H.R. 1585, A BILL TO ESTABLISH AN OFFICE TO OVERSEE RESEARCH COMPLIANCE AND ASSURANCE WITHIN THE VETERANS HEALTH ADMINISTRATION OF THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JULY 15, 2003

Printed for the use of the Committee on Veterans' Affairs

Serial No. 108–20

U.S. GOVERNMENT PRINTING OFFICE

94–195PDF WASHINGTON : 2005

For sale by the Superintendent of Documents, U.S. Government Printing Office
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H.R. 1585, A BILL TO ESTABLISH AN OFFICE TO OVERSEE RESEARCH COMPLIANCE AND ASSURANCE WITHIN THE VETERANS HEALTH ADMINISTRATION OF THE DEPARTMENT OF VETERANS AFFAIRS

TUESDAY, JULY 15, 2003

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC

The subcommittee met, pursuant to notice, at 10:03 a.m., in room 334, Cannon House Office Building, Hon. Rob Simmons (chairman of the subcommittee) presiding.

Present: Representatives Simmons, Miller, Boozman, Beauprez, Buyer, Rodriguez, and Snyder.

OPENING STATEMENT OF CHAIRMAN SIMMONS

Mr. SIMMONS. The hearing will come to order.

I want to welcome our distinguished witnesses and others in attendance. Thank you for coming to this subcommittee hearing of the Veterans' Affairs Committee, Subcommittee on Health.

This is a legislative hearing to discuss a bill before the subcommittee, introduced by my fellow veteran, the gentleman from Indiana, Mr. Buyer, and other Members, on April 3, 2003.

The bill, which is designated H.R. 1585, would establish an independent research, compliance, and assurance office within VA's health care system.

The VA research program is a biomedical program. VA carries out an extensive array of research and development to complement its affiliations with 109 medical schools and scores of other health profession schools nationwide. I am told the program involves over 150,000 research volunteers and 3,800 investigators.

The research is targeted directly to the needs of veterans, which is appropriate, but the work has also defined new standards of care that benefit all Americans. Among the major emphases of VA research are aging, chronic diseases, mental illness, substance use disorders, sensory losses, and trauma-related illnesses.

Over the years, the committee has tried to build a solid foundation to improve funding for VA's research programs, and this has been difficult at times because of competing needs for funding both within VA and other agencies.

The President proposed an increase in VA's research budget of only 2 percent in 2004, which was about $8 million. This committee

has recommended an additional $52 million be added to the 2004 budget in order to keep VA research on pace with funding developments.

By saying the foregoing, what I mean to describe is a VA research program which is exceedingly important. The issue of accountability in this program has been raised, both in the media and by Members, over the last 5 years. Mr. Buyer's bill is an accountability measure, one that would require VA to permanently partition research management and administration from independent VA research, compliance, and assurance functions.

It is my understanding that VA has already partitioned some of these, but perhaps those administrative efforts have not gone far enough, and that is one reason why it is important to have a hearing on this legislation. I look forward to hearing from our witnesses.

That being said, I would ask if my friend, Mr. Rodriguez of Texas, our Ranking Member, has an opening statement that he wishes to make.

[The prepared statement of Chairman Simmons appears on p. 29.]

OPENING STATEMENT OF HON. CIRO D. RODRIGUEZ

Mr. RODRIGUEZ. Thank you, Mr. Chairman.

I want to thank you for conducting and holding this hearing today to express the VA's progress and to identify the VA's progress, also, in complying with the common rule—that is, protecting human subjects involved in research.

The VA has more than a billion dollars invested in biomedical research, and the VA grants fund only a portion of the total research portfolio.

Grants from other Federal agencies and private industries make up the rest of the budget.

The VA manages the assurances for research conducted in many of the labs, but in some instances, medical schools affiliates oversee the VA research endeavors, and in still others, the responsibility is shared.

Stakes are high for the scientists.

Billions of dollars are invested in research and development of new pharmaceutical and assistive technologies every year.

In the environment, it is essential—excuse me—in this environment, it is essential that strong centralized guidance and oversight be placed.

We are all acquainted with the unfortunate misadventures that have occurred at the Albany VA medical center, discovered last fall.

Since that time, the VA has taken steps to address some of the problems that may have led to the untimely deaths of one or more of the research participants.

I hope that changes will offer Congress some of the assurances that these unfortunate events will no longer occur.

H.R. 1585 would institutionalize some of the practices the VA has established and would also look at probably others that are being looked at.

So, I am very interested in hearing from the witnesses and looking forward to looking at—seeing how we might do with the legislation—how we might be able to impact in a positive way.

Thank you, Mr. Chairman.

Mr. SIMMONS. I thank the gentleman.

The legislation before us has been proposed by my colleague, Mr. Buyer.

He has a statement that he has inserted for the record, which should be in Members' pockets but I would also like to extend him the courtesy of making an opening statement, if he so desires.

OPENING STATEMENT OF HON. STEVE BUYER, CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

Mr. BUYER. Thank the chairman, and I want to thank you for having the hearing.

This committee has a history with this issue dating back to Chairman Terry Everett, and the committee has invested a lot of time.

I extend compliments to Dr. Roswell's predecessors, Dr. Kaiser and Dr. Garthwaite, who, under a previous administration, took the issue head-on.

I think they were correct in creating the independent body for oversight and for compliance issues, and I was disappointed that this administration ended—actually dismantled ORCA and ended the periodic reviews, and then, of course, when you have an incident that breaks out, then everybody wants to have another reorganization, and the purpose of this legislation is so we don't have these administrations going back and forth and let us just set up an independent oversight review.

So, this isn't something that I just woke up one day and said this is something that we ought to do. This committee and the oversight committee has a great history in this, Mr. Chairman, and I think that even the testimony we are going to find here today is that everybody is going in the same direction on perhaps parallel tracks, it is how we get there, and I want to thank you for holding this hearing, and this will be very productive.

I yield back.

[The prepared statement of Chairman Buyer appears on p. 39.]

Mr. SIMMONS. I thank the gentleman.

Unless any other member has an opening statement, I would like to now go to our first panel. We have representatives from the Department of Veterans Affairs. We have Dr. Robert Roswell, who is the Under Secretary for Health. He is accompanied by Dr. David Weber, Acting Chief of VA's Office of Research Oversight.

Dr. Weber, good to have you here.

Dr. Lynn Cates, who is the Assistant Chief of Research and Development, and Dr. Mindy Aisen, who is the Deputy Chief Research and Development Officer.

Welcome. Thank you all for coming.

Dr. Roswell, the microphone is yours.

STATEMENT OF ROBERT H. ROSWELL, M.D., UNDER SECRETARY OF HEALTH, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY MINDY L. AISEN, M.D., DEPUTY CHIEF RESEARCH AND DEVELOPMENT OFFICER; DAVID A. WEBER, ACTING CHIEF, OFFICE OF RESEARCH AND OVERSIGHT; AND LYNN CATES, M.D., ASSISTANT CHIEF RESEARCH AND DEVELOPMENT OFFICER

Dr. ROSWELL. Well, thank you, Mr. Chairman and members of the subcommittee.

As always, it is a real pleasure to be here. You have already introduced my colleagues, so I will just give a brief oral statement. My full statement has been submitted for the record.

VA fully supports efforts to protect human research subjects, ensure animal welfare and research safety, oversee research compliance, and assure full compliance with research regulations.

The Secretary recently approved the establishment of the new independent Office of Research Oversight, which is designed to achieve precisely these ends and is, we believe, fully compliant with the provisions of H.R. 1585. H.R. 1585, though, would codify this action into law.

Should the committee proceed with this bill, my formal statement describes several revisions that we feel are necessary to assure effective and appropriate functioning of this new office.

Mr. Chairman, I applaud Chairman Buyer for his leadership in responding to recent inappropriate research activities which have occurred in the Department of Veterans Affairs.

I also applaud his efforts to assure the safe conduct of human research, both now and into the future, and believe that the process of improvement has enhanced our ability to provide research oversight through the positive and productive interactive dialogue we have had with his office as we have formulated the new Office of Research Oversight, along with the PRIDE office, the Program for Research Integrity, Development, and Education, in the Office of Research and Development.

During his June 18th oversight hearing, I outlined steps that we were taking to respond to these recent events, including the streamlining of research oversight activities. We have revised the organizational structure for research oversight to align policy and training within the Office of Research and Development and to focus the Office of Research Oversight on compliance with regulatory and policy aspects of human subject protection, animal welfare, research safety, and research misconduct.

Following its inception in 1999, ORO's predecessor, the Office of Research Compliance and Assurance, or ORCA, contributed in many ways to the improvement of VA's protection of human subjects participating in research.

ORCA provided prospective compliance consultations, retrospective compliance reviews, a compliance assurance program, and a training, education, and development function. However, our experiences have compelled us to establish mechanisms for more rapid, broad, and effective development and dissemination of policy and education.

These actions are directed to go beyond the assurance of compliance and assure the adequacy and integrity of the research operations.

Recently, VA established the Program for Research Integrity, Development, Education, or PRIDE, within the Office of Research and Development. PRIDE is a ground-breaking program that is responsible for all education, training, and policy development related to human research protection at the VA.

While a new infrastructure has been developed in the Office of Research and Development to support effective, rapid improvement in research conduct, VA believes strongly in independent oversight, as specified in H.R. 1585.

As described, policy and programmatic educational activities now reside in the Office of Research and Development.

Oversight of compliance with policy, regulation law, and ethics is the responsibility of the Office of Research Oversight.

All human resources of the predecessor office, ORCA, are now contained in the Office of Research Oversight and are now devoted to these oversight activities.

The activities of the Office of Research and Development and the Office of Research Oversight are increasingly complementary.

Problems identified through oversight are addressed through aggressive solutions by the Office of Research and Development.

In our revised program of protections, the oversight office will enjoy greater role clarity in discharging the function of its predecessor organization. The increased focus on oversight activities will assure that problems are investigated and corrected, with the Office of Research and Development as a committee peer office providing effective and timely policy and training.

Research programs that fail to apply safeguards—appropriately safeguard patients and the values of ethical research conduct will have funding terminated. We will continue to this so that the Department of Veterans Affairs maintains the highest quality research programs in the country and most responsibly serves the needs of our nation's veterans.

Mr. Chairman, this concludes my oral statement. My colleagues and I would be pleased to answer any questions you or the committee may have.

[The prepared statement of Dr. Roswell appears on p. 48.]

Mr. SIMMONS. I thank the gentleman.

I have two questions, and I will phrase them both, and then you can respond as you see fit.

Dr. Roswell, on page 1 of your testimony, you make the statement that, "We do not believe this legislation is needed," and you have given some of your reasons for that. My colleague, Mr. Buyer, has also stated on the record that part of his concern is that, if you don't place some of these provisions in statute, there is fluctuation from Administration to Administration. There may be one Administration or one set of Administrators who are doing a fabulous job and then we have a change of personnel, and without a statutory obligation, they may make a different set of decisions.

So, my question to you is, absent a statutory authority, how do we get stability in the process with this important issue?

Then the second question is—as I turn and look at the various organizations that are involved in providing oversight in one form or another—the research office, the National Patient Safety Center, the National Center for Ethics, the Office of Research Oversight, the medical inspector, the IG, I suppose, employee education, the Learning University, etcetera, etcetera—how do you coordinate all of these oversight activities?

Those are my two questions.

Dr. ROSWELL. Well, thank you, Mr. Chairman. Let me begin with your first question.

In my formal statement, it does state that we don't feel the H.R. 1585 provisions are needed at this point, because we believe the actions the department has taken, as approved recently by the Secretary, coupled with the actions within the Office of Research and Development, fully comply with the intent of H.R. 1585.

You do raise a valid point about how we would safeguard in future administrations, and certainly codifying this provision or this structure in law would be one way to achieve that end.

Another way would be through the continuous oversight function that this committee provides to the way VA research is conducted.

I believe, as I said in my opening statement, that the product we have today is substantially better than the product we had in 1999.

I believe that the evolution of the research oversight and assurance product within VA is a combination of an evolutionary process, an effective oversight from this committee, and consultation with committee members and staff.

That collaborative arrangement of oversight, I believe, yields the most effective safeguarding of human research experimentation in VA that we can possibly achieve.

With regard to your second question concerning the multiple bodies that are involved in oversight, you are absolutely correct.

In addition to a number of agencies within the Department of Veterans Affairs, there are also external agencies, such as the Office of Human Research Protection and the Food and Drug Administration, many of which have oversight functions, as well.

We believe that pluralistic oversight strengthens the overall quality of research and work within the Office of Research and Development and my office to coordinate those activities to assure full compliance across a spectrum of regulatory agencies and guidelines.

Mr. SIMMONS. Thank you for those responses.

Now I would ask my colleague, Mr. Rodriguez, if he has questions.

Mr. RODRIGUEZ. Based on your testimony, you are already kind of doing what the law kind of says. I think my usual response is what is wrong with having it?

Let me get to that incident that occurred in Albany. There have been some concerns there from Congress and the Central Office that have expressed about being informed of the suspected problem in the research involved for some time, and then the situation in Albany, my understanding is that there was a failure in communication, was largely to blame in allowing it to continue, and that we knew that falsification was occurring. Yet, we allowed it to happen.

How does this—all these changes kind of help correct that situation?

Dr. ROSWELL. Mr. Rodriguez, I appreciate the question. As you know, the Albany situation is still under investigation, and I can't speak directly to that issue, but let me point out that we have implemented a number of changes, many of which were implemented as a direct outcome of the situation in Albany.

For example, we have a very comprehensive research credentialing process that is now fully in place throughout the department.

We have also structured the organization to better address issues and to assure timely notification of my office and allow us to provide the effective oversight across the research spectrum.

Let me ask Dr. Aisen to address your question in more detail.

