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Report/Article Title Memorandum for Agent Orange Working Group (AOWG) Science Subpanel on Exposure Assessment, from Alvin L. Young, regarding Recap of Action from March 28, 1986 Meeting with attachments, dated April 2, 1986

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

April 2, 1986

MEMORANDUM FOR AOWG SCIENCE SUBPANEL ON EXPOSURE ASSESSMENT

FROM: AL YOUNG

SUBJECT: Recap of Action from 28 March 1986 Meeting

1. Effective 28 March 1986 and at the request of Dr. Ian Macdonald, Acting Assistant Secretary of Health, HHS, the Agent Orange Working Group Science Subpanel on Exposure Assessment will be chaired by A.L. Young, OSTP. Concurrence memorandum signed by Acting Science Advisor is attached.

2. Membership of the AOWG Science Subpanel on Exposure Assessment will be: A.L. Young, OSTP; C. Keller, NIEHS; A. Blair, NCI; M. Fingerhut, NIOSH; D. Barnes, EPA; B. Shepard, VA; H. Kang, VA; R. Christian, DOD; J. Bricker, DOD; J. Murray, DOD; and an observer from CDC (to be named), Dr. Flanders in attendance at meeting of 28 March.

3. Task of the AOWG Science Subpanel on Exposure Assessment: "To review pertinent information, including the results of an AOWG Science Panel Pilot Study, on exposure levels of military personnel to Agent Orange and its associated dioxin; and, to prepare a report of their evaluation for the Agent Orange Working Group." This report will be provided to the CDC for use in the protocol for the Congressionally-mandated Epidemiologic Study of Ground Troops. An explanatory memorandum for this task was sent to the AOWG members on 28 February 1986 and is attached.

4. Review of Previous Actions and Activities. Two previous meetings of this Subpanel have been held (summaries of these meetings are attached). A briefing to the Institute of Medicine (NAS) was provided by ESG on 7 March 1986.

5. Suggested General Approach to Resolution of Task. Using available data from herbicide applications, ground troop movements and locations, and the ESG conducted Pilot Study, a series of pertinent questions will be posed. For each question, a background statement will be prepared, followed by a summation of all available data, and concluded with a Subpanel assessment. A series of recommendations will be provided.

6. Recap of Requested Action:

A. Young - Inquire with CDC as to responsibility of Institute of Medicine in conducting exposure assessment.

- Request that the CDC Observer be the Principal Investigator of CDC Study.

- Inquire with CDC as to current activity on exposure assessment and how they plan to use AOWG Subpanel Report.

A. Blair - Draft a list of questions appropriate for Subpanel to address in preparing report.

M. Fingerhut - Conduct Review of previous epidemiologic studies on phenoxy herbicides and TCDD to ascertain if any data on exposure assessment and health end-points may have application to AOWG Subpanel task.

H. Kang - In concert with D. Barnes, assemble and evaluate available risk assessments on 2,3,7,8 TCDD and the phenoxy herbicides (2,4-D and 2,4,5-T).

D. Flanders - Prepare a computer listing of perimeter applications of herbicides in III Corps during the period October 1966 through March 1969.

R. Christian - Prepare a list of ESG-tasked action items requested by General Murray and give status.

- Prepare a concise statement describing the Pilot Study currently being conducted by ESG and what format will be used in reporting results (C. Keller to assist in this latter task).

J. Bricker - Continue preparing ESG document on "Agent Orange Exposure Probability Modeling for Vietnam Field Conditions."

7. Next Meeting Dates for Subpanel:

10 April 1986, Thursday, 1:00-3:00 p.m., NEOB, Room 5026

21 April 1986, Monday, 1:00-3:00 p.m., NEOB, Room 5026

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

March 27, 1986

MEMORANDUM FOR JOHN McTAGUE

FROM: AL YOUNG Al Young

THROUGH: Bob Rabin

SUBJECT: Subpanel Chair for Evaluation of Agent Orange Exposure

Beginning in early September 1985, the Centers for Disease Control (CDC) began to express frustration with their methodology to identify veterans (ground troops) likely to have been exposed to Agent Orange during combat operations in Vietnam, 1967-1969. CDC had been tasked in 1983 by Congress with the conduct of an epidemiologic study of ground troops exposed to Agent Orange. The failure to identify an exposed cohort of at least 6000 men will mean that the Congressionally-mandated study cannot be conducted.

