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Author

Corporate Author

Report/Article Title Correspondence regarding Centers for Disease Control (CDC) Agent Orange Study between Office of Technology Assessment, United States Senate, Veterans Administration, Department of health and Human Services, dated September to Decmber 1985

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Year 1985

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Color ☐

Number of Images 18

Descripton Notes Alvin L. Young filed these documents together with others in a folder labelled, "Agent Orange Working Group Science Panel, Current Folder."

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Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, DC 20510

JOHN H. GIBBONS
DIRECTOR

September 23, 1985

The Honorable Jake Garn
Chairman
Subcommittee on HUD-Independent
Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

RECEIVED SEP 30 1985

Dear Jake:

I am writing to inform you about recent developments in the Centers for Disease Control (CDC) Agent Orange Study. In March, OTA reviewed the method by which the CDC proposed to assign relative exposure ratings to participants in the Agent Orange Study. OTA was critical of the method, which relied on classifying each man according to a location assigned to his battalion, a single point that would be used to represent about 1,000 men on any given day. This method differed from CDC's earlier plan, which was to rely on the location of the man's company, representing about 200 men. The battalion approach produces a less precise estimator of an individual soldier's location than would a company-level approach. According to CDC, the change to the battalion approach was necessitated because records of company locations were not available for enough companies on a large enough number of days during the study period. In discussions with the U.S. Army Environmental Support Group (ESG), the group that is abstracting location information from the military records for CDC, OTA staff learned that the ESG believed they <u>could</u> provide company locations. The Staff Memorandum included with my April letter to you states:

> If there are no improvements, OTA may decide that the problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange.

Since April, the CDC researchers have been working toward a method for assessing exposure based on company locations. We understand they have made substantial progress and they expect to supply OTA a revised plan in October. After we receive that plan, we will hold a meeting of the OTA Agent Orange Advisory Panel and will report our findings to you. Our critique will probably come to you in late November or in December.

ESG has already begun "qualifying" men for the Agent Orange study, and has begun supplying CDC with names of potential participants. CDC plans to begin interviews for the Agent Orange study in January 1986. Undoubtedly, this will be before the details of the exposure assessment method are worked out. Since exposure scores do not affect the <u>selection</u> of participants for the Agent Orange study, that schedule should not cause any difficulties if a suitable method for exposure assessment is devised.

Without having seen CDC's revised method, OTA does not know if the proposal will be complete enough that a judgment can be made that it will or will not work, or if the proposal will need reworking before a decision can be made. Nevertheless, a final decision about the adequacy of the exposure index must be made before very many interviews and examinations are completed. Otherwise a mindset may develop that the study is too far along to be called back. OTA realizes that a decision not to go ahead with the Agent Orange study or to stop it would be a drastic step, but unless the exposure assessment is much improved, that course may be recommended. Whatever difficulties might flow from such steps would be minor compared to completing a study that lacks solid estimates of exposure.

Everyone involved with the Agent Orange study has known since the earliest days that a reliable measure of exposure is the key to a valid study. There has always been uncertainty about whether such a measure could be developed, not because of any inadequacies in the researchers struggling with the question, but because the information simply may not exist to construct a valid exposure index.

I will keep you informed of any significant progress in the Agent Orange study and will report specifically on CDC's October document describing their method for assessing Agent Orange exposure.

Sincerely,

Jack

John H. Gibbons

REPORT OF CONTACT

NOTE: This form must be filled out in ink or on typewriter, as it becomes a permanent record in veterans' folders.

VA OFFICE

IDENTIFICATION NOS. *(C, XC, SS, XSS, V, K, etc.)*

LAST NAME—FIRST NAME—MIDDLE NAME OF VETERAN *(Type or print)*
REISS, Marty

DATE OF CONTACT
Oct. 23, 1985

ADDRESS OF VETERAN
Senate Appropriations Subcommittee

TELEPHONE NO. OF VETERAN
224-7284

PERSON CONTACTED
SEVERN, Karen S.

