

REPUBLICANS

CHRISTOPHER H. SMITH, NEW JERSEY, CHAIRMAN

MICHAEL BILIRAKIS, FLORIDA
TERRY EVERETT, ALABAMA
STEVE BUYER, INDIANA
JACK QUINN, NEW YORK
CLIFF STEARNS, FLORIDA
JERRY MORAN, KANSAS
RICHARD H. BAKER, LOUISIANA
ROB SIMMONS, CONNECTICUT
HENRY E. BROWN, JR., SOUTH CAROLINA
JEFF MILLER, FLORIDA
JOHN BOOZMAN, ARKANSAS
JEB BRADLEY, NEW HAMPSHIRE
BOB BEAUPREZ, COLORADO
GINNY BROWN-WAITE, FLORIDA
RICK RENZI, ARIZONA
TIM MURPHY, PENNSYLVANIA

PATRICK E. RYAN
CHIEF COUNSEL AND STAFF DIRECTOR

DEMOCRATS

LANE EVANS, ILLINOIS, RANKING

BOB FILNER, CALIFORNIA
LUIS V. GUTIERREZ, ILLINOIS
CORRINE BROWN, FLORIDA
VIC SNYDER, ARKANSAS
CIRO D. RODRIGUEZ, TEXAS
MICHAEL H. MICHAUD, MAINE
DARLENE HOOLEY, OREGON
SILVESTRE REYES, TEXAS
TED STRICKLAND, OHIO
SHELLEY BERKLEY, NEVADA
TOM UDALL, NEW MEXICO
SUSAN A. DAVIS, CALIFORNIA
TIMOTHY J. RYAN, OHIO

C. MICHAEL DURISHIN
STAFF DIRECTOR

U.S. House of Representatives

COMMITTEE ON VETERANS' AFFAIRS

ONE HUNDRED EIGHTH CONGRESS

335 CANNON HOUSE OFFICE BUILDING

WASHINGTON, DC 20515

<http://veterans.house.gov>

June 20, 2003

Honorable Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Dr. Roswell:

Since I was unable to ask these questions before the close of the Subcommittee on Oversight and Investigations' hearing on human subject protection in VA medical that was held on June 18, 2003, I would appreciate it if you would answer the enclosed questions by Monday, July 14, 2003. We were not able to address the following issues that are core to the Department's commitment to the safety of veterans who participate in VA medical research.

Please address your response to the attention of Arthur K. Wu, Staff Director, Subcommittee on Oversight and Investigations, Room 337A, Cannon House Office Building, Washington, DC 20515.

In addition, please restate the question in its entirety before the answer.

Sincerely,



STEVE BUYER
Chairman

SB:vtc
Enclosure

VA Human Subjects Protection Medical Research
June 20, 2003
Post Hearing Questions for VA from Chairman Steve Buyer

1. The GAO's testimony is highly critical of VA's efforts to implement the recommendations made in its September 2000 report on human subjects protections. It does, however, praise ORCA for the actions its staff took during the same period of time. In light of this, please explain VA's rationale to the abolish ORCA.
2. Dr. Wray recently held a training seminar for senior VHA officials in Ann Arbor, MI. Before that training seminar, how many similar seminars were held since 1999?
3. Does the VA believe it is essential to give the Office of Research Oversight the authority to not only monitor situations where there may be problems, but also to give it the authority to initiate random checks?
4. For researchers who violate either the Common Rule or VA's internal policy on human subject protections, but do not actually commit a crime, does the Department have a set procedure concerning disciplinary actions? Does VA have a minimum level of discipline? What disciplinary actions were taken against the researchers at West LA in 1999?
5. Did the VA consult with Office of Human Research Protection (OHRP) when it moved to create a new organizational structure within the Office of Research and Development?
6. Is the VA familiar with the *Report to the Advisory Committee to the Director, NIH from the Office for Protection from Research Risks Review Panel*, published in 1999? Was this gold plate standard utilized during VHA's reorganization of ORD & ORCA?
7. VA's written testimony discussed the "stand down" which was completed on June 6th with the submittal by each VAMC of a written report to central office. Since you have established the new Office of Research Oversight to check on research compliance, what is ORO's role in evaluating the reports for their adequacy? When will ORO provide Under

Secretary for Health with an assessment of the adequacy concerning actions taken by the VAMCs during the “stand down?”

8. When the GAO submitted its report in September 2000, entitled: “Protection for Human Subjects Need to Be Strengthened,” the VA agreed to promptly fulfill the five recommendations. The VA agreed to issue current, comprehensive and clear guidance, including a new Handbook on Human Subjects Protections. Despite commitments made by VA at three previous hearings before this committee, the Handbook has not yet been published. Why has it not been published? When will it be published?
9. VA also agreed to determine the funding levels needed to support human subjects protection and ensure the appropriate allocation of funds? When was this assessment made? What funds are now allocated to a dequately support the resources needed at VAMCs to support a robust human subject protection program?
10. VA’s testimony briefly discussed the status of the external accreditation program for the Human Research Protection Programs at VAMCs through a contract with the National Committee for Quality Assurance (NCQA). At the September Hearing last year, VA testified that it had directed the former ORCA to complete an evaluation of this accreditation program. The Subcommittee was provided with a copy of the program evaluation last December with one overall recommendation and eight general recommendations. Did VA endorse the recommendations and what has been done to implement them? How is the NCQA certification process progressing?
11. Secretary Principi issued a memo on April 15, 2003 expressing great concern about the lack of training for the senior level in management of VA research training in ten crucial areas. Has ORD’s training addressed all ten of his concerns? Please provide the Subcommittee with its written plan that responds to the Secretary’s memo?
12. During Dr. Wray’s teleconference on March 10, 2003 she stated that “the Office of Human Research Oversight will be a much, much smaller office and have responsibility only to do focus reviews for cause when I report to them for cause.” Is this still the Department’s position about ORO’s role?
13. When the VA established the former ORCA, now ORO, it was stated to the Committee during the April 21, 1999, hearing that “ORCA will be an independent, objective and unbiased entity in its compliance and oversight activities.” In particular, ORCA would not be a part of the

Office of Research and Development (ORD) to ensure that there would be no jeopardy to its impartiality and credibility. In January 2003, VA's original plan was to incorporate ORCA as a component of ORD. What precisely were the reasons for this change of direction?

14. During the four hearings this committee has held since 1999, including the two that the current VA Under Secretary for Health testified at last year, there was unequivocal support for the former ORCA. Without consulting with Congress, VA decided to eliminate ORCA and incorporate it into the Office of Research and Development (ORD). Now we have a new organization the Office of Research Oversight. What assurances can you give the Subcommittee that ORO will be able to conduct its work with the independence needed to ensure that it is a credible entity, beyond reproach and of the highest integrity.
15. H. R. 1585 would require the entity, and I presume it will be ORO, to provide regular counsel to the Under Secretary for Health on all matters within its scope of responsibility. In order to avoid any conflict in this role vis-à-vis ORD, should it state that ORO is the primary advisor to the USH in these matters?
16. H. R. 1585 would require that ORO to conduct periodic inspections and evaluations of research integrity at VAMCs. Is ORO able to immediately conduct such prospective investigations and evaluations?
17. H. R. 1585 would require the Director of ORO to suspend, restrict, or modify research as determined to be appropriate. The Subcommittee understands that the former ORCA did make such determinations in consultation with OHRP/DHHS. How did that process work and do you think that the Director of ORO can appropriately discharge this responsibility?