask all the time when we are considering whether MRI should move in a new direction:

- Is it good for the hospital?
- Is it good for the patients?
- Is it good for our professional role as physicians?

This is the thinking I consider most important if the corporations are to live up to their potential.