Before such a conclusion is adopted by the Agent Orange Working Group (AOWG), the Department of Health and Human Services (HHS) and the Domestic Policy Council (the reporting body for the AOWG); the Acting Assistant Secretary for Health (Dr. Ian Macdonald) has asked me to chair a subpanel of the AOWG to evaluate available military records and the problems associated with determination of exposure to Agent Orange. I have tentatively identified members for the subpanel and have been assured of full cooperation from all of the participating agencies. If the task is undertaken, a report is to be ready for the Assistant Secretary by mid-May.

As you are aware, my extensive experience with Agent Orange and its use in Vietnam will permit me to input the best available science in resolving this issue. The proposed report will address only the issues of exposure assessment and the likelihood of identifying a sufficiently large number of individuals to conduct the epidemiologic study. The decision to not conduct the study must rest with CDC, HHS, and eventually the Domestic Policy Council in concert with the Congress.

It is requested that you approve my participation and chair responsibility to the AOWG Science Panel's "Subpanel for Determination of Agent Orange Exposure."

J P McT Approve _____ Disapprove

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

February 28, 1986

MEMORANDUM TO: Domestic Policy Council
Agent Orange Working Group
Members and Staff

FROM : Dixon Arnett, Acting Chair
Agent Orange Working Group

SUBJECT : Agent Orange CDC Study

The following is a statement for the record of the agreements reached by the Agent Orange Working Group of the Domestic Policy Council.

During recent months it has become apparent that it may not be possible to identify large numbers of Vietnam veterans who were clearly exposed to Agent Orange from existing military records. The Science Panel reported that only a small proportion of U.S. Army Combat veterans could be documented to have ever been very close to fixed-wing aerial applications of Agent Orange. This assessment was based on incomplete information, and the Science Panel recommended that additional pilot data should be generated and compared to exposure criteria in order to determine whether an Agent Orange Study of Combat Veterans can be expected to produce scientifically valid results. Meanwhile, the investigators at CDC have postponed interviewing study subjects for the Agent Orange Study pending approval of study design changes made necessary by this and other exposure assessment issues.

At its January 29, 1986 meeting, the Agent Orange Working Group reviewed the status of cohort selection for the Agent Orange Study being conducted by CDC, and accepted the report and recommendations from the Science Panel. As Acting Chair of the Working Group, I have directed the Science Panel to examine the additional pilot data which is being developed by the U.S. Army

and Joint Services Environmental Support Group, and to evaluate the feasibility of a scientifically valid study of the possible long-term health effects which may have been caused by exposure to Agent Orange among combat veterans who served in Vietnam. For this purpose, I proposed that a sub-panel, which could include appropriate scientists not already on the Science Panel, should be assembled to review pertinent information on exposure assessment and prepare a report of their evaluation to the Agent Orange Working Group before its next scheduled meeting.

cc: Dr. Ralph Bledsoe
Executive Office of
the President

Dr. William Roper
The White House

Dr Jerry Bricker 423-4821 Local

2/26/86 Don Barnes

XO - ~~ESG~~ ~~IAG~~ ~~DFAG~~ READING FILE

SUMMARY OF THE AO SCIENCE PANEL SUBCOMMITTEE
ON EXPOSURE ASSESSMENT

Present:
Dick Christian
Jerry Bricker
Carl Keller,
Aaron Blair, NCI
Don Barnes
Dana Flanders, CDC
Marilyn Fingerhut
Barclay Shepherd
General Murray, consultant on military records

1. Keller read a draft of the subcommittee's charge: to provide an assessment of the exposure issues associated with the ground troops study. The Undersecretary will make the call on whether or not to go forward.

2. A variety of issues were discussed and/or identified as important:
   a. The extent of ground troop exposures as a consequence of Ranch Hand operations vs. perimeter spraying; and both of these vs. the exposure experienced by Ranch Handers themselves.
   b. The quality of the military records and what they could -- and could not -- do for us.
   c. The fate and transport of phenoxy herbicides and their contaminants.
   d. How much AO it would take to cause manifest toxicity in humans.
   e. The expected, worst-case, and/or documentable exposure to AO in Vietnam; including issues such as bioavailability.
   f. The dispersion of ground troops around a reported company location.
   g. Criteria for exposure used in other epidemiological studies which might serve as guidance for us in this study.

3. Item a: A general consensus, although undocumented at this time, was that perimeter spray operations (and operators) might lead to greater exposures to some troops than would the overhead Ranch Hand spray operations.
   There was concern that Ranch Handers might be better stratified by likelihood of exposure, rather than military rank.

4. Item b: General Murray testified to the high quality of the records and the folks who are reviewing the records. He provided a good, having-been-on-the-scence perspective.

5. Item c: Barnes will gather information on the envrionmental halflife of 2