TYPE OF CONTACT *(Check)*
☐ PERSONAL ☒ TELEPHONE

ADDRESS OF PERSON CONTACTED
Budget Service (041A)

TELEPHONE NO. OF PERSON CONTACTED
389-3464

BRIEF STATEMENT OF INFORMATION REQUESTED AND GIVEN

SUBJ: DM&S - October 11 Report of Contact (copy attached)

A. How does DM&S put its personnel Budget together?

1. Marty still wants information.
2. Still wants to meet with DM&S/Budget Service to discuss.
3. Wants it soon.

B. Repeat a breakout of $196 million reduction similar to the Budget Service chart for $296 million reduction.

Two versions: a) What the Controller's Office thinks.
b) What DM&S thinks.

C. Where is the CDC Study?

We've given all this money?
Where are we?
What are we expecting?
Is the design adequate to get reliable data?

Office of Technology and Assessment in a letter to Senator Garn, expressed concern that the design of the survey will not give the data we are seeking.

DISTRIBUTION:
001
10
10R
04
041
041A
041F

DIVISION OR SECTION
Budget Service (041)

EXECUTED BY *(Signature and title)*
Karen S. Severn
KAREN S. SEVERN, Deputy Director

VA FORM 119 JUL 1977 EXISTING STOCKS OF VA FORM 119, JUL 1974 WILL BE USED.

Meeting on Status of Epidemiology Study
Held at Request of HVAC Congressional Staff

On October 30, 1985, a meeting relating to the conduct of the Epidemiology Study by the Centers for Disease Control (CDC) was called and chaired by Mr. Jack McDonell (HVAC). The meeting was held in the HVAC hearing room, the Cannon House Office Building. A list of the attendees is attached.

Opening comments were made by Mr. McDonell who stressed the importance of the Epidemiology Study, and its ultimate successful conclusion, to Vietnam veterans and their families and to various members of Congress. Mr. Jonathan Steinberg (SVAC) addressed the attendees making a strong statement stressing the importance of the study, pointing out that on this issue, that is, the successful conduct and conclusion of the study, the credibility of the Congress and the executive branch was at stake. He stated further that the study must be conducted on a sound scientific basis such that it would withstand peer review and be completed in a timely fashion. However, the "worst scenerio" would be to complete the study and then have it discredited because of technical or scientific flaws.

CDC representatives were asked to describe the status of the methodology whereby study subjects would be selected based on exposure or non-exposure to Agent Orange. Dr. Vernon Houk, CDC, briefly discussed the background and history of events leading up to the present. He also described the status of the Vietnam Experience Study, one of the three components comprising the total Epidemiology Study. This phase of the study is scheduled for completion in 1987.

Dr. Peter Layde, CDC, elaborated on some of the concerns and problems related to the development of an exposure index. Mr. Dan McGee, CDC, discussed in more detail the consequences of misclassification of study subjects with regard to exposure.

Mr. Richard Christian, Director of the Army's Environmental Support Group (ESG) and members of his staff responded to comments made by CDC concerning the status of the study, particularly with regard to the development of an exposure index. Mr. Christian indicated that the ESG had not approved CDC's proposed index nor had the ESG been given adequate time to review that part of the methodology provided by CDC. He rebutted CDC's claim that the ESG had not provided CDC with all of the documents they required for the conduct of the study.

CDC admitted that they have not yet completed their work in developing a useable exposure index. Part of the delay, according to the CDC representatives, was due to the difficulties in establishing an internal validation process. Another cause of delay was OTA's rejection of their attempts to set up a mathematical computer model based on the "centroid" concept. This was a theoretical model developed by CDC to establish locations of troop units. The reason for its rejection was that it did not accurately reflect actual troop locations based on available operational records.

The meeting concluded with comments by Mr. Steinberg who strongly urged CDC and the ESG to meet as soon as possible for the purpose of developing a workable exposure index so that the study can proceed on schedule. He pointed out that he hoped that such a methodology would be in place before the physical examinations scheduled to begin in January 1986 are initiated. Both CDC and the ESG agreed to this cooperative endeavor. Mr. Steinberg's final comments included the observation, that in his judgement, constitutionality questions not withstanding, the OTA would be regarded by the Congress as the body responsible for determining the scientific validity of the exposure index to be used for the conduct of the study.