Dr. AISEN. Well, I should ask Dr. Cates, since she was hired to specifically develop the policy and guideline component of this program. But, I think that a lot of what has been said today about accountability we are trying to do in fact and in spirit now in the—on the research side of the house.

There has been a much greater effort to educate all of our researchers about the obligation of ethical conduct, about what the common rule is and what it means. There has been—I think there is an entire spirit—you know, not everyone has embraced it yet. There is still a lot of feeling like, yet another thing to do, another bureaucratic thing that we must oblige the Central Office with, but there has been a great deal of attention paid to the structure of the IRB's, to the importance of the IRB's. We are beginning to make provision to reimburse people for their time, for serving IRB's.

We are thinking about a lot of creative ways to have the research committees and people who serve on the IRB's be better connected with Central Office, and to have very current information.

Lynn Coates has developed a comprehensive on-line education program. She has reached out to the community and has done an incredible amount of education in a very short period of time.

So, I guess we see this beyond just patient safety.

We see it as wanting to create a research program that is safe in the VA, so that, at the same time, (even though this hasn't been the specific push of the committee here,) we have reached out to the oversight of VHA to help us do better bio-safety performance, guidance, education.

So, I think that, overall, our attitude is this is something we must do, that we will do, that we will give people credit for, that we will honor people for doing, and we will also reimburse them for their time, but I would really like it if we could have Dr. Cates talk about the incredible job she has done in a very short time since arriving at VA.

Dr. CATES. I arrived here only 4 months ago. The first day of the Stand Down was my first day of work, and that was the day that we did announce something very different for the VA from the rest of the country for human subjects research protection, but I think it is very important. We started the spirit of seeing that virtually everyone, short of secretarial staff, was both credentialed and trained in human research protection, so that everyone would be

empowered and recognize the privilege it was to deal with veterans who had volunteered for human subject studies.

In that time, we did create an on-line course in good clinical practices, and we can document that over 15,600 researchers in the VA have taken that course to date.

We also did credentialing and can attest that of all facilities at the VA who were participating—who participate in human research protection responded to this, verifying that—98 percent of them were able to verify complete compliance with regulations. Only two had minor issues that they were dealing with, and those are being corrected as we speak.

Eighty-four percent documented that their training of all individual researchers had been completed.

Some individuals could not be trained because they had been called up for the war, for instance. Credentialing is in progress.

Any researcher who did not comply is not permitted to do research at the VA now.

In addition to that, we have embarked on a very active training program.

We were delighted that Secretary Principi mandated that the leadership in the VA get training in human research protection.

We started this with 136 medical center directors in Ann Arbor, Michigan, in May, and will continue this at the end of July with over 500 leaders, including the chief of staff, etcetera.

In addition to that, we have massive education programs planned to roll out this fall.

We also have a blue ribbon panel that will be advising us, and I can go on and on, but you can see that we are being very aggressive and taking this very seriously.

Mr. RODRIGUEZ. Let me ask you—I know that Dr. Wray is pretty new as a research area there, and I know that—and I was wondering if Dr. Roswell—I know that she has been identified as a maverick, and I am glad to hear, also, about the enthusiasm right now, but that enthusiasm can come and go, and sometimes you need the legislation in order to make sure that it occurs, because I think, you know, a year from now, 2 years from now, you know, you get new staff or—and I was wondering how—if Dr. Roswell, maybe hear from you in terms of your support of Dr. Wray's efforts or that enthusiasm is there, and once again, if you are already doing what the—at least that you claim—what the Congressman is trying to do, what is wrong with that?

Dr. ROSWELL. Thank you, Mr. Rodriguez.

Certainly, I am very enthusiastic in my support of Dr. Wray.

She is deeply committed to assure not only the safe conduct of research but to make sure that veterans have access to cutting edge technologies, which is only available through their participation in human research, in many cases.

Life-threatening and, in some cases, fatal illnesses present a very serious catastrophic situation to a veteran in need of medical care.

The opportunity to participate in human research affords hope, optimism for extension of life or enhanced quality of life that might otherwise not exist.

So, I believe deeply, as does, I think, Dr. Wray, that making human experimentation an opportunity enhances the quality of

care we provide our veterans, and we are deeply committed to preserve that to assure that veterans—all veterans have access to state-of-the-art technology even before final approval by the Food and Drug Administration.

That is the benefit of human research participation in VA.

Dr. Wray is also committed to translating research into enhanced clinical practice and to assure that the research of today becomes the clinical care of veterans tomorrow.

Translation of research findings into actual practice has always been difficult in research in America, but I believe the Department of Veterans Affairs, under Dr. Wray's leadership, is ideally situated to enhance that translation.

A fundamental change in a research program such as that does cause some anxiety, because it represents a threat to those involved in the research enterprise, but we truly believe that our focus must be on preserving human research, assuring the safety of all who participate in that, and make sure that the research program within the Department of Veterans Affairs fully serve the needs of our veteran constituents.

Mr. RODRIGUEZ. Thank you very much.

Mr. SIMMONS. I thank the gentleman.

Mr. Buyer is recognized for 5 minutes of questions, followed by Mr. Snyder.

Mr. BUYER. I welcome my colleagues to review testimony at a June 18th hearing I conducted, a statement by Dr. Kovsky.

He is the former director of the Office of Human Research Protections, the Office of Secretary of the Department of Health and Human Services. His testimony was extremely helpful, and his recommendations to try to seek uniformity on how we, as the government, conduct our oversight, whether it's with Health and Human Services or here within the VA.

He testified that, quote, "The organizational restructuring at the VA that eliminated ORCA and returned, at least in part, oversight of research activities to ORD, caused great concern."

Then he went on and then he gave a series of recommendations, some of which we followed, some of which I found extremely fascinating.

My question to you, Dr. Roswell, is that here we have the FDA, NIH, and other Federal agencies within their umbrella, when they have their oversight over the human research, there is a lot of power within a site review team. When they go to a particular site and they find a particular problem, they have specific authority to suspend, restrict, or modify the research on-site, but here, within your reorganization, ORO does not have that authority, correct? They have reserved that to ORD. So, that is a lot different than how it is conducted within the National Institutes of Health, correct?

Dr. ROSWELL. Not exactly, Mr. Buyer.

ORO doesn't have the authority. I retain that authority.

Mr. BUYER. Isn't that what I just said?

Dr. ROSWELL. ORD doesn't have the authority. In other words, I retain that authority. ORO reports directly to me. If ORO recommends a program need be terminated, I stand ready and willing and, in fact, have a precedent for acting to close or terminate a re-

search program. That is not an authority that is delegated to the Office of Research and Development.

Mr. BUYER. All right. I have got to get this right.

I mean, I am looking at a white paper here issued by the VA, and they say that section 7303(e)(3)(D) would provide that one mission with the new office is to, quote, "to suspend, restrict, or modify research or take such actions as the director determines appropriate." Under the VHA structure, ORO does not have this authority.

The provision in section 7303(e)(3)(D)(ii) states that action to suspend, restrict, or modify research would be taken to preserve the integrity and validity of the research, and under the existing VHA structure, ORO does not have this authority.

This aspect of the mission description is within the mission of ORD.

Are you saying that the white paper here is incorrect?

Dr. ROSWELL. I am sorry, Mr. Chairman. I am trying to locate—I believe I have the white paper you are——

Mr. BUYER. Second page, at the top, second full paragraph, where it says section 7303.

Dr. ROSWELL. Okay.

Mr. BUYER. I will give you a moment to look at that.

Dr. ROSWELL. There may be an error, Mr. Chairman, in the white paper, but the Under Secretary for Health retains the authority to terminate activities on the recommendation of ORO, Office of Research Oversight.

Mr. BUYER. If you have a team that specifically goes to a site, do they have the authority, right now, to suspend or modify or restrict research? You have retained that.

Dr. ROSWELL. I retain that. In previous situations, under ORCA, a phone call was all it took if an action was needed.

Mr. BUYER. How do you reconcile that with Dr. Wray's teleconference of March 10, 2003, where she stated, "The Office of Human Research Oversight will"—this is her quote.

"The Office of Human Research Oversight will be a much, much smaller office and have responsibility only to do focused reviews for cause when I report them for cause." That is her quote.

Dr. ROSWELL. I believe that is an accurate quote, but I believe the date you said was March?

Mr. BUYER. I won't quibble about the dates.

Please reconcile the intent of how she is going to run her office, make it much, much smaller, not do the periodic reviews, and then I am confused about who has authority to do what now.

Dr. ROSWELL. I believe that the quote you are referring to was before the current organization was approved by the Secretary.

This was a time when we were actively engaged in dialogue with your office, with Mr. Wu, your staff director, and I do not concur in that statement.

I don't argue the fact that Dr. Wray made that statement, but that statement has not been incorporated into the policy that currently has been approved by the department.

However, back then we were talking about human research. We have since expanded the Office of Human Research Oversight to

become the Office of Research Oversight, which includes laboratory animal and biological—the BSL, the bio-safety lab function.

They also have full and independent autonomy in determining what they will investigate related to compliance, and they have the ability to report directly to me on any program that needs termination.

I retain the authority to terminate a program immediately on the——

Mr. BUYER. Let me ask this.

Do you believe these teams that are in the field should have authority that is similar at NIH, if they find or see a specific problem, that they can restrict or immediately modify or suspend the research in the field? Do you believe that is a good idea?

Dr. ROSWELL. Not without my concurrence.

Mr. BUYER. So you think we should run a billion-dollar Federal agency much different than what NIH does.

Dr. ROSWELL. I think there is a fundamental difference.

NIH provides external oversight and has that authority. The ORO is an intra-departmental function that allows us to provide oversight.

Mr. BUYER. That is why I love independence.

I yield back.

Mr. SIMMONS. Mr. Snyder, followed by Mr. Miller.

OPENING STATEMENT OF HON. VIC SNYDER

Dr. SNYDER. Thank you, Mr. Chairman.

Dr. Roswell, I just wanted to make one couple and a couple of questions.

I am generally sympathetic to Congress not micro-managing agencies, doing things by statute that can be done reasonably well by your own administrative decisions, but I wanted to just put a cautionary note on your comment that, you know, Congress' oversight function can serve as a long-term way of evaluating this.

I would like to think we are wonderful at providing oversight, and I think we are depending on the chair or the subcommittee chair, depending on the Congress, depending on the energy, but I think that is, over the long term, very unreliable.

I will give you just a personal example right now. I think the House Armed Services Committee, of which I am a member, is doing a sinful job of providing oversight of what is going on in Iraq.

I think it just sinful. You know, I am not sure why that is.

I think we did quite a remarkable job of providing oversight when we had a Democratic president and a Republican-controlled legislature.

Now, maybe that is part of the motivation, I don't know, but I just think it's unreliable to say that we are going to rely on congressional oversight in this kind of thing. I don't think that will work.

If someone were to come in your position, or a new Secretary of Veterans Affairs, and make a decision, we need to save money and I think the first place that I want to save money is on cutting out all the energy that is going into oversight of research, I want to only do those things that we are statutorily required to do, what

things are things are you statutorily required to do in terms of oversight of research?

Is there much of anything?

Dr. ROSWELL. We do have a statutory requirement for the Office of the Inspector General, which has an independent oversight function of a broad range of activities, including research and including human research. Beyond that, I would have to defer to our legal counsel to specify exactly what statutory oversight is required.

The Office of Medical Inspector, I believe, there is a statutory provision that creates that office within the Veterans Health Administration, but again——

Dr. SNYDER. Let me ask that as a question for the record, if I might, Mr. Chairman.

Would you provide for us, please, what you feel your statutory obligations are for oversight of research conducted at the VA?

Dr. ROSWELL. I would be happy to provide that.

Mr. SIMMONS. Without objection, so ordered.

Dr. SNYDER. Dr. Aisen, I think it was maybe your comment that you were talking about the staff and how you are encouraging them to comply with this new program, that it not be perceived as just another bureaucratic thing, and I understand that.

Maybe part of the doctrine we always see is, you know, we rebel against that kind of stuff, but would that not be the helpful part of a statutory obligation, that, you know, you don't have to give people a dozen cookies when they do a good job?

I mean if it is set out in statute this is what you will do—I mean this is very important, I think, to the American people and to the families of veterans and, I think, to you, and so, why would not that be helpful when you would be able to say, you know, this isn't just one of these bureaucratic things, this is something the President signed into law, and there are statutory requirements, if you don't do it, you are breaking the law.

Why would that not be helpful?

Dr. AISEN. Well, I can tell you philosophically why I think it wouldn't be helpful.

Of course, if it is the law, people will follow the law, but you know, I think a fundamental problem has been that there hasn't been an overall spirit throughout the whole medical research community that a lot of the rules and regulations, and I'm talking about: within VA and outside of VA and clinical researchers everywhere doing pharmaceutical trials, that the fundamental core of the research is to help the population being studied and that the individual has got to be not only thanked but treated with great honor because they are participating, and I think there are a lot of different pressures on physicians in the clinic seeing patient individually and enrolling patients individually, and I don't think a rule and a regulation are going to have the kind of impact that changing the culture will.

So, you know, I almost feel—you know, I am not part of this discussion, really, about, you know, do you legislate it or not.

I don't think legislation would ever be enough, and I think that people have to celebrate that this is an important component of being a physician, a clinician, that it is an honorable profession, that it is a great honor to do research, that it is an important thing

to do, and you know, frankly, we have alluded to some situations where some terrible things happened, and they were breaking the law, and that didn't stop them.

Dr. SNYDER. That is a good point.

Dr. AISEN. So, you know, I think that whether it is legal or not, the efforts that we are making in terms of guidance and policy and creating a culture that really understand what oversight really means and what ethical behavior really means and allows people the time to think about bio-ethics is really what is important.

