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Veterans Administration

REFERENCE SLIP

	TO (Name or title–Mail routing symbol)	INITIALS–DATE
1.		
2.	DR Alvin Young	
3.		
4.		
5.		

REASON FOR REFERENCE

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REMARKS

My assessment of my meeting with the Senate Vet Affairs Comm is enclosed.

FROM Seth

DATE 5/20/

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TRIP REPORT
CONFIDENTIAL

TRIP SITE: Senate Veterans Affairs Committee
DATE: May 17, 1984
ATTENDING FROM VACO:
Dr. Richard Greene, Director, Medical Research
Drs. Barkley Shepard & Larry Hobson, Agent Orange Projects Office
Bill Ramsey & Quentin Kinderman, Legislative Affairs

Four Senate Veterans Affairs Committee staffers were present: Julie Susman, Vic Raymond, and two very young staffers whose names I didn't catch and who remained quiet throughout the two hour briefing. Helen Gelband from OTA, who is responsible for OTA's Agent Orange activities, was also present.

A question and answer period followed my presentation of the advantages and components of the VETS. The discussion centered around the following topics:

POWER - Vic Raymond did most of the questioning in this area. He was concerned about the power of the VETS relative to the CDC study. I explained that direct comparisons are difficult because CDC has not yet made public the tests and measures included in their protocol. I said that for discontinuous measures (for example, cancer, diabetes) the VETS had relatively low power. However, for continuous measures (for example, liver function tests, cholesterol, exercise capacity), the VETS had considerable power. I mentioned that while the VETS would therefore probably be unable to detect an increase in diabetes resulting from exposure to Agent Orange, it would be able to detect a small increase in fasting blood sugar with high statistical reliability. I elaborated on the concept that the design of the VETS is not intended to identify an increase in the incidence of disease but rather more subtle changes such as relatively small changes in liver function, psychological tests, or life history.

I emphasized that the VETS design provides the most information for the research dollar, since data obtained from twins has four to five times the statistical power by comparison with standard research designs. I noted that the Agent Orange component of the VETS is only examining 130 pairs because we were directed to reduce the cost of the clinical assessment component to less than $9 million. For an additional $2 million, the Agent Orange component could be expanded to 360 pairs and the power thereby considerably increased.

Hobson noted that the Agent Orange component of the VETS is designed as a pilot study. Statistically valid differences discovered by the VETS can then be examined in greater detail in additional, more focused studies.

Julie Susman was concerned that even if a study of 130 pairs is

statistically valid, the public might not accept conclusions based on an examination of such a relatively small number of veterans.

Raymond asked that we provide the committee with a written discussion of the power of the VETS (particularly the Agent Orange component) by comparison with the CDC and Ranch Hand studies and an analysis of the increase in power resulting from an increase in the number of pairs who undergo the Agent Orange tests.

CONTRACT COSTS - Susman expressed concern about the "ridiculously high" cost of the CDC protocol. She said that after she learned of CDC's estimated medical evaluation and test costs she thought that she should quit her present job and "go to medical school". She didn't think that a physician contractor should buy his "third house in Florida" with the money earned on a research project.

I presented our estimated cost data: $610 per medical exam (including extensive history, physical and laboratory components), $320 per psychiatric exam, $295 per psychological exam, and $295 per life history evaluation. Each Agent Orange evaluation will cost approximately $3611, but this includes some very expensive tests (for example, the chromosomal analysis is almost $1000 per participant. The chromosomal analysis will be the largest study ever performed on any dioxin exposed group and particularly the sister chromatid exchange portion will have extremely high statistical reliability.).

Susman was concerned that our proposed budget is probably already known to some potential bidders and that responses to our RFP would probably come very close to the amount allocated. I predicted that there will be a relatively large number of respondents to the RFP and therefore healthy competitive bidding is likely to occur. Greene noted that a bidder's knowledge of our proposed budget will not be particularly helpful since the contractor must substantiate all costs. In addition, contracts the size of the VETS are uniformly audited following completion. Every item must be justified. Greene also noted that the money allocated for VA construction projects is known by all bidders since the amounts are line-itemed in the federal budget. Yet effective competitive bidding still occurs.

(Susman seemed satisfied by our estimated examination costs and Greene's explanation of the bidding and contract review process.)

CURRENT STATUS OF THE VETS CLINICAL PROTOCOL - I explained that the VETS clinical assessment protocol had undergone two reviews by VA committees composed primarily of non-VA scientists and a third review will occur in June. Additional reviews by non-VA convened committees will occur shortly. Greene explained that our protocol has been reviewed by Cooperative Studies Program committees but that the CSP has little expertise in the area of epidemiology. For this reason and because of the large amount of

money involved, the VA feels an outside review is very important. Greene said that the VA would like OTA to review our protocol and asked how Senator Simpson might respond to a request from Walters for an OTA review. Susman said she felt the Senator would respond positively and Greene said that Simpson will probably shortly receive a request from the VA Administrator. Brief discussion was also given to other possible review groups: NAS (NAS would take too long, cost too much, and might represent a conflict of interest because of their participation in the process of finding twins), NIH (no comments), Agent Orange Working Group (no comments). Gelband commented that OTA is overcommitted and that it would be difficult for OTA to perform a review quickly. Shepard noted that OTA had performed excellently in the past and hoped that OTA could expedite the review.