BARCLAY M. SHEPARD, M.D.
Director, Agent Orange Projects Office (10X2)
November 13, 1985

Cannon House Office Building Meeting
of
October 30, 1985

Attendees-

SVAC Staff

Mr. Tony Principi
Mr. Jonathan Steinberg
Mr. Bill Brew

HVAC Staff

Mr. Jack McDonell
Mr. Mac Flemming
Mr. Pat Ryan
Mr. Vic Raymond
Mr. Dick Fuller
Ms. Barbara Dean

CDC Staff

Dr. Vernon Houk
Dr. Peter Layde
Dr. Dan McGee

ESG (US Army)

Mr. Richard Christian
Mr. Doug Clark
Major Tenberg (US Army)
Mr. Dan Hakenson

DHHS Staff

Dr. Carl Keller
Dr. Peter Beach

OTA Staff

Dr. Michael Gough
Ms. Helen Gelband

VA Staff

Dr. Barclay M. Shepard

Veterans Administration

Memorandum

Date: NOV 13 1985

From: Director, Agent Orange Projects Office (10X2)

Subj: VA Policy Relative to Communication with Centers for Disease Control (CDC) on Conduct of Epidemiology Study

To: Chief Medical Director (10)
THRU: ACMD for Programs, Planning and Policy Development (10X)

1. Recent developments relating to the conduct of the Epidemiology Study on the Health Status of Vietnam Veterans by the Centers for Disease Control (CDC) have shown that there is a serious breakdown in communication between the Veterans Administration (VA) and CDC on the conduct of that study. These developments include the creation and submission by CDC of a proposed exposure index for review by the Office of Technology Assessment (OTA) and the award by CDC in mid-September 1985, of a contract to the National Academy of Sciences Institute of Medicine to monitor the Epidemiology Study and review and evaluate the methodology for an Agent Orange exposure index. Although the CDC provides quarterly status reports to the VA on their Epidemiology Study research activities, neither of these events were reflected in these reports, nor were they the subject of open discussions with the VA or in meetings of the Agent Orange Working Group (AOWG). We became aware of them only after being informed about them by sources external to this agency.

2. The two events described above were the subject of a meeting held at the Cannon House Office Building on October 30, 1985. This meeting, called at the request of the House Veterans Affairs Committee Staff, was attended by key congressional staff including Mr. Jack McDonald (HVAC) who chaired the meeting, Mr. Jonathan Steinberg (SVAC), CDC representatives, Army Environmental Support Group (ESG) staff, OTA representatives, other DHHS staff and myself. The lack of progress by CDC in developing a useable exposure index and the award of the NAS contract were obviously of great concern to Mr. McDonald and Mr. Steinberg who emphasized the importance attached by a number of other key congressional staff in both the House and Senate to the successful conduct of the study. This meeting concluded with an agreement for CDC and the ESG to resolve the matter of developing an exposure index methodology prior to the initiation of physical examinations of the Epidemiology Study participants in January 1986.

3. It should be noted that the VA will be submitting, on or before February 15, 1986, the first status report on the Epidemiology Study to the appropriate congressional committees. This report is mandated by Public Law 96-151 enacted December 20, 1979. Although CDC is responsible for the preparation of this report, the VA remains the agency mandated by law to transmit that report to Congress with any recommendations the Administrator of Veterans Affairs deems appropriate. As shown, the VA cannot rely solely on the quarterly status

reports submitted to us by CDC to remain abreast of such significant developments, activities which may bear heavily on any recommendations or observations which will be included in the letter transmitting the first mandated report to Congress.

4. Accordingly, I recommend that:

(1) The VA more actively follow the CDC's conduct of the Epidemiology Study without in any way advising or assisting the CDC in the design or conduct of that study and

(2) The attached letter to the Acting Assisting Secretary for Health, DHHS, be sent as evidence of CDC's failure to keep the VA fully informed of the difficulties encountered in the study's design and conduct. In pursuing the first recommendation, quarterly meetings would be held between staff of the VA's Agent Orange Projects Office and appropriate CDC officials to discuss the content and implications of that agency's quarterly status reports.