Dr. ROSWELL. Dr. Snyder, if I may, I think all of us would concede that legislation that would codify into law this oversight function would not in any way be detrimental, but it takes more than just that. We have to develop a departmental culture.

Dr. SNYDER. I agree with that. I think it is like law enforcement.

I mean we have had some police departments around the country that have had great problems, and yet, the legislation was clearly there about trying to establish the kind of atmosphere you want.

I wanted to ask how much of a challenge is that, on these dual appointments that you have, where you have people who work for medical schools, 60 percent, and 40 percent VA, or 75/25 or whatever it is, when it comes to the research component—and a lot of these are researchers. Is that a fair statement? They are involved in research.

Is the situation out there now that they have two sets of, in your words, bureaucratic requirements that they have to comply with, or are you also consistent that it is one set?

I mean do you understand what I am getting at?

Do you have a state medical school or a private medical school set of responsibilities that are dramatically different from the Federal oversight, the VA oversight of research?

Is that a challenge, and would that be complicated by legislation?

Dr. ROSWELL. I think you will find some local variation, but in all cases, the most important local vehicle to assure compliance is the Institutional Review Board, or the IRB.

In the majority, I would say, of our highly affiliated VA medical centers, we have an integrated institutional review board, and so, that integrated IRB provides commonality of its oversight of the research program across the academic campus, but let me ask Dr. Cates or Dr. Aisen to expand on that.

Dr. CATES. We required training in protection of human subjects during the Stand Down, and the course that was required for that was the same course that academic affiliates take.

They had their choice of one created by the NIH or another course, but those are already taken at academic institutions.

The good clinical practices course that we created was specific to the VA, but we are working to develop courses this summer that could be used by the academic affiliates, as well.

Dr. SNYDER. Thank you.

Mr. SIMMONS. Mr. Miller?

Mr. MILLER. No questions.

Mr. SIMMONS. Mr. Beauprez.

OPENING STATEMENT OF HON. BOB BEAUPREZ

Mr. BEAUPREZ. Thank you, Mr. Chairman.

Doctor, I sit up here a little bit in a fog, I will confess, as to exactly how all of this, the research is being both directed and then overseen, and I'd like you to explain that a little bit for me, because I am feeling that, in a simplistic manner, we have got an obligation, one, certainly to the American taxpayer, who is providing this billion dollars a year, or thereabouts, to do research, and two, an ethical/moral obligation to veterans are submitting themselves to this research, and I want to pose, I guess, a question to you and then ask you to, again, tell me how it is addressed.

I want to make sure that the fox isn't watching the henhouse, and in the business I am familiar with, banking, compliance and oversight and operations, not just in name but in fact, have to be very clearly autonomous. Go that direction for me, if you would.

Dr. ROSWELL. I would be happy to, Mr. Beauprez.

Research within VA is managed through the Veterans Health Administration by the Office of Research and Development.

There is a separate Congressional appropriation that provides approximately $400 million a year specifically for the conduct of research.

Those monies are administered through the Office of Research and Development through a competitive grant process with peer review.

Grant awards are made to investigators who, in the majority of cases, are VA clinicians. They receive their grant monies and conduct research.

If the research involves any human participation, they then must comply with a series of oversight functions, beginning with the local institutional review board that I spoke of.

That complies—that is managed in accordance with what Dr. Aisen referred to as the common rule. The common rule is within the Office of Human Research Protection, external to our department and administered by the Department of Health and Human Services.

So, HHS has, through its Office of Human Research Protection, has primary oversight for all human research, and our responsibility is to assure compliance with that.

In addition to that external oversight, if there are medical devices or pharmaceuticals involved, the Food and Drug Administration has oversight. There is independent oversight by our Office of Inspector General, which is a statutory requirement, that reports directly to the Secretary.

We have gone beyond that, though, and sought external accreditation on a contractual basis with the National Committee on Quality Assurance, or NCQA, and we actually use them to independently accredit and review all of our research programs.

We went beyond that in 1999 with the creation of the Office of Research Compliance and Assurance within the Veterans Health Administration to provide an additional measure of independent oversight of human research.

The reason for this hearing and the one that Mr. Buyer held earlier this summer was because, despite those efforts, we had an egregious case where harm came to a veteran who participated in VA research.

We don't believe that it is in any way near the norm, but the point is a situation developed where a veteran had an adverse outcome as a direct result of their participation in human research, which is untenable to me, and I hope it is—and I am sure it is untenable to everybody at this table.

We are deeply committed to assure that that doesn't happen.

So, with these multiple levels of external oversight, we have fortified and strengthened our internal Office of Research Oversight, independent from the Office of Research and Development, that administers the program and provides the funding to provide direct consultation to my office about the conduct.

Let me point out that, while we have extensive external oversight through the Office of Human Research Protection and the Food and Drug Administration, through our own Office of Inspector General reporting to the Secretary and to the Congress, and through the external contracted NCQA accreditation of all of our research programs, the span of oversight is great for all of those agencies.

The Office of Research Oversight within the Veterans Health Administration, for which I am responsible, has a staff of 28 people that is providing oversight over a very limited number of research programs within the VA. So, the oversight span of control or span of responsibility is much smaller, which we believe gives us a more effective way to look at our research.

The autonomy we have given to that Office of Research Oversight allows them to focus on areas of compliance anywhere across the gamut of human research, while the Office of Research and Development still retains the responsibility to administer the programs in compliance with those regulatory—those set of regulations and assure the safe conduct of research.

Mr. BEAUPREZ. I want very much to believe only the best of all people that are trying to do a good job, and yourselves included, but respond for me—and you have done it in fashion already—again to the question—thinking about those two groups, taxpayers and veterans—and I expect every member of this committee and the full committee feel a very large obligation to pass the straightface test to both of those groups, both currently as well as in the future, that something didn't go by on our watch either squandering the taxpayers' money or abusing our veterans that participate in any of these projects. Wouldn't we then—wouldn't you and this committee be better served by codifying at least some of this?

I am not a big fan of rule and regulation to the tenth power, but you know, going back to my previous life again in banking, it always helped to go to the manual and say what were we supposed to be doing and when were we supposed to do it?

Dr. ROSWELL. The point is well taken, and as I said previously, I would concede that there would be no reason not to codify this in law.

Our only position is we have already, we believe, complied with the intent, if not the precise——

Mr. BEAUPREZ. But you have done it more from an internal policy standpoint than by reference to a written law, back to what I think Dr. Snyder was going for. Would it not be better for perpetuity to codify?

Dr. ROSWELL. The only argument I personally would have against that is that perpetuity is not uniform.

Health care changes, research changes, the research regulatory environment will change, and so, codifying something in law would require periodic oversight of that statutory requirement to assure it's consistent with the state of research practice, but with that one minor caveat, I see no deleterious effect of codifying this in law, and in fact, it does address some of the concerns that you and other members of the committee have pointed out.

Mr. BEAUPREZ. But the kind of evolving changes that you are referring to, and I accept, probably occur less frequently than changes in management or personnel within an agency such as the VA.

Dr. ROSWELL. That is probably an accurate assessment.

Mr. BEAUPREZ. Thank you, Doctor.

Thank you, Mr. Chairman.

Mr. SIMMONS. Mr. Rodriguez?

Mr. RODRIGUEZ. No questions.

Mr. SIMMONS. I would like to just conclude with a comment, I think, at this point, but let me ask a question first of Dr. Weber.

It is my understanding that you are the Chairman of a group called Adverse Events Research Advisory Committee. Is that correct?

Mr. WEBER. That is correct, yes.

Mr. SIMMONS. That being the case, it would be my assumption that you have done some work, maybe even have published or issued a report, as a member of this committee. Is that the case?

Mr. WEBER. We have worked on a procedure to improve the adverse event reporting policies that we have followed within our office over the last 3 years.

Basically, we want to improve the protection of the patient and we want to minimize the risk to the patient participating in research. The handling of adverse events is a complex issue. There is diversity of opinion on how it should be reported. Each of the different Federal agencies have somewhat different policies for adverse event reporting and differences in terminology. This has caused confusion in reporting and, sometimes inconsistent reporting of adverse events. We are trying to improve upon that.

We have developed what, within the VA, we call a handbook to establish a policy for reporting adverse events to Central Office. We have a rough draft of that, and that is where we are at at the moment.

Mr. SIMMONS. Would it be possible for us to have a copy of that handbook?

Mr. WEBER. Yes, you could.

I don't have one with me, but certainly one could be made available to the committee.

Mr. SIMMONS. Well, let me make an official request for it.

I think it would be useful to review that.

You mentioned the issue of terminology, and I just want to make a note for the record—Dr. Roswell used the word—or the term "human research," but he also used the word "human experimentation," and let me just speak as a veteran, as a Vietnam veteran, as somebody who served in uniform for many years.

I saw a show on TV the other night that had to do with the Baatan Death March, and one of the phrases that was used by the veterans was we felt that we were expendable. We felt we were expendable.

I worked for Senator John Chafee, who is a veteran of World War II. He was at Guadalcanal. He also felt that he was expendable at the time.

Veterans don't like to feel that they are involved—or at least I would say for myself, that I would be involved in human experimentation.

I would not like to feel that I was a guinea pig, for example.

I would like to feel that, if I was an organ donor, if I was somebody who could be used in a research project, that I was twice the hero, that I had offered my life up for my country once in uniform and now, at a certain point in my life, perhaps when I have an illness that is incurable, that if research and science can extend me a little bit or make it less painful, but also if research can learn something from my condition, that my giving of my life in this capacity is something that is respected and honored, and that I am not a guinea pig, and so, I would also suggest that the terminology we use to describe patients in this condition is important, and the respect that we extend to them is important, and perhaps that is even more important than legislation that we pass here or committees that we form or commissions or councils that we establish. Do any of you want to comment on that?

Dr. ROSWELL. Mr. Chairman, I agree with you completely, and I respect your opinion. You are a true patriot. Thank you.

Mr. SIMMONS. Well, I wasn't speaking for myself. I was actually speaking for those veterans who volunteered for research projects, not only in VA but elsewhere. Those are the ones that I think are the patriots.

Any other comments for the panel? Questions?

[No response.]

Mr. SIMMONS. That being the case, I want to thank you for appearing, and we will prepare for our second panel.

Let the record show that the subcommittee invited the following organizations to appear and offer testimony today on this bill—the Federation of American Societies for Experimental Biology, the National Association of Veterans' Research and Education Foundations, the Friends of VA Research, and the American Federation for Medical Research.

These organizations declined to testify, but Dr. John Clarkson, Dean of the School of Medicine at the University of Miami, is testifying today on behalf of the Association of American Medical Colleges, an organization that represents medical school interests.

Dr. Clarkson has appeared before the subcommittee before. We are happy to have him back.

We welcome you. It appears that you will be a solo cameo appearance on behalf of the entire American medical research and scientific establishment outside of VA. Congratulations for your courage, Dr. Clarkson, please proceed.

STATEMENT OF JOHN G. CLARKSON, M.D., SENIOR VICE PRESIDENT FOR MEDICAL AFFAIRS AND DEAN, SCHOOL OF MEDICINE, UNIVERSITY OF MIAMI, FLORIDA, ON BEHALF OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Dr. CLARKSON. Thank you, Mr. Chairman, and thanks to the members of the subcommittee for allowing me this opportunity.

As the dean of a medical school, I am used to sitting alone.

I would like to begin, before I read my formal statement, by just commenting on your last question, or your comment, and Dr. Roswell's response.

I think the participants in clinical trials, such as the women who participated in the Women's Health Initiative, are heros in their own way, and by the way, every single time that happens, it has to happen with informed consent, and I think the use of the term "experimentation" perhaps is unfortunate, because in every instance, it has to be done with complete—as complete as possible knowledge by the participants, but I think individuals who do participate in clinical trials, veterans and non-veterans, are heros, and it is how we learn whether treatment A is better than treatment B, and it is in a setting where we really don't know which is better.

So, I certainly commend you on your position, but I think we ought to acknowledge that clinical research is the key to the future of our health care.

I am, as you indicated, Dr. John Clarkson. I am senior vice president for medical affairs and dean at the University of Miami School of Medicine, and I am here today on behalf of the Association of American Medical Colleges, an organization that represents the 126 medical schools and over 400 major teaching hospitals, including over 70 VA medical centers, more than 105,000 faculty and 96 academic and scientific societies, the nation's 66,000 medical students, and almost 100,000 physicians in training.

I am here today to talk about a number of issues related to the research program administered by the Office of Research and Development of the Veterans Health Administration.

I shall first address the legislation to establish an office to oversee research compliance and assurance within the VHA, but then I wish to turn my attention to two other issues that have been receiving much attention lately amongst my colleagues in the research community.

Those issues are the reports of the new vision of the ORD leadership for VA research which appears to be—appears to involve a shifting of priorities in the allocation of VA research dollars and alleged actions by ORD leadership that have been perceived as threatening the integrity of the peer review system.

Before going into the details, I think it is important to offer the subcommittee some context as to why these issues are so important to medical schools and why the AAMC is an essential stakeholder in these decisions.

107 of the nation's medical schools maintain formal affiliation agreements with VA medical centers. These affiliations, which stem from the seminal VA policy memorandum number 2 published in 1946, have proven over nearly six decades to be mutually beneficial by affording each party access to resources that would otherwise be unavailable.

As stated in the policy memorandum, the affiliations allow the VA to provide veterans a much higher standard of medical care than would be given to him—this was in 1946—with a wholly full-time medical service.

In return, the medical schools gain access to invaluable undergraduate and graduate medical education opportunities through medical student rotations and residency positions at the VA hospitals and faculty with joint VA appointments are afforded opportunities of research funding and access that are restricted to individuals assigned as VA employees.

They represent the full spectrum of generalists and specialists which, if there were not the association, the affiliations with medical schools, would be much more difficult to hire, to have on behalf of service of our veterans.

