

S T A T E M E N T



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Of The

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On

Oversight of the VA Research Program

Presented By

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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