5. Your review and approval of the above recommendations is appreciated.

Lawrence B. Hobin, M.D.

for BARCLAY M. SHEPARD, M.D.

Attachment

AGREE to follow and dispatch

DISAGREE _____

John W. Ditzler

JOHN W. DITZLER, M.D.
Chief Medical Director

DEC 5 1985

10X2

James O. Mason, M.D., Dr. P.H.
Acting Assistant Secretary for Health
Department of Health and Human Services
Washington, D.C. 20201

Dear Dr. Mason:

The January 1983 interagency agreement between the Veterans Administration (VA) and the Centers for Disease Control (CDC), relative to the conduct of the Epidemiology Study of the Health Status of Vietnam Veterans, provides for the preparation by CDC of a quarterly status report to the VA on the conduct of that study. These reports are of great assistance to the VA in responding to frequent inquiries from many sources regarding the progress of the study.

Recently, the VA became aware through external sources of a significant development not mentioned in any of the quarterly reports received to date by the VA. The development concerned the creation and submission by CDC of a proposed exposure index for review by the Office of Technology Assessment (OTA). We have learned, again from sources other than CDC, that the OTA review found this exposure index methodology to be unsatisfactory. The lack of progress by CDC in developing an exposure index has never been mentioned in any of the quarterly status reports received by this agency. Additionally, to the best of our knowledge this fact was never communicated in discussions with the VA or in meetings of the Agent Orange Working Group (AOWG).

The purpose of the quarterly status reports, as originally envisioned during the development of the interagency agreement, was not only to provide a full report on CDC's progress on the conduct of the Epidemiology Study, but also, to alert the VA to any real or potential problems encountered by CDC which might impact on that study's progress and eventual successful completion. As you will appreciate, unanticipated difficulties in the research can affect its ultimate outcome and the manner in which it will be perceived by veterans. I'm sure that you will agree that the future inclusion of such significant developments will assist both the VA and CDC in fulfilling our respective agency responsibilities as they relate to this major study. It would be very beneficial to the VA for the appropriate CDC officials to provide a briefing on the content and implications of the status reports to Dr. Barclay M. Shepard, Director, Agent Orange Projects Office and members

of his staff immediately following the submission of the report to that office. Accordingly, I request your consideration and approval for this activity for all future reports.

I appreciate your assistance in this matter.

Sincerely,

JOHN W. DITZLER, M.D.
Chief Medical Director

cc: 02C
101B11

SUMMARY

Purpose: To alert the Centers for Disease Control (CDC) of need to keep VA fully briefed on significant developments related to conduct of the Epidemiology Study of Health Status of Vietnam Veterans.

General: CMD advises the Acting Assistant Secretary for Health, DHHS, that VA has become aware of a significant development related to the conduct of the Epidemiology not reported in CDC's quarterly status report to this agency or in open discussions. Particularly cited by the CMD is the development and submission by CDC of a proposed exposure index for Office of Technology Assessment review and its ultimate disapproval. The CMD requests that the appropriate CDC officials brief the Director, Agent Orange Projects Office and members of his staff on the content and implications of the information contained in all future status reports to that office.

The CMD reminds CDC of the need for full and complete information to assist the VA in responding to frequent inquiries from many sources concerning the status of the study. He states that he believes such information will assist both the VA and CDC in successfully completing their respective missions.

Implications: It is essential that CDC keep the VA fully briefed on developments. The first congressionally mandated report to Congress is due February 15, 1986.

Recommendations: Approve and dispatch

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JOHN H. GIBBONS

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, DC 20510

JOHN H. GIBBONS
DIRECTOR

Health

bcc: Director
Asst Directors
T.McGurn
CPA
Health (2)

DEC 19 1985

The Honorable Patrick J. Leahy
Ranking Minority Member
Subcommittee on HUD-Independent
Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Senator Leahy:

I am writing to inform you about OTA's continuing review of progress in the mandated Agent Orange study being carried out by the Centers for Disease Control (CDC). The item of greatest concern has been the lack of a method for assessing exposure to Agent Orange among study subjects. We last addressed this issue in March 1985, at which time we expressed serious doubt to you about the exposure assessment method CDC had proposed in a February report to OTA. In September, I wrote to you expressing concern that, although CDC's timetable called for interviewing Agent Orange study subjects beginning in January 1986, a revised exposure assessment method had yet to be produced.