These jointly appointed clinician investigators are typically attracted to the affiliated VA medical center both by the challenges of providing care to the veteran population and by the opportunity to conduct disease-related research under the VA auspices.

With regard to H.R. 1585, which would establish an Office of Research Compliance and Assurance within the VHA, let me first say that the AAMC fully supports the principle and intent of this legislation.

The AAMC is deeply committed to promoting clinical research and is recognized for its strong commitment to strengthening and assuring the protection of human research subjects.

The Association, several years ago, actively supported the establishment of the Office of Human Research Protections in the Office of the Secretary, Department of Health and Human Services.

Similarly, when the VA first created the Office of Research Compliance Assurance, ORCA, in 1999, the AAMC supported the placement of that office with the Under Secretary for Health, and the Association shared the concerns of many when the VA decided to eliminate ORCA and establish an office with very similar responsibilities within the purview of the Office for Research and Development.

We believe, in principle, as this bill would require, that oversight and compliance functions should generally be separate from the promotion and funding functions of a program.

Accordingly, we were reassured earlier this year when the VA announced its reconsideration of its earlier decision and a return to the Office of the Under Secretary a new Office of Research Oversight to assume the compliance responsibilities formerly exercised by ORCA.

I would like now to return to two issues that I mentioned earlier.

The AAMC is certainly aware and very disturbed by the uncertainty, anxiety, and anger that seem to be roiling in the VA research community over recent decisions reported to have been made by the leadership of ORD about the future directions and practices of the VA research program. We suggest that there has been a lack of transparency and clarity about both the reformulated research goals and the practices by which they are to be implemented. We believe that this lack has contributed to confusion, as well as possible misinterpretation and misunderstandings about a number of important issues.

I see the light in front of me is red, and my full statement is in front of each of you, but what has occurred, effectively, if I can summarize——

Mr. SIMMONS. Please do. Thank you.

Dr. CLARKSON. Okay.

Mr. SIMMONS. No, please continue, but if you could summarize, that would be helpful.

Dr. CLARKSON. Yes, sir.

When the new leadership in the Office of Research and Development came on board, there were already in process a number of research applications, they had been submitted under the previous research administration, and without clear communication to the research community, the peer review process by which proposals are reviewed was modified, or the proposal to modify was created, and in addition, because of concerns about budgetary restrictions and of stated concerns about a lack of quality of the peer review process, an arbitrary decision was made, what appeared to be arbitrary, not to fund certain proposals where there had been previous oral communication to research investigators that they, in fact, were going to receive funding. This announcement was faxed to the investigators on the day the funding was to have begun.

They had received an oral communication from the VA administrative leadership several months previously indicating that their grants were, in fact, going to be funded, and there were a total of 18 such communications. One was rescinded, the other 17 sustained.

The other—so, what appeared to be an arbitrary decision not to fund, even though the peer review process had begun under another administration and the rating scores were fundable, was upsetting to these investigators, number one.

Number two, there was concern expressed about the peer review process and that it wasn't stringent enough and that a new peer review process was to be developed and that some blue ribbon panels had been appointed. No one knew who were the members of these panels at the time. No one knew what the process by which these proposals—no one knew the process under which these proposals were going to be reviewed, how it was defined.

So, the research community—and I simply remind you that nearly all these people are medical school faculty members.

Some of them are un-funded. Some of them are quite uncertain about the standards to which they are going to be held.

There are several ways that it is addressed. One is where are they in their career development. Another is where have they published articles and whether the peer review publications fit into a certain mold.

So, the research community is concerned about the lack of transparency, the lack of real communication on this, not that anyone denies the VA both the right and the responsibility for determining how they allocate their funds, but it is a participative process. Physicians, as you well know, are an independent lot and do like to be included in decisions that affect their future.

That concludes my remarks.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Clarkson appears on p. 52.]

Mr. SIMMONS. Thank you, Dr. Clarkson, very much.

I mean, in looking at the VA research and looking at the research that comes under the medical colleges, under the ambit of your association, it begs the question as to whether this activity, which is so vast and so extensive and so complicated, can ever be appropriately overseen by anybody under any circumstances, but that is the challenge we face.

Looking specifically at the legislation before us, it is my understanding from your testimony that AAMC supports the principle and the intent of the legislation and that you believe that oversight and compliance functions should be separate from the promotion and funding functions of a program.

We have discussed or heard questions and testimony today, this morning, on whether that should be discretionary within the regulatory discretion of VA or whether it should be mandatory, laid out in statute. That seems to be the crux of what we are looking at today.

Would you find aid and comfort in a statutory effort to regulate this, or would you go with the VA on the regulatory approach?

Dr. CLARKSON. Well, I don't think the AAMC really has a position on that. I will tell you that no one likes increasing regulation or encumberance.

At the same time, we need to be held accountable, and you need to be accountable to our—your constituents in terms of your comfort level.

We wish there were never any mistakes. We wish that what happened at Duke and Hopkins and Albany now at the VA Medical Center had never happened, and it is not unreasonable that, in the setting of these sorts of things happening, that we look at—that they mandate closer scrutiny and that compliance have a zero tolerance.

Therefore, speaking on behalf of the AAMC, I don't think the AAMC has a problem with the VA overseeing this. As you know, at a medical school, as was indicated by Dr. Roswell, we have a VA—or a combined VA-medical school IRB. We have three other IRB's.

The oversight at the VA is one set of—although the regulations are similar, it is one set of regulations. The other three IRB's are dealing with different sets of regulations, and as a medical school dean, it is my responsibility to make absolutely certain that we are compliant with all these rules.

HIPPA is another thing that has been imposed on us, and all of these things are costly, and yet, we—until we get to the point where there are no mistakes, which is a goal, we will need to continue to wrestle with these issues.

Mr. SIMMONS. Thank you.

Mr. Rodriguez.

Mr. RODRIGUEZ. Let me ask you—I know you mentioned those 18 projects of research that were, I guess, not funded, with the blue ribbon panels that were established.

Has that kind of worked out to the—I guess not. It hasn't worked out to the satisfaction of the colleges across the country?

Dr. CLARKSON. Well, I think each—there were 17 that were not funded, and my understanding is that they are not going to be

funded. We are in the process of working with the VA to work out how these proposals are going to be reviewed.

Investigators need to know the standards to which they are going to be held, and to some degree, the investigators ought to be invited into the conference to agree or disagree with regard to how they are going to be judged.

For instance, one of the things that was mentioned was that, if you published in certain journals, you were felt to be a more productive researcher than if you didn't publish in other journals.

Well, that may apply, but it is going to vary. I happen to be an ophthalmologist. The journal that was cited was the New England Journal of Medicine.

The New England Journal of Medicine is a wonderful medical journal. It has very little relevance, however, to vision research.

Most of the vision research to which I would look are in the journals specifically related to ophthalmology, the American Journal of Ophthalmology, the Archives of Ophthalmology, Vision Research.

So, when you look at research in general, there is a vast array of medical journals, and simply to limit the judgement of a person's productivity based on publication in certain journals, I think is—it does not allow enough flexibility to recognize the breadth and depth of research publication.

Those grants, back to your specific question, are not going to be funded. We simply want to have a dialogue with the VA so that we will not have surprises like this in the future.

Mr. RODRIGUEZ. That, I guess, has not occurred yet.

Dr. CLARKSON. I think it is in process. I think there have been meetings, but we still aren't completely aware of what the blue ribbon panels have recommended should be the criteria by which a proposal is judged.

Mr. RODRIGUEZ. Let me ask you, also—I know that there has been some talk about both—not only in terms of journals but whether Ph.D.'s and M.D.'s and the research there—have you all have difficulty with that?

Dr. CLARKSON. Well, one could presume, erroneously, that basic research has no application to patient care. I would argue with that.

I think every medical research initiative ultimately has to translate to improving patient care or we shouldn't be funding it, but some laboratory research has the potential for great clinical relevance, even though it is not termed clinical research.

So, that is another point that we are concerned about, and that is the statement that the VA wants to emphasize clinical research, as opposed to laboratory research. I don't know where you draw the line. I don't know how you draw the line with regard to what translates to improved patient care.

That is what all medical research is about, and by the way, by statute, all VA-supported research much be clinically relevant in the sense that it must be dedicated—or its goal must be to improve the health of veterans.

Mr. RODRIGUEZ. Yeah, but in some cases, you might not know the clinical relevance until years later.

Dr. CLARKSON. That is correct.

Mr. RODRIGUEZ. Okay. Thank you.

Mr. SIMMONS. Mr. Boozman.

Mr. BOOZMAN. You said that 17 weren't funded. How many did you say were funded?

Dr. CLARKSON. I am sorry, I am not aware of the number.

Dr. AISEN. About 120 were funded.

Dr. CLARKSON. I don't know whether you heard the answer.

Over 100 were funded, and I guess, of the 17, two additional have been funded. So, the number now un-funded was 15.

Just to explain, in case you are not aware of that, apparently under the previous research administration, it was the habit to call investigators, to inform them that their grants had been approved.

A call is never the final word, but all of these investigators had received a telephone call under the previous research administration indicating that their project was going to be funded, and there was a change, and that is certainly the prerogative of the new administration to change that, but it was—it seemed arbitrary. Whether it was or not, it seemed arbitrary.

Mr. BOOZMAN. So was the problem, then, with the protocol or the subject matter?

Dr. CLARKSON. The implication was, yes, that these were not—and I assume, although I don't know this for a fact, that each of these investigators generally—when a proposal is submitted and a final decision is made, it is accompanied by a synopsis, an assessment that explains why it was scored as it was and why it was funded and whether it met the funding level or not, and I assume that happened, but I don't know that for a fact.

Mr. BOOZMAN. So, you are unhappy that the process was done in that way, that the day of the funding and you are all geared up and you are ready to go and probably have gone to some expense, and then, all of a sudden, you find word that you are not going to——

Dr. CLARKSON. Correct. That is correct. We are concerned about the process and the lack of transparency and the lack of input.

Mr. BOOZMAN. So, not as opposed to—maybe selections were based—in other words, you think the selection process was—besides the notification—was fair.

Dr. CLARKSON. I have no evidence to say that it wasn't, you know, not from my point of view. I don't think the AAMC does, but it happened in a way that was abrupt, and in some instances, since people were under the assumption they were going to be funded, they didn't submit applications elsewhere, and now they find that they have no funding for a period of time, and it simply—you know, it creates a great deal of uncertainty and anxiety amongst not only those researchers but the people that are working with them.

Mr. BOOZMAN. Thank you.

Dr. CLARKSON. So, it is process, not the lack of fairness in terms of the judgement. I can't comment on that.

Mr. SIMMONS. Do any other members have questions for our witness?

[No response.]

Mr. SIMMONS. Hearing none, is there any other business to come before the subcommittee this morning?

[No response.]

Mr. SIMMONS. Hearing none, I want to simply say for the record that my colleague, Mr. Rodriguez, and I are hoping to schedule at least one hearing in September on related bills and one markup in September, which might present the opportunity to mark up this and other legislation that we have before us.

I want to thank our witnesses and the subcommittee members for their participation today. I particularly appreciate Chairman Buyer's attendance and his questions and his active participation.

I want to thank our witnesses from the Veterans Administration for coming today. As always, you have been gracious and informative in your responses to our questions.

I want to thank Dr. Clarkson.

It is an important issue that we have been discussing. It goes to the issue of the safety of our veterans, on the one hand, and also the future of medical research, so that the lives of not only our veterans but many Americans and many people around the world might be enhanced by the fruits of this research.

I thank you all for attending.

We are adjourned.

[Whereupon, at 11:24 a.m., the subcommittee was adjourned.]

APPENDIX

I

108TH CONGRESS
1ST SESSION

H. R. 1585

To establish an office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2003

Mr. BUYER (for himself, Mr. SMITH of New Jersey, Mr. EVANS, Mr. EVERETT, Mr. BILIRAKIS, Mr. MICHAUD, Ms. CARSON of Indiana, Mr. FILNER, Mr. BEAUPREZ, Mr. MILLER of Florida, Mr. BOOZMAN, Mr. STEARNS, Mr. QUINN, Mr. SWEENEY, Mr. BROWN of South Carolina, Ms. GINNY BROWN-WAITE of Florida, and Mr. MCHUGH) introduced the following bill; which was referred to the Committee on Veterans' Affairs

A BILL

To establish an office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ESTABLISHMENT OF OFFICE OF RESEARCH COMPLIANCE AND ASSURANCE.

(a) IN GENERAL.—Section 7303(e) of title 38, United States Code, is amended to read as follows:

"(e)(1) There is established within the Veterans Health Administration an office to oversee research com-

pliance and assurance, to promote responsible research conduct, and to ensure the ethical treatment and safety of research subjects (hereinafter in this subsection referred to as the 'Office'). The Office shall be an independent entity within the Veterans Health Administration.

"(2) There is a Director of the Office. The Director shall report directly to the Under Secretary for Health.

"(3) The mission of the Office is as follows:

"(A) To provide regular counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety.

"(B) To promote and enhance the ethical conduct of research.

"(C) To investigate allegations of research impropriety and misconduct.

"(D) To suspend, restrict, or modify research, or take such other actions as the Director determines appropriate—

"(i) to ensure the safety and ethical treatment of human research subjects;

"(ii) to preserve the integrity and validity of research;

"(iii) to prevent mistreatment of laboratory animals used in research; and

"(iv) to assure compliance with requirements under law with respect to the conduct of research.

"(4) The Director of the Office shall carry out the following duties:

"(A) The conduct of periodic inspections and evaluations of research integrity at research facilities of the Department.

"(B) The observation of external accreditation site visits for human subjects and animal welfare.

"(C) The investigation of allegations of—

"(i) research improprieties, endangerment or mistreatment of research subjects,

"(ii) research misconduct, and

"(iii) non-compliance with applicable research policies and regulations.

"(D) The immediate notification of the Under Secretary for Health when endangerment of human research subjects is evident or suspected.

"(E) The notification of Congress in the case of a finding of impropriety or misconduct with respect to a research project conducted by the Department.

"(F) The advancement of research assurance and compliance activities within the Department and with established academic affiliation arrangements.

"(G) The negotiation and maintenance of research assurances with each medical center of the Department conducting research involving human subjects or laboratory animals.

"(5) Amounts for the activities of the Office, including field offices, shall be derived from amounts appropriated for the Veterans Health Administration for Medical Care, and shall not be derived from amounts appropriated for the Veterans Health Administration for Medical and Prosthetic Research).".

(b) REPORT.—(1) The Comptroller General of the United States shall conduct a study to assess the efficacy of the office established under section 7303(e) of title 38, United States Code, as added by subsection (a).

(2) Not later than January 1, 2005, the Comptroller General shall submit to Congress a report on the study conducted paragraph (1), and shall include recommendations for any changes in legislation or administrative action as the Comptroller General determines appropriate.

○

Opening Statement
Honorable Rob Simmons
Chairman, Subcommittee on Health
Committee on Veterans' Affairs
July 15, 2003

The Subcommittee will come to order.

Welcome our distinguished witnesses and others in attendance.

This is a legislative hearing to discuss a bill before the Subcommittee, introduced by my fellow veteran and the gentleman from Indiana, Mr. Buyer and other Members on April 3, 2003. The bill, H.R. 1585, would establish an independent research compliance and assurance office within VA's health care system.

VA's research program is a biomedical program:

- VA carries out an extensive array of research and development to complement its affiliations with 109 medical schools and scores of other health-professions schools nationwide. This program involves over 150,000 research volunteers and 3,800 investigators.

- VA research is targeted directly to the needs of veterans -- as it should be -- but also the work has defined *new standards of care* that benefit all Americans.

- Among the major emphases of VA research are aging and chronic diseases, mental illnesses, substance-use disorders, sensory losses, and trauma-related illnesses. VA's research programs and investigators are internationally recognized and have made important contributions in virtually every area of medicine, health, and health systems.

Over the years the Committee has tried to build a solid foundation to improve funding for VA's research programs, and this has been an uphill fight, given all the competing needs for funding, both within VA itself and among VA and other agencies. The President proposed an increase in VA's research budget of only two percent in 2004, or $8 million. This Committee has recommended that an additional $52 million be added to the 2004 budget in order to keep VA research on pace with funding developments in the remainder of Federal biomedical research.

By saying all the foregoing, I mean to describe VA research as an important program. But VA research needs better accountability as shown by several issues with which this Committee has been concerned over the past 5 years. This has been demonstrated through multiple reviews by the General Accounting Office, hearings to consider the problems at the Los Angeles facility in human subjects protection, and similar problems at a number of other VA medical centers, most recently including the Albany, New York situation. The Albany problem may in fact be a crime involving research fraud. According to the press, the local U.S. attorney is considering other charges, including manslaughter, in that ongoing investigation.

Mr. Buyer's bill is an accountability measure, one that would require VA to permanently partition research management and administration from independent VA research compliance and assurance functions. It is my understanding that VA has already partitioned these functions consistent with the intent of H.R. 1585, but in the details, VA has not made some of the changes in responsibilities that would be dictated by this bill. I look forward to hearing testimony today on whether this bill offers a further useful remedy to VA's dilemma with research assurances and the safety of volunteers who participate in VA research.

Does my friend Mr. Rodriguez of Texas, our Ranking Member, have an opening statement he wishes to make?

[Mr. Rodriguez's statement]

Thank you Mr. Rodriguez.

Welcome our first panel. We have representatives from the Department of Veterans Affairs, Dr. Robert Roswell, Under Secretary for Health, accompanied by Dr. David Weber, Acting Chief of VA's Office of Research Oversight, Dr. Lynn Cates, Assistant Chief Research and Development Officer.

Dr. Roswell, please proceed.

[Panel proceeds with testimony]

Thank you for your testimony.

I have a number of questions.

[Proceed with Question-Answer period]

To Mr. Rodriquez for questions.

[Mr. Rodriguez proceeds with questions]

Member questions in 5 minute rounds; Questions in order of Members' arrival, rotate by R and D.

I'd like to thank the panel for appearing before us today.

Our second panel. Let the record show that the Subcommittee invited the following organizations to appear and offer testimony today on this bill: The Federation of American Societies for Experimental Biology; the National Association of Veterans' Research and Education Foundations; the Friends of VA Research; and the American Federation for Medical Research. These organizations declined to testify at this hearing. Dr. John Clarkson, Dean of the School of Medicine at the University of Miami, is testifying today on behalf of the Association of American Medical Colleges, the organization that represents medical school interests. Dr. Clarkson has appeared before this Subcommittee in the past.

We welcome you, Dr. Clarkson. Apparently you will be speaking on behalf of the entire American medical research and scientific establishment outside VA proper, since none of your brothers or sisters would agree to appear.

Dr. Clarkson, please proceed.

[2nd panel proceeds with testimony]

Thank you for your testimony.

I have a few questions.

[Proceed with Question-Answer period]

Mr. Rodriguez, do you have any questions for Dr. Clarkson?

[Mr. Rodriguez proceeds with questions]

Do any of our Members have questions for this witness?

[Member questions in 5 minute rounds; Questions in order of Members' arrival, rotating by R and D]

Do any other Members wish to question our witness?

Is there any other business before the Subcommittee at this hearing?

This has been a very interesting and helpful hearing.

I thank all our witnesses, and our Subcommittee Members, for their assistance today. I appreciate Chairman Buyer's attendance and active participation as well, particularly for the quality of the discussion we have conducted today on a very important topic - the safety of veteran volunteers in VA research.

We thank you all for attending.

We are adjourned.

[Gavel]

WHITE PAPER
Realignment of Human Research Protection Responsibilities

Issue: How does the Veterans Health Administration (VHA) realignment of human research protection responsibilities compare with the provisions of H.R. 1585, "To establish an office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs?"

Discussion: VHA realigned the human research protection responsibilities formerly assigned to the Office of Research and Development (ORD) and the Office for Research Compliance and Assurance (ORCA). ORD now has complete responsibility for education and policy development. The newly created Office of Research Oversight (ORO) has total responsibility for ensuring compliance and oversight of research involving human and animal subjects, conducting biosafety and biosecurity oversight, and managing Federal-Wide Assurances.

The current realignment largely reflects the provisions of H.R. 1585. ORO is an independent entity within VHA, and its director reports directly to the Under Secretary for Health (USH). The new office provides counsel to the USH on matters relating to the protection of human research subjects, laboratory animal welfare, biosafety, and research misconduct involving human or animal subjects. ORO will conduct periodic inspections and evaluations of research integrity at VA research facilities and will investigate, when human or animal subjects are involved, allegations of research improprieties, research misconduct, and non-compliance with research policies and regulations. The office will notify the USH when the endangerment of human research subjects is evident or suspected.

Several VHA procedures differ from the provisions of H.R. 1585. Those differences follow.

Section 7303(e)(1) would establish within VHA "an office to oversee research compliance and assurance, to promote responsible research conduct, and to ensure the ethical treatment and safety of research subjects." The promotion of responsible research conduct primarily involves providing education and information to researchers and facilities. This role has historically been within the mission of ORD.

Section 7303(e)(3)(A) would define the mission of the new office as providing "regular counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety." Within VA, ORD is responsible for education, training, and policy matters. In this capacity, the VHA Chief Research and Development Officer (CRADO) regularly advises the Under Secretary for Health on these subjects.

The provision in section 7303(e)(3)(B) would provide that the mission of the new office would include promoting and enhancing the ethical conduct of research. Under the existing VHA structure, this education mission is carried out by ORD.

Section 7303(e)(3)(D) would provide that one mission of the new office is "to suspend, restrict, or modify research, or take such other actions as the Director determines appropriate." Under the existing VHA structure, ORO does not have this authority. The provision in section 7303(e)(3)(D)(ii) states that action to suspend, restrict, or modify research would be taken "to preserve the integrity and validity of research." Under the existing VHA structure, ORO does not have this responsibility. This aspect of the mission description is within the mission of ORD.

Section 7303(e)(3)(D)(iv) would require that the action to suspend, restrict, or modify research would be taken "to assure compliance with requirements under law with respect to the conduct of research." This provision, as written, applies broadly to all research conducted within VA, including to research that does not involve human or animal subjects. Under the existing VHA structure, VHA has authorized ORO to assure compliance with the requirements under law with respect to the conduct of *human and animal* research, while ORD and VA's Office of the Inspector General retain responsibility for research that does not involve human or animal subjects.

In section 7303(e)(4)(A), the bill states that the Director's duties include "the conduct of periodic inspections and evaluations of research integrity at research facilities of the Department." Under the existing VHA structure, VHA authorizes ORO to conduct periodic inspections and evaluations or research integrity *with regard to human and animal subject investigations* at research facilities of the Department. ORD and the Office of the Inspector General are responsible for the conduct of research that does not involve human or animal subjects.

Section 7303(e)(4)(B) states that the Director's duties include "the observation of external accreditation site visits for human subjects and animal welfare." No VHA offices observe external accreditation site visits.

Pursuant to section 7303(e)(4)(C)(ii), the duties of the Director would include investigation of allegations of, among other things, research misconduct. The ORO director investigates allegations of research misconduct *involving human and/or animal research subjects*." Under the existing structure, ORD and VA's Office of the Inspector General are responsible for research that does not involve human or animal subjects.

Section 7303(e)(4)(C)(iii) states that the duties of the Director would include "non-compliance with applicable research policies and regulations." The ORO director investigates allegations of non-compliance with applicable research policies and regulations *that involve animals and/or human subjects*. This section of the bill would broaden that authority to include all research policies and regulations.

Section 7303(e)(4)(E) states that the duties of the Director would include "the notification of Congress in the case of a finding of impropriety or misconduct with respect to a research project conducted by the Department." Under the existing structure, the ORO does not have this responsibility. Rather, the ORO director informs the USH of such improprieties or misconduct, and that official notifies the Secretary of Veterans Affairs.

Statement of the Honorable Steve Buyer
Subcommittee on Health
Committee on Veterans Affairs
Hearing on H.R. 1585
July 15, 2003

Thank you, Chairman Simmons, for hold this hearing on, H.R. 1585, legislation I introduced to establish an independent office to oversee research compliance and assurance within the Veterans Health Administration of the Department of Veterans Affairs.

This legislation has bipartisan support, including Chairman Chris Smith and Ranking Democratic Member Lane Evans, along with 14 other members of the Veterans Committee, who are original cosponsors of the bill.

The intent of this legislation is to ensure that all research funds are directed with focus and accountability. Enactment of H.R. 1585 would not result in any new appropriation of dollars, nor would it increase VA's existing operational expenses. This measure does not seek to impede the VA from continuing with the important research it conducts.

Before I summarize the bill, I want to provide some pertinent background information as to why this legislation is necessary. In 1999, problems with human subject protections in VA's research programs dating back to 1993 were identified. In response to this VA established the Office of Research Compliance and Assurance (ORCA), which was an

independent oversight office that reported directly to the Under Secretary.

ORCA served as the primary advisory component for the Under Secretary for Health on all matters affecting the integrity of research in the protection of human subjects. ORCA's major responsibilities included providing direction, guidance, and oversight to its field offices that perform their delegated roles and responsibilities, in promotion of the office's mission.

Earlier this year, problems concerning alleged research misconduct involving human subjects at the Albany VA medical center, were first reported in the media. As a result of the lack of definitive action taken by VA to the alleged endangerment of human

subjects at Albany, VA decided to integrate ORCA into the Office of Research and Development. This action was taken because the Department felt that ORCA had not kept the Under Secretary sufficiently informed about the alleged transgressions that took place at the Albany facility.

I, along with several other Members of the Oversight Subcommittee, including Representative Lane Evans, strongly objected to this proposal because we felt that the oversight office needed to remain independent, and requested the Department review its decision and brief the Subcommittee before any further action was taken.

I want to thank Under Secretary Roswell and his staff for listening to my reservations and, for the most part, working to address the issues that prompted me to request that VA suspend implementation of its initial proposal. The current administration's actions demonstrate their commitment to and understanding of the importance of providing that the strongest possible human subjects protections are in place. However, what concerns me now, and the reason I introduced H.R. 1585, is that there is no guarantee that subsequent administrations will not weaken these protections.

When the Department of Health and Human Services decided to reorganize its oversight of NIH's research programs, it commissioned a report to help determine what an oversight office would need to be optimally

effective. The report published on June 3, 1999, entitled *Report to the Advisory Committee to the Director, NIH from the Office for Protection from Research Risks Review Panel*, provides the blueprint for the bill I have introduced.

H.R. 1585 would create an independent office to oversee research compliance assurance whose director reports directly to the Under Secretary for Health. This legislation also provides that one of the missions of this office will be to offer regular counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare and bio-safety; to promote and enhance the ethical conduct of research; to investigate allegations of

research impropriety and misconduct; to suspend, restrict, or modify research to ensure the safety, and ethical treatment of human subjects; to preserve integrity and validity of research; to prevent mistreatment of laboratory animals used in research; and to assure compliance in the conduct of research.

The bill would require that the director of the office conduct periodic inspections at research facilities; observe external accreditation site visits; investigate allegations of research improprieties, research misconduct, and non-compliance with research policies and regulations. The bill would also require the immediate notification of the Under Secretary for Health when endangerment of human research subjects is evident or suspected and requires that

Congress be notified when impropriety of misconduct of research conducted by the Department has been found.

The bill would provide that funding for this new office would come from the medical care account of the Veterans Health Administration rather than from Office of Research and Development funding.

Finally, the legislation mandates that the Comptroller General of the United States conduct a study of the effectiveness of the new office and submit a report to Congress by January 1, 2005.

Mr. Chairman, I want to reiterate for the Members of this subcommittee why I introduced this legislation – it is because I firmly believe it is imperative that we

have an independent oversight body, unsusceptible to unilateral administrative reorganization. This can only be accomplished by placing it in statute.

Thank you, again, for holding this hearing on H.R. 1585.

STATEMENT OF
ROBERT H. ROSWELL, M.D.
UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES
July 15, 2003

Mr. Chairman and Members of the Committee.

I am pleased to be here this morning to present the Administration's views on H.R. 1585, a bill to establish an office to oversee research compliance and assurance within the Veterans Health Administration. We fully support efforts to protect human research subjects, ensure animal welfare and research safety, oversee research compliance, and assure full compliance with research regulations. The Secretary recently approved the establishment of the new independent Office of Research Oversight that is designed to achieve precisely these ends, and we therefore do not believe this legislation is needed. However, should the Committee decide to proceed with this bill, we recommend that several of its provisions be revised.

Mr. Chairman, H.R. 1585 would amend current law to establish an independent office within VHA to oversee research compliance and assurance. The Director of the new office would report directly to the Under Secretary for Health. The mission of the office would be multi-faceted. It would provide counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety. It would also promote and enhance the ethical conduct of research, investigate allegations of research impropriety and misconduct, and suspend, restrict, or modify research.

Under the bill, the Director of the new office would be responsible for conducting periodic inspections and evaluations of research integrity at VA

research facilities, and observing external accreditation site visits for human subjects and animal welfare. The Director would also investigate allegations of research improprieties, endangerment or mistreatment of research subjects, research misconduct, and non-compliance with research policies and regulations. The Director would notify the Under Secretary for Health when endangerment of human research subjects is evident or suspected, and would notify Congress regarding impropriety or misconduct with respect to a VA research project. Other responsibilities would include the advancement of research assurance and compliance activities within VA and with academic affiliates, and the negotiation and maintenance of research assurances with VA medical centers conducting research involving human subjects or laboratory animals. Finally, the bill would direct the Comptroller General of the United States to conduct a study to assess the efficacy of the office, and to report to Congress regarding any recommendations for legislative or administrative changes.

One mission of the new office would be to provide regular counsel to the Under Secretary for Health on all matters related to the protection of human research subjects, research misconduct, laboratory animal welfare, and bio-safety. Mr. Chairman, we recommend revising that provision to state that the office would provide regular counsel to the Under Secretary on all *compliance* matters related to these subjects. Within VA, the Office of Research and Development – ORD – is responsible for education, training, and policy matters. In this capacity, the Chief Research and Development Officer regularly advises the Under Secretary for Health on these subjects. Our suggested revision would clarify that the Director of this new office would deal specifically with compliance matters related to these subjects.

The bill also provides that the mission of the new office would include promoting and enhancing the ethical conduct of research. We recommend modifying that portion of the mission description to clarify that the new office will promote and enhance the ethical conduct of research through its oversight activities, and that the education missions remain with ORD. With regard to this important mission area, the Secretary has recently directed ORD to create the

Program for Research Integrity Development and Education – known as PRIDE. The PRIDE program will provide important education, training, and policy guidance to the field.

The bill also provides that the mission of the new office is to suspend, restrict, or modify research, or take other appropriate actions. We recommend revision of that provision to clarify that this type of action would only be carried out with the concurrence of the Under Secretary for Health. Incidents that require the suspension or restriction of research demand the immediate attention of the Under Secretary for Health, whose programs would be directly affected by such action. We also suggest removing the provision stating that the mission of the new office includes the authority to modify research. The Office of Research and Development has responsibility to fund and monitor all research projects and should continue to make significant decisions concerning research protocols and needed modifications to research projects.

Mr. Chairman, this portion of the mission statement goes on to state that the office can take this action to suspend, restrict, or modify research within the context of preserving the integrity and validity of research. Requiring the new office to preserve the validity of research suggests that this office may have responsibility for overseeing the scientific validity of VA research. As mentioned above, this important function should remain with the Director of ORD.

The bill states that the responsibilities of the Director of this new office would include the observation of external accreditation site visits for human subjects and animal welfare. We recommend deleting this provision. Mr. Chairman, the presence of VA central office organizations in any type of external accreditation site visits does not add value to the inspection; rather, it creates coordination problems for the facility, and may even be construed as an attempt by central office to influence the evaluation. Historically, ORD has sent accreditation reports to the compliance office. I propose to communicate accreditation information to any new compliance office by continuing to send the office copies of all accreditation reports.

As provided in the bill, the duties of the Director would include notifying Congress of any finding of impropriety or misconduct with respect to a research

project conducted by the Department. I am concerned about this provision, as it does not follow the chain of command within the Department. We suggest deleting this provision, or revising it to require the Secretary to notify Congress in the case of a finding of impropriety or misconduct with respect to a VA research project involving human subjects or animal welfare.

Mr. Chairman, I am also concerned that this provision, as it is currently written, may lead to the reporting of many incidents of a minor nature that are relatively inconsequential to the protection of human subjects or animal welfare. My experience has shown that some reported problems, when thoroughly discussed and reviewed, are not compliance issues. Day-to-day communication about the status of all ongoing cases may be difficult to manage. It may cause problems, both for Congress and the new compliance office, in assessing the significance and importance of the alleged impropriety or misconduct, and the appropriate actions for responding to the conduct. One option would be to revise the provision to require reporting of serious cases of impropriety or misconduct that lead to a site visit to assess and resolve the incident. A second alternative would be to require the more comprehensive reporting on a quarterly, semi-annual, or annual basis.

As I stated earlier, nearly all of the functions that the bill directs VA to undertake are generally being carried out in VHA, either within the existing compliance office – the Office of Research Oversight – or within ORD.

Mr. Chairman this concludes my testimony. I would be pleased to answer any questions you may have.

STATEMENT

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On

Oversight of the VA Research Program

Presented By

John G. Clarkson, M.D.
Senior Vice President for Medical Affairs and Dean
University of Miami School of Medicine

Before the

Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives

July 15, 2003

Good Morning. Thank you Chairman Simmons and members of the subcommittee for the opportunity to testify before you today. I am Dr. John Clarkson, senior vice president for medical affairs and dean of the University of Miami School of Medicine. I am testifying today on behalf of the Association of American Medical Colleges (AAMC), an organization that represents the nation's 126 accredited medical schools, over 400 major teaching hospitals and health systems – including over 70 VA medical centers, more than 105,000 faculty in 96 academic and scientific societies; and the nation's 66,000 medical students and 97,000 residents.

I am here today to talk about a number of issues related to the research program administered by the Office of Research and Development (ORD) within the Veterans Health Administration (VHA). I shall first address the legislation to establish an office to oversee research compliance and assurance within the VHA, but I then wish to turn my attention to two other issues that have been receiving much attention lately and have generated a good deal of confusion and consternation within the VA research community, much of which is composed of medical school faculty with joint VA appointments. Those issues are the reports of a new vision of ORD leadership for VA research, which appears to involve a shifting of priorities in the allocation of VA research dollars, and alleged actions by ORD leadership that have been perceived as threatening the integrity of the peer review system. Before going into the details, I think it important to offer the Subcommittee some context as to why these issues are so important to medical schools, and why the AAMC is an essential stakeholder in these decisions.

One hundred seven of the nation's medical schools maintain formal affiliation agreements with VA medical centers. These affiliations, which stem from the seminal VA Policy Memorandum No. 2 published in 1946, have proven over nearly 6 decades to be mutually beneficial by affording each party access to resources that would otherwise be unavailable. As stated in the Policy Memorandum, the affiliations allow VA to provide veterans "a much higher standard of medical care than could be given him with a wholly full-time medical service." In return the medical schools gain access to invaluable undergraduate and graduate medical education opportunities through medical student rotations and residency positions at the VA hospitals, and faculty with joint VA appointments are afforded opportunities of research funding and access that are restricted to individuals designated as VA employees. They represent the full spectrum of generalists and specialists required to provide high quality medical care to veterans, and, importantly, they include accomplished sub-specialists who would be very difficult and expensive, if not impossible, for the VA to obtain regularly and dependably in the absence of the affiliations. These jointly appointed clinician-investigators are typically attracted to the affiliated VA Medical Center both by the challenges of providing care to the veteran population, and by the opportunity to conduct disease-related research under VA auspices.

With regard to H.R. 1585, which would establish an Office of Research Compliance and Assurance within VHA, let me first say that the AAMC fully supports the principle and intent of this legislation. The AAMC is deeply committed to promoting clinical research and is recognized for its strong commitment to strengthening and assuring the protection of human research subjects. The Association several years ago actively supported the establishment of the

Office of Human Research Protections (OHRP) in the Office of the Secretary of the Department of Health and Human Services. Similarly, when VA first created the Office of Research Compliance and Assurance (ORCA) in 1999, the AAMC supported the placement of that office under the Under Secretary for Health, and the Association shared the concerns of many when VA decided to eliminate ORCA and establish an office with very similar responsibilities within the purview of ORD. We believe in principle, as this bill would require, that oversight and compliance functions should generally be separate from the promotion and funding functions of a program. Accordingly, we were reassured earlier this year when VA announced its reconsideration of its earlier decision and returned to the Office of the Under Secretary a new Office of Research Oversight (ORO) to assume the compliance (but not the educational) responsibilities formerly exercised by ORCA.

I shall now turn to the two other issues that I mentioned earlier. AAMC is certainly aware and very disturbed by the uncertainty, anxiety, and anger that seem to be roiling the VA research community over recent decisions reported to have been made by the leadership of ORD about the future directions and practices of the VA research program. We suggest that there has been a lack of transparency and clarity about both the reformulated research goals and the practices by which they are to be implemented, and we believe that this lack has contributed to confusion, as well as possible misinterpretations and misunderstandings about a number of important issues.

The AAMC recognizes that the Department of Veterans Affairs supports medical research as part of its mission to provide and improve health care to our nation's veterans. The AAMC believes, and I think VA shares in this, that a high quality biomedical research program enhances the quality of veterans' health care. We understand that all components of the VA research program - laboratory and clinical research, rehabilitation research and development, and health services research - play a major role in this enhancement. The Association also respects that fact that it is the prerogative and appropriate function of the Office of Research and Development periodically to review and, when deemed desirable, to re-balance funding across its research portfolio in the way the office determines will best serve the needs of the veteran population. However, AAMC also recognizes that such review and re-balancing can create great anxiety by threatening settled expectations within the research community, and, therefore, believes the process is best accomplished with broad consultation involving all stakeholders, and with clarity and transparency to avoid misunderstanding. Put differently, the VA's biomedical research community is overwhelmingly composed of jointly appointed medical school faculty who would better be treated as colleagues.

The Association is concerned that the way the current process has been conducted, and recent changes announced, often incompletely in the scientific and trade press, has not sufficiently engaged the VA research community or given them appropriate opportunity either to provide input into the decisions, or to understand and adjust to the potential consequences for their own programs and careers.

Under the newly proposed shift of funding, it has been reported that there will be a de-emphasis on basic science, what VA refers to as "laboratory science." The AAMC suggests that ORD should proceed cautiously here because "laboratory science" is frequently conducted by jointly appointed, sub-specialist clinician faculty members, whose loyalty and commitment to VA could well be destabilized by the perceived loss of opportunity to pursue their research interests. As I stated before, replacing the quality and spectrum of health care services provided by such physicians either by full-time VA practitioners, or, reliably and dependably, from the private sector would at best be difficult and at worst, may not be possible. The AAMC is already hearing anecdotal evidence from some of its members that the threat of shifting dollars away from basic or laboratory science is causing some faculty to consider dropping the VA portion of their appointment.

The AAMC is aware that the Office of Research and Development has sought consultation from several "Blue Ribbon Committees" as it developed its plans, but the identity of the "Blue Ribbon" panelists was only just recently revealed on the ORD Web site. We think it unfortunate that the formation of these committees, their charges, and their rosters were not more promptly and fully communicated to the VA research community. And although we commend VA for posting the Panel rosters, a full explication of the consultative process, as well as the Panels' final recommendations, remains to be disseminated.

The final matters I shall address are the alleged actions by ORD leadership that have been interpreted by many as threatening the integrity of the VA merit review system. Peer review is the bedrock of quality assurance in research and scholarly accomplishment. It is a process deeply respected among scholars, and, arguably, it is one of the major reasons that the U.S. has attained a position of world leadership in biomedical research since World War II. The academic medical community is a fierce champion of the peer review system, which we firmly believe is the best way to ensure that public investment in science will be directed to the most outstanding and creative research proposals. Recent actions by ORD leadership appear to have changed the way merit review scores inform funding decisions by superimposing without prior notice new criteria to address the "relevance of the research to the veteran population," the investigator's "prior productivity," and the "investigator's stage in their career." As an aside, let me note for the record that research conducted under this program has always been statutorily required to be relevant to the veteran population, and that the number of designated research areas was expanded from 9 to 17 just a few years ago.

The AAMC certainly agrees that these criteria are relevant to the merit evaluation process, but we argue that proper peer review should always, and in my own experience, in fact does, take into account an applicant's productivity and record of prior accomplishments. Evaluation of productivity and relevance to agency mission is not only necessary but intrinsic to a robust merit review process; that is, these considerations should be incorporated into the peer review process and not superimposed after the fact. AAMC does acknowledge that in assessing "borderline" proposals, that is, those whose merit scores cluster around the pay line, funding agencies often do exercise discretion in selecting for funding those applications deemed most important and

relevant to the agency's mission, and we respect that ORD has that authority. However, in the current instance, the perception of the research community has been of arbitrary administrative manipulation after the fact, and it is that which has so roiled the community. The AAMC strongly urges that if ORD believes its Merit Review Panels are not performing to expectations, those expectations should be made clear, and the panels refreshed and recharged, as necessary. I emphasize that the AAMC's key concern here is that the integrity of the peer review process not be undermined or otherwise compromised, in appearance or in fact.

In conclusion, let me re-emphasize the AAMC's unwavering support of the VA affiliations, which we affirm to be mutually beneficial relationships from which both partners receive great value. The AAMC believes that the VA research program has been respected over the decades for its generally very high quality and relevance to VA's health care mission, and, as I previously stated, it has served as an important recruitment tool, especially for high quality medical sub-specialists. AAMC respects the prerogative of ORD to monitor the quality of its research programs, and periodically to review and re-balance funding across its research portfolios. However, we urge that any re-balancing be accomplished through a deliberative process that includes communication and appropriate consultation with stakeholders, whose careers can be unsettled as a result. Without such clear and effective communication, confusion can be rampant in the research community, and the perception of destabilization may lead some highly talented and medically essential faculty members to drop the VA portion of their appointments, a result that would benefit neither partner.

The AAMC has been discussing these matters in meetings between VA leadership and AAMC executive staff and constituents; these sessions have been candid and cordial. The Association will continue to pursue these approaches with the goal of assisting VA to sustain a research program of the highest quality and greatest potential benefit to the veteran population.

We appreciate the opportunity to testify before the Subcommittee about these very important issues

Statement of Robert D. Wells, Ph.D.

President, Federation of American Societies for Experimental Biology
Subcommittee on Health, Committee on Veterans' Affairs
U.S. House of Representatives
July 22, 2003

Mr. Chairman and distinguished Members of the Subcommittee, I am Robert D. Wells, PhD., President of the Federation of American Societies for Experimental Biology (FASEB) and the Founding Director of the Institute of Biosciences and Technology in Houston. I also hold the Welch Endowed Chair as well as being a Regents Professor at Texas A&M University. FASEB, comprised of 22 scientific societies with more than 60,000 scientists as members, serves as the voice of biomedical scientists nationwide and is the largest coalition of biomedical research associations in the United States.

As you are aware, we declined the Chairman's invitation to testify to the specific questions raised by H.R. 1585 at the July 15 hearing because our federation had not previously examined the administrative details of the research compliance programs at the VA that are addressed by the legislation. We therefore could not respond to the changes proposed by the legislation within the time frame afforded by your request. However, we would like to take this opportunity to comment on three issues that are related to the VA Office of Research and Development (ORD) and directly relate to our expertise as working scientists. The first of these is the fundamental importance of peer review. Second is the need for transparency in research administration. Finally we wish to emphasize the value of basic research.

It is FASEB's firm position that merit review, conducted by scientific peers, is the best way to allocate research funds. This peer review system, used not only by the Department of Veterans Affairs but also by the National Institutes of Health and the National Science Foundation, is widely respected and has been one of the major reasons why the U.S. is the world leader in scientific research. While peer review is a not a perfect system, it is the best in the world. FASEB strongly believes that using peer review in funding decisions is the best way to ensure that public investment in science yields the most outstanding research. Any action that compromises the integrity of the VA peer review system will deter the best scientists from participating in the program. Our position was conveyed to Nelda Wray, M.D., Chief Research and Development Officer, in a May 7, 2003 letter from Steven L. Teitelbaum, M.D., who was President of FASEB at that time. Dr. Teitelbaum expressed our disappointment over the VA's recent decision to diminish the role of the peer review process when making determinations about grant funding. The use of journal impact factors and funding from other agencies should not be used to adjust or weight the deliberations of expert reviewers. Factors such as productivity and past performance can and should be incorporated into the peer review process. In fact, those factors had been considered by Merit Review Boards involved in considering research applications at that time. We urged the Department of Veterans

Affairs to renew its commitment to peer review and to openly establish clear selection criteria to be used by Merit Review Boards. VA funds should go to the best uses, and we remain convinced that such "evaluations can and should be made **within** the peer review system and not outside of it."

A second concern regarding peer review involves the recently announced policy requiring applicants to have an approved "letter of intent" before peer review committees can consider their proposals. This pre-screening of the proposals can be seen as an effort to usurp the evaluation role of the peer review process and to steer research funding to a set of selected projects.

The research funding process needs to be transparent and consistent. Decision making processes must be clearly articulated in advance before the review process begins and should not vary from cycle to cycle. This transparency is necessary to insure that all participants view the selection process as legitimate. Without this legitimacy, the review process will not attract the participation of the highest caliber scientists and the entire research program will decline. In this respect, we share the views expressed by Senators Arlen Specter and Bob Graham in their letter to Secretary of Veterans Affairs Anthony J. Principi and in the testimony submitted to this committee by John G. Clarkson, M.D. of the Association for American Medical Colleges.

We feel that the VA has the prerogative, indeed the obligation, to set its own priorities between basic and clinical research. However, we might remark that basic research is fundamental to innovations in medicine and improved health care. The VA has a distinguished tradition in this area and has been a leader in many areas of biomedical research. A few recent examples of major breakthroughs from VA-sponsored basic research include elucidation of mechanisms that regulate myocardial angiogenesis, neural mechanisms that control blood pressure, hormone action in bone cells, molecular basis of insulin resistance and the role of inflammatory mediators in acute stroke. Moreover, the VA program of basic and translational research has attracted many distinguished specialists and sub-specialists to the VA health care system where they are able to improve the quality of care given to veterans. Restrictions on the broad opportunities afforded through VA research threaten the stability of a system that attracts the highest quality medical specialists to the system. The broad research focus of the VA system also makes it an integral part of our nation's system of medical education and has been a major contributor to the development of physician/scientists, particularly during their formative years. This symbiotic relationship also ensures that the nation's leading medical researchers and educators are active participants in the medical treatment of our nation's veterans.

Dr. Wray has agreed to meet with our leadership and other experts of our member societies on August 7, 2003 so that we can discuss these concerns in person. It is our hope that such a meeting will inaugurate an open flow of communication between ORD and the research community so that we can accelerate progress in medical research of importance to this nation's veterans and increase he quality of life of those who served our country.

Alliance for Academic Internal Medicine

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July 21, 2003

The Honorable Anthony J. Principi
Secretary
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Principi:

On behalf of the Alliance for Academic Internal Medicine (AAIM)—the nation's largest academic specialty organization—we write to request an immediate six-month moratorium on changes to the Department of Veterans Affairs (VA) health research program as well as a summit on the future of VA research. The moratorium would allow time for a consensus-driven strategy for the VA research program—which will only succeed as a partnership with academic medicine—to be agreed upon by all stakeholders in the VA research program, including veterans, VA, Congress, and the research community. Without such consensus, veterans' patient care will suffer, the quality of VA research and educational programs will deteriorate, and the department will experience increased costs for medical care. To address these concerns, AAIM proposes a summit of senior VA officials and the academic medicine community during the moratorium period to review recent changes to the research program, discuss the results of the "blue-ribbon" panel reports, and develop consensus on the future goals and needs of VA research.

For over 50 years, VA has affiliated with medical schools and their faculties to ensure the nation's veterans receive care of the highest possible quality. As the leading department in medical schools, departments of internal medicine have played major roles in these affiliations through provision of care services ranging from primary care to highly specialized interventions and through the conduct of research resulting in improved health services for veterans and the entire population. Likewise, both partners have benefited from the training medical students, residents, and fellows receive in VA settings.

The request for a six-month moratorium stems from two tightly integrated concerns. First, the process by which VA has developed the changes—and indeed the specifics of the changes themselves—continues to be opaque, resulting in mistrust, misunderstanding, and poor decision-making. As a prime example, despite two interactions with the head of VA research and thorough examinations of published reports, it is impossible for AAIM to understand the scope, timeline, or anticipated outcomes of the changes proposed for the VA research program. How can the academic internal medicine community, or VA's own cadre of outstanding medical researchers, even begin to respond to or plan for changes when such details are unknown?

Moreover, the lack of transparency in the change process itself calls into question the validity of proposed changes to the VA research system. While VA publicly announced the empanelling of "blue ribbon" committees, the membership of, charge to, or timeline for these groups was withheld until after their work was completed. As such, the research community had no opportunity to provide input into their deliberations. The lack of dissemination of such critical elements of the planning process causes observers to wonder if the process was designed to determine the best future for VA research or only the future envisioned by VA's research leadership. Certainly, AAIM respects the need for strategic planning for the VA research service—especially at the start of new leadership—but such planning must take into consideration the needs of all partners in the research enterprise.

As a second concern, publicly disseminated elements of the changes to VA research illustrate that the consequences of these changes have not been thoroughly anticipated or appreciated. A prime demonstration of such a consequence comes from the long line of VA physicians and departmental faculty now forming outside internal medicine department chairs' offices. These faculty are not coming to speak in favor of VA's plans for research. Rather, the faculty state plainly that proposed changes to VA research—especially including the great narrowing of even the possibility of receiving a VA merit award—lead them to want to leave the VA system. These faculty range from general internists, who provide the bulk of primary medical care in VA, to subspecialists, such as endocrinologists who treat veterans for diabetes and gastroenterologists who screen veterans for colon cancer. Their dissatisfaction with and subsequent withdrawal from the VA system will require VA to take expensive steps to contract for care services, steps that will negatively impact veterans' health as funds for other services are funneled to contracts. Moreover, the withdrawal of faculty from the VA system will diminish the department's productive partnership with academic internal medicine and may negatively impact the quality of veterans' medical care.

In another example, the consequences of the research program's recent changes to the peer review system in VA have caused tremendous uncertainty among potential applicants and undermine researchers' trust in participating in the VA research program. Moreover, implementing a new review process that de-emphasizes peer review in favor of untested models threatens the research community's confidence in the quality of VA-sponsored research. While these proposed changes to the peer review system are well intentioned, they have also been extremely disruptive to the research community.

Because of these grave concerns and consequences, AAIM requests a moratorium on the current or future implementation of any modifications to the VA research program. The most crucial activity during the moratorium will be the development and implementation of a process whereby partners in the VA research program can discuss and agree upon the direction and pathway for the program—likely through a high-level summit. Such consensus building is extremely vital to developing a plan that will succeed by avoiding the consequences outlined above and building a common understanding of the vision and strategy for the future. Another important action would be convening the Secretary's National Research Advisory Committee to consider recent changes and necessary improvements to the VA research program. This approach, adopted by former Undersecretary for Health Ken Kizer, MD, in the mid-1990s, was extremely useful as VA plotted a new course for its research program.

Some leaders within VA may choose to interpret these remarks as a simple attempt to preserve the *status quo* of VA-funded research. To the contrary, AAIM could support structural changes to VA's research program as long as such efforts are mutually determined and recognize the instability in the environment academic internal medicine and VA inhabit. As an example, creating a perception that cardiologists cannot conduct VA-funded research may lead to the withdrawal of this specialized faculty effort from VA clinical activity, limiting educational opportunities for trainees (bad for academic internal medicine) and costing VA more to acquire cardiology services through contracts (bad for veterans and VA). For

example, the alliance strongly supports VA efforts to secure facility indirect cost payments for National Institutes of Health-funded research conducted in VA medical centers.

VA research is most successful through partnerships with departments of internal medicine and medical schools as a whole. The alliance strives to ensure academic internal medicine and VA continue their strong, mutually beneficial partnership; changes on either side of this partnership must be made through an open process that considers all variables and repercussions. AAIM believes the current difficulties between academic internal medicine and VA can be overcome if the proposed moratorium and subsequent steps are followed. Neither party will benefit if communication and constructive change do not occur.

Thank you for your consideration of these issues. If you have questions about this letter, AAIM, or the alliance proposal to implement a moratorium and form a summit, please contact AAIM Vice President for Policy Charles P. Clayton at (202) 861-9351, cclayton@im.org, or the address on this letter.

Sincerely,

Laurence B. Gardner, MD
Co-Chair
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Statement on the **Oversight of the VA Research Program**

Prepared by
Charles P. Clayton
Vice President for Policy
Alliance for Academic Internal Medicine

For the
Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives

July 15, 2003

On behalf of the Alliance for Academic Internal Medicine (AAIM), thank you for the opportunity to comment on recent changes in the research program of the Veterans Health Administration in the Department of Veterans Affairs (VA).

AAIM is the nation's largest academic specialty organization, representing educators responsible for training 30 percent of all physicians-in-training; conducting $2.5 billion in National Institutes of Health (NIH)-funded research annually; and providing care—from primary care to highly specialized services—to veterans, Medicare and Medicaid beneficiaries, and others in need of these services. The alliance includes the Association of Professors of Medicine, the Association of Program Directors in Internal Medicine, the Association of Subspecialty Professors, the Clerkship Directors in Internal Medicine, and the Administrators of Internal Medicine.

With regard to the development of an independent research oversight organization in VA, the alliance joins other members of the research community in support of HR 1585. With a research portfolio in excess of $1 billion, the VA research enterprise comprises a large number and wide variety of research subjects, investigators and related staff, facilities, and affiliated institutions. Strong central oversight independent of research administration is required to ensure appropriate systems are in place. Such systems protect human subjects—the most valuable partners in studies—from the serious consequences of research errors.

Oversight of VA research may matter little in the coming years, however, because concern and confusion over changes to the strategic direction, structure, and function of VA research are presently undermining the enterprise. If allowed to continue, these changes may reduce the VA research enterprise to little more than a shadow of its current stature. Among the impacts of these changes could be diminished veterans' patient care and increased VA medical costs.

To this end, AAIM has recently written VA Secretary Principi to request an immediate six-month moratorium on changes to the VA health research program as well as a summit with the academic medical community to develop the needed consensus on the future goals and needs of VA research. This consensus needs to be one that can be agreed upon by all stakeholders in the VA research program, including veterans, VA, Congress, and the research community.

For over 50 years, VA has affiliated with medical schools and their faculties to ensure the nation's veterans receive care of the highest possible quality. As the leading department in medical schools, departments of internal medicine have played major roles in these affiliations through provision of care services ranging from primary care to highly specialized interventions and through the conduct of research resulting in improved health services for veterans and the entire population. Likewise, both partners have benefited from the training medical students, residents, and fellows receive in VA settings.

The request for a moratorium stems from two tightly integrated concerns.

First, the process by which VA has developed the changes—and indeed the specifics of the changes themselves—continues to be opaque, resulting in mistrust, misunderstanding, and poor decision-making. As a prime example, despite two interactions with the head of VA research

and thorough examinations of published reports, it is impossible for AAIM to understand the scope, timeline, or anticipated outcomes of the changes proposed for the VA research program. How can the academic internal medicine community or VA's own cadre of outstanding medical researchers even begin to respond to or plan for changes when such details are unknown?

Moreover, the lack of transparency in the change process itself calls into question the validity of proposed changes to the VA research system. While VA announced publicly the empanelling of "blue ribbon" committees, the membership of, charge to, or timeline for these groups was withheld until after their work was completed. As such, the research community had no opportunity to provide input into their deliberations. The lack of dissemination of such critical elements of the planning process causes observers to wonder if the process was designed to determine the best future for VA research or only the future envisioned by VA's research leadership. Certainly, AAIM respects the need for strategic planning for the VA research service—especially at the start of new leadership—but such planning must take into consideration the needs of all partners in the research enterprise.

Second, publicly disseminated elements of the changes to VA research illustrate that the consequences of these changes have not been thoroughly anticipated or appreciated. A prime demonstration of such a consequence comes from the long line of VA physicians and departmental faculty now forming outside internal medicine department chairs' offices. These faculty are not coming to speak in favor of VA's plans for research. Rather, the faculty state plainly that the proposed changes to VA research—especially including the great narrowing of even the possibility of receiving a VA merit award—lead them to want to leave the VA system. These faculty range from general internists, who provide the bulk of primary medical care in VA, to subspecialists, such as endocrinologists who treat veterans for diabetes and gastroenterologists who screen veterans for colon cancer. Their dissatisfaction with and subsequent withdrawal from the VA system will require VA to take expensive steps to contract for care services, steps that will negatively impact veteran health as funds for other services are funneled to contracts. Moreover, the withdrawal of faculty from the VA system will diminish the department's productive partnership with academic internal medicine and may negatively impact the quality of veterans' medical care.

In another example, the consequences of the research program's recent changes to the peer review system in VA have caused tremendous uncertainty among potential applicants and undermine researchers' trust in participating in the VA research program. Moreover, implementing a new review process that de-emphasizes peer review in favor of untested models threatens the research community's confidence in the quality of VA-sponsored research. While these proposed changes to the peer review system are well intentioned, they have also been extremely disruptive to the research community.

Because of these grave concerns and consequences, AAIM requests a moratorium on the current or future implementation of any modifications to the VA research program. The most crucial activity during the moratorium will be the development and implementation of a process whereby partners in the VA research program can discuss and agree upon the direction and pathway for the program—likely through a high-level summit. Such consensus building is extremely vital to developing a plan that will succeed by avoiding the consequences outlined

above and building a common understanding of the vision and strategy for the future. Another important action would be convening the Secretary's National Research Advisory Committee to consider recent changes and necessary improvements to the VA research program. This approach, adopted by former Undersecretary for Health Ken Kizer, MD, in the mid-1990s, was extremely useful as VA plotted a new course for its research program.

Some leaders within VA may choose to interpret these remarks as a simple attempt to preserve the *status quo* of VA-funded research. To the contrary, AAIM could support structural changes to VA's research program as long as such efforts are mutually determined and recognize the instability in the environment academic internal medicine and VA inhabit. As an example, creating a perception that cardiologists cannot conduct VA-funded research may lead to the withdrawal of this specialized faculty effort from VA clinical activity, limiting educational opportunities for trainees (bad for academic internal medicine) and costing VA more to acquire cardiology services through contracts (bad for veterans and VA).

VA research is most successful through partnerships with departments of internal medicine and medical schools as a whole. The alliance strives to ensure academic internal medicine and VA continue their strong, mutually beneficial partnership; changes on either side of this partnership must be made through an open process that considers all variables and repercussions. AAIM believes the current difficulties between academic internal medicine and VA can be overcome if the proposed moratorium and subsequent steps are followed. Neither party will benefit if communication and constructive change do not occur.

AAIM thanks the committee for this opportunity to present its perspective on these issues. The alliance encourages the committee to consider these issues among the highest priorities in VA for the coming year. To ensure the continuation of high-quality research within VA, to protect the quality of veteran patient care, and to avoid dramatic new VA medical costs, AAIM asks the committee to support efforts to open discussion of VA research to all partners in the research enterprise.

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Oversight of the VA Research Program

Subcommittee on Health
Committee on Veterans' Affairs
United States House of Representatives

July 21, 2003

The American Thoracic Society thanks the Committee for the opportunity to submit written testimony regarding the structure and functioning of the VA Office of Research and Development (ORD) and its interaction with the Office of Research Compliance and Assurance (ORCA).

The American Thoracic Society, founded in 1905, is an independently incorporated, international professional society which focuses on respiratory and critical care medicine. The Society's members help prevent and fight respiratory disease around the globe through research, education, patient care and advocacy. The Society's long-range goal is to decrease morbidity and mortality from respiratory disorders and life-threatening acute illnesses.

The ATS is a strong supporter of the VA Medical and Prosthetics Research Program and its mission. A significant number of ATS members work in the VA, treating veterans and conducting research to advance the scientific understanding and ultimately the health of veterans with lung-related diseases.

ATS/VA Joint Research Program

The ATS support of the VA research program is tangible. In January 2003, ATS named two Department of Veterans Affairs (VA) clinician-scientists as the first recipients of its new ATS/VA Research Career Development Award. These two Research Career Development Awards, jointly funded by the ATS and VA, help fulfill our shared mission of improving VA patient care through research. The VA's network of medical centers and clinics provides an ideal environment for medical and health care research. VA research projects focus directly on diseases that affect the approximately 3.5 million patients the VA treats each year. While the joint ATS/VA research funding program is still in its infancy, the ATS hopes to expand its relationship with the VA research program in the near future.

Clearly, the ATS strongly supports the VA Research Career Development Program, a component of the VA Medical Research Program. Over the years the Career Development Program has nurtured the careers of young investigators who became established and highly productive investigators. Furthermore, a significant number of these individuals have stayed in the VA system and have provided outstanding medical care for veterans.

ATS Advocacy for the VA Research Program

The ATS has also long been an advocate before Congress for the VA research program. For the past 4 years, ATS members have testified before the House VA-HUD Appropriations Subcommittee in support of the VA research program. Additionally, for several years the ATS has been a member of executive committee of the Friends of VA Health Care and Medical Research (FOVA) - a coalition over 70 veterans' service organizations, medical professional societies and patient organizations that support the VA research program. The FOVA

executive committee plays a leadership role in articulating to Congress the broad community support for the VA research program.

It is with this background of strong support and tangible commitment to the VA research program that the ATS offers the following comments and concerns about the VA research program.

ORCA

Research on patients always involves some element of risk. However, the ATS believes that appropriate steps can be taken to reduce risk and protect the safety of veterans enrolled in clinical trials. Peer review and institutional review boards (IRBs) are two key components in ensuring clinical trial safety. A third important component in ensuring clinical trial safety is strong and independent oversight function of clinical research programs. The ATS agrees with the intent of H.R. 1585 to ensure that the research oversight and compliance activities - through the Office of Research Compliance and Assurance (ORCA) - are separate from the research funding office.

The ATS concurred with VA's decision in 1999 to move ORCA from the ORD to become an independent office reporting to the Under Secretary of Health. The ATS believes that research oversight and compliance functions should be separate from the funding function of the program. We note that the Department of Health and Human Services (HHS) separates research funding functions at the National Institutes of Health from the oversight functions at the Office for Human Research Protection (OHRP). Such a separation of functions ensures the integrity of each important process and ultimately bests protects the interest of patients enrolled in clinical trials.

We feel believe that returning research oversight functions to the Under Secretary for Health's office is an important step in ensuring safety in VA clinical trials.

Peer Review Process

Within the VA research community there has been much confusion and concern regarding proposed changes to the VA peer review system. The ATS believes strongly that the peer review system is an essential part of the entire research enterprise. In the peer review process, expert panels review research proposals and rank proposals based on their strengths. Funding is allocated to research proposals with the highest ranking. The peer review process ensures that public funds will support research that best can advance the state of knowledge on biologic and disease processes that impact human health.

ORD has announced its intent to add a layer of criteria review to the peer review process. These new criteria include: relevance of the research to the veteran population, the investigator's prior productivity, and the investigator's stage in their career. The new criteria will be administered in a points system that will

essentially create a second grant review process controlled by ORD. The new criteria were announced to the field without prior notice, input or validation.

To a large extent, we believe that the new criteria are redundant. A researcher's productivity and ability to complete the proposed research are components of are taken into account in the existing peer review system. The publication record and investigator's prior contribution to science are considered carefully by the current peer review panels in the VA system, exactly as they are in the NIH peer review study sections. Additionally, the VA research program is already targeted toward the needs of the veteran population. The VA has identified 17 priority areas of research and invite submission of research proposals in these areas. Grant proposals are already judged on the relevancy to these 17 priority areas. It is unnecessary to introduce another "relevancy review" in the funding process.

The ATS encourages ORD to reconsider its decision to add the new review criteria.

Medical Research Service

New leadership at ORD has forcefully articulated a new vision for the VA research program. The new vision will emphasize Health Services Research and Development (HSRD) as a tool to better disseminate research findings to improve the care of all veterans. The ATS recognizes the value and importance of health services research in improving both individual patient care and patient care systems.

However, the ATS is extremely concerned that growth in the HSRD function will come at the direct expense of the Medical Research Service - recently renamed "laboratory" research. Laboratory research plays three important roles in the VA health system. First, laboratory research promotes good science. Laboratory research projects are the "seeds" that grow and bear the "fruit" of improved diagnostic, treatment and prevention tools for human diseases.

Over time, the VA laboratory research has been fertile ground for improving veterans' health. For example, VA laboratory researchers have analyzing how the changing bacterial flora in the lungs affects the health of patients with chronic obstructive pulmonary disease (COPD). COPD is the fourth leading cause of death in the U.S. Developing a better understanding of interaction between COPD and bacteria in the lung is essential to reducing the morbidity and mortality cause by this disease.

VA laboratory research has also developed an oral smallpox drug, proven effective in mice. While additional study is needed before the vaccine can be tested in humans, this research may prove invaluable in protecting the U.S. against bioterrorist attacks.

Second, laboratory research attracts good physicians to the VA health system. The ability to participate in the VA intramural research program is a powerful incentive for physicians serving in the VA. Many physicians, and particularly subspecialists, choose the VA as a career because it offers them the opportunity to see patients and pursue a research career. Without the ability to conduct research, many subspecialists would likely choose career paths outside the VA.

Third, laboratory science promotes quality patient care. By attracting and retaining top-notch physicians from a wide variety of specialty backgrounds, the laboratory research program helps ensure that the VA health system has an appropriate mix of specialists to meet the needs of the veteran's population. The ATS is especially concerned that a rapid reduction in the size and distribution of laboratory funds will destabilize many VA research programs and ultimately lead to an exodus of physician investigators from the VA. Such an exodus would likely mean the loss of highly trained subspecialists who provide unique medical skills in the VA system. The loss of these subspecialist physicians from the VA will result in extremely long waits for veterans needing specialty care.

Management Transparency

The ATS recognizes the need for the ORD to have the authority to define and change the VA research program. We fully understand that doing things "because that's how they have been done in the past" is not adequate justification for continuing those practices in the future. We further recognize the new leadership provides a unique opportunity re-focus, re-define and re-energize the VA research program. New leadership needs the administrative authority to translate a new vision into reality.

Under new leadership, the ORD has issued a series of management changes and described a new vision for the VA research program that is concerning to many VA physician-investigators. Some of the changes are welcomed, including a reduced lag in the application/funding cycle, promises of better grant data management and renewed emphasis on patient protections in clinical trials.

Other changes are more concerning. As has been previously mentioned, the additional criteria for the peer review process are troubling. We are also concerned about efforts to rapidly change and reduce the size and nature of the laboratory and medical research service.

The perception among much of the VA physician community is that these program changes have been developed without broad field input or consultation. The ORD has commissioned expert panels to advise on the future of the VA research program. The ATS strongly urges release of these documents for public comment and debate. These changes have been announced to the field in a rapid, disjointed and confusing manner. Many specialist VA physician-investigators have expressed concern and frustration the recently announced changes. Others now question their career path within the VA.

The ATS understands the need for swift action when patient safety is at issue. We understand and support ORD's immediate response to allegations of failed patient safety precautions. Crisis situations need quick response. However, the overall VA research program is not in crisis. Management changes and changes in the research focus of the program should be made in a more deliberate and evolutionary - not revolutionary - manner. The steady pursuit of excellence in the VA research program will help ensure that we preserve those aspects of the system that best serve our veterans while simultaneously striving to improve the system.

Conclusion

The ATS remains a strong supporter of the VA Medical and Prosthetics Research Program. We will continue to support the VA research program through our advocacy in Congress, our plans for joint funding of VA researchers and our collaborative interactions with ORD. We hope that the Veterans' Affairs Committee and ORD will receive our comments in the spirit of cooperation with which they are offered. Our goal is to preserve what is best about the VA research program while working toward an even more robust and vibrant VA research enterprise.

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