RELATIONSHIP OF THE VETS TO MEDICAL RESEARCH SERVICE AND THE AGENT ORANGE PROJECTS OFFICE - A series of questions were asked about the relationship among the VETS, Medical Research Service, and the AOPO: Who is administratively responsible for the VETS? (Answer: Medical Research.) Does the AOPO have any responsibility for the VETS? (Answer: No, except to assist when requested.) Why then are both Shepard and Hobson present today? (Answer: In case staffers have questions about Agent Orange.) Was the VETS ever an Agent Orange proposal? (Answer: Yes, originally.) Why did it change? (Answer: Because of concern about the validity of the Agent Orange risk of exposure index.)

COMPARISON OF VETS WITH THE NATIONAL NEEDS ASSESSMENT STUDY - I said that a detailed comparison is impossible because the National Needs Assessment protocol does not yet exist. However, my review of the National Needs RFP reveals that the VETS will be much more cost-effective, will be much more detailed (several days of examinations versus several hours for the National Needs), will have an extensive medical component (the National Needs has none), and will have much greater statistical reliability (the National Needs RFP requires only an 80% reliability). I gave a detailed example of a few of the many important questions the VETS will be able to carefully address which the National Needs will not.

AGENT ORANGE EXPOSURE INDEX - Gelband asked about the validity of the Agent Orange risk of exposure index. I explained that the index will be provided by Christian of the Army Agent Orange Task Force and that it is the same index used by the CDC Birth Defects and the sarcoma/lymphoma components of the CDC epidemiology study. Gelband noted that the index used by the Agent Orange component of the CDC epidemiology study is more accurate than that used by the other components. She also commented that she had participated in many discussions about the index and questioned its reliability.

A PERSONAL ASSESSMENT

It was unclear prior to the presentation why the committee

requested a VETS briefing. Following the briefing the reason remained obscure. Although quite cordial, the staffers were relatively "poker-faced" throughout. They seemed to neither approve nor disapprove of the VETS. Their potential criticism of medical examination costs seemed blunted by the data given to them. They remained concerned about the statistical power of the Agent Orange component of the VETS by comparison with the CDC and Ranch Hand studies. I had the feeling they weren't impressed by the usefulness of the Ranch Hand results and wanted to avoid another study with conclusions no clearer then Ranch Hand's. In this regard, I believe the staffers are unrealistic. They seem to want a study that will provide simple and unqualified answers to the complex questions facing Congress. No single study will accomplish this. The staffers seemed unimpressed by the argument that several studies, using different designs, are the only hope for understanding the effect of the Vietnam experience on health.

It was unclear why the staffers questioned VACO representatives so closely about the relationship between the AOPO and Medical Research Service and the change in emphasis of the VETS from Agent Orange to Vietnam experience.

The staffers seemed to agree that review of our protocol by a non-VA group is desireable.

The staffers didn't seem particularly impressed by the fact the the VETS provides much more information per research dollar then any other related research project. They also made no comments (favorable or unfavorable) about increasing the validity of the results by augmenting the budget to permit an increase in the number of participants who can undergo the Agent Orange examinations.

Greene's agenda for the briefing seemed clear. He wanted to communicate to the staffers that in spite of the considerable time and financial investment the VA already has in the VETS, the project will not be funded until it is reviewed and approved by a non-VA affiliated group, specifically OTA. After the briefing, Greene said that the letter from Walters to Simpson requesting OTA review had not been sent because "Walters didn't want to send a letter that Simpson didn't want to receive." Greene felt that Susman had told him that Simpson would favorably review a letter from Walters. The letter will now be sent promptly.

"LESSON'S LEARNED"

In future presentations, discuss in greater detail the distinction between the VETS ability to detect disease and differences in laboratory values.

In future presentations, be prepared to compare the power of the VETS with other similar research projects.

The Agent Orange component of the VETS remains vulnerable to

criticism because of its small sample size and the questionable validity of the risk of exposure index.

MEETING WITH JEFF RYAN, SUPPLY SERVICE

I met with Ryan to review the VETS contracting procedures. In response to one of my questions, Ryan said that our protocol could serve as part of the bid package. He agreed, however, that it would be helpful to potential bidders to also be able to read a summary which emphasized what we consider to be important aspects of the contract.

Ryan asked us to review our prior response to the "24 questions", revise where appropriate, and then submit the response with a copy of our protcol to him. "I will get it out of my office within 48 hours" for review and approval by the acting CMD and the Administrator. Once approved, the details of putting the entire package together can be managed.

Ryan noted that responsibility for the VETS may soon be reassigned to someone else. Discontinuity and delays may therefore result.

DISCUSSION WITH HOBSON

I noted to Hobson that in past reviews of Agent Orange related research, OTA has provided critical comments but has never made an approval/disapproval recommendation. I suggested that OTA's review of the VETS will probably be in a similar format. Thus, I expected some supportive comments, neutral comments, and some critical comments. How, I asked, will the VA use OTA's analysis to decide whether to fund the VETS? Hobson agreed with my analysis and said, "the VA will make the decision it wants to."

Seth Eisen, M. D.