On November 18, we received a report from CDC titled "Exposure Assessment for the Agent Orange Study, Interim Report Number 2." We had by then arranged to have the OTA Agent Orange Advisory Panel meet on December 14 to review CDC's report. Based on our reading of the November 18 report, OTA staff requested some additional information from CDC, without which it would have been impossible for the Advisory Panel to adequately evaluate the exposure assessment method. On December 9, we received another report, dated December 8, which contained much of the information that had been requested. A final packet from CDC, containing specific information requested by OTA staff, arrived on December 13. The Advisory Panel met the following day. Their advice to OTA is reflected in this letter.

In sum, the recent reports from CDC outline an Agent Orange study of radically different design than the one that was initially reviewed and approved by OTA. The changes in design are of sufficient magnitude to require interruption of any plans for initiating interviews or examinations of study subjects. Further, the plan still appears to be in a state of change. While all or some of the changes proposed by CDC may be necessitated by relatively new information about troop locations and eligibility of men as study subjects, the reasons for the changes have not been coherently or convincingly presented in any of the reports OTA has received from CDC.

When the original Agent Orange study design was approved by OTA, there were still many unanswered questions and uncertainties which only would be resolvable when representative data from the military records had been assembled. There now exists a body of data which, while not complete, gives an indication of what the records contain. CDC should now be able to make some final decisions about study design and about the quality of the exposure

data on which the study results will be based. OTA, therefore, requests a new statement of study design, incorporating, as necessary, new plans for exposure assessment, a plan for selecting study subjects, and new plans for data analysis. The discussion of exposure assessment should contain an explicit analysis of the probability of misclassification within the "likely to have been exposed" group. Finally, there should be discussion about whether the range of exposures likely to be found among the study subjects forms a firm underpinning for the proposed study. As CDC stated in its original protocol of November 1983, "Since many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study assessments." The data collected to date should serve as an adequate pilot test of the methods and representation of results of exposure assessment.

At the same time that the new study protocol has been evolving, the study has faced a severe managerial problem. This problem, which seems soluble, is one of collaboration of CDC and the Environmental Support Group (ESG). Steps should be taken to insure that this problem is resolved expeditiously. The Agent Orange Working Group Science Panel may be the appropriate body to catalyze discussion between the two groups. If other military experts are required as consultants, they should be brought into the process, with a clear statement of their roles. While it is not appropriate for OTA to moderate the dispute, we can evaluate the resolution. It is important that formal work statements for data abstraction from military records and for assessing data quality be agreed upon jointly by CDC and ESG. OTA would like to be provided copies of these work statements when agreement has been reached.

I am sending copies of this letter to both CDC and ESG. OTA staff currently are writing a detailed set of comments which address the issues raised in this letter. Copies of those comments will be sent to CDC and ESG, and to the appropriate Congressional committee staff dealing with Agent Orange issues.

If OTA is to consider the revised Agent Orange study protocol for approval, another review will be necessary. Our Agent Orange Advisory Panel is prepared to meet again in early 1986. I believe that sometime in March or April is a realistic expectation for that meeting. In our view, no major new phase of the study should be undertaken before the new design and exposure assessment method are found acceptable and the managerial problems resolved.

If you would like further discussion on this matter please do not hesitate to call me at 4-3695, or Hellen Gelband of the OTA staff at 6-2070.

Sincerely,

John H. Gibbons

The Honorable Patrick J. Leahy
Ranking Minority Member
Subcommittee on HUD-Independent
Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Senator Leahy

The Honorable Frank H. Murkowski
Chairman
Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510
Mr. Chairman

The Honorable Alan Cranston
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510
Alan

The Honorable Jake Garn
Chairman
Subcommittee on HUD-Independent
Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Jake

The Honorable G. V. Montgomery
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515
Mr. Chairman

The Honorable John P. Hammerschmidt
Ranking Minority Member
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, D.C. 20515
Congressman Hammerschmidt

The Honorable Edward P. Boland
Chairman
Subcommittee on HUD-Independent
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Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Mr. Chairman

The Honorable Bill Green
Ranking Minority Member
Subcommittee on HUD-Independent
Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Congressman Green

The Honorable Orrin G. Hatch
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510
Orrin

The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510
Ted

The Honorable Henry A. Waxman
Chairman
Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515
Henry

The Honorable Edward R. Madigan
Ranking Minority Member
Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515
Congressman Madigan

The Honorable William H. Natcher
Chairman
Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Mr. Natcher

The Honorable Silvio O. Conte
Ranking Minority Member
Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Congressman Conte

The Honorable Lowell P. Weicker, Jr.
Chairman
Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Mr. Chairman

The Honorable William Proxmire
Ranking Minority Member
Subcommittee on Labor, Health
Human Services, and Education
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Senator Proxmire

The Honorable Silvio O. Conte
Ranking Minority Member
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Congressman Conte

The Honorable Jamie L. Whitten
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515
Mr. Chairman

The Honorable John C. Stennis
Ranking Minority Member
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Senator Stennis

The Honorable Mark O. Hatfield
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510
Mark

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515
John

The Honorable James T. Broyhill
Ranking Minority Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515
Congressman Broyhill

The Honorable Harry N. Walters
Administrator
Veterans Administration
810 Vermont Avenue, NW
Washington, D.C. 20402
Harry

REPORT OF CONTACT

NOTE: This form must be filled out in ink or on typewriter, as it becomes a permanent record in veterans' folders.

VA OFFICE

IDENTIFICATION NOS. *(C, XC, SS, XSS, V, K, etc.)*

LAST NAME—FIRST NAME—MIDDLE NAME OF VETERAN *(Type or print)*

DATE OF CONTACT
12/23/85

ADDRESS OF VETERAN

TELEPHONE NO. OF VETERAN

PERSON CONTACTED
Kingston Smith

TYPE OF CONTACT *(Check)*
☐ PERSONAL ☒ TELEPHONE

ADDRESS OF PERSON CONTACTED
HVAC

TELEPHONE NO. OF PERSON CONTACTED

BRIEF STATEMENT OF INFORMATION REQUESTED AND GIVEN

Kingston Smith, Minority Staff, House Veterans' Affairs Committee, called to discuss a letter the Committee had received from the Office of Technology Assessment concerning the progress of the Agent Orange study mandated by Pub. L. No. 96-151. The OTA had expressed serious reservations about the approach being taken by the CDC. They especially questioned the methodology being suggested for deterrmining the exposure of study subjects. This has been a topic of concern for about three months and was the subject of a meeting held on the Hill at the end of October. Attending that meeting were representatives from the House and Senate Veterans Affairs Committees, the Department of Defense's Environmental Support Group, the CDC and the VA. (A copy of a memo summarizing this meeting is attached.)

Mr. Smith stated that the Agent Orange study, which he characterized as the most politically sensitive part of the effort, was in serious difficulty. He strongly hinted that hearings on the progress of the study was a definite possibility and that it would probably not be a pleasant experience for the CDC. I noted that the VA had adopted a posture of neutrality regarding the study following its transfer to CDC at the request, in part, of the Committee's Chairman. For that reason, I suggested that the VA had no comments to offer concerning this development. I did note that this controversy did not affect the progress of the Vietnam Experience Study which is now underway nor the selected cancers study which is also being conducted by the CDC. Mr. Smith stated that he would forward a copy of the OTA letter to the VA in the next few days.

DIVISION OR SECTION
Special Assistant to the General Counsel (02C)

EXECUTED BY *(Signature and title)*
Frederick L Conway

VA FORM JUL 1977 119 EXISTING STOCKS OF VA FORM 119, JUL 1974 WILL BE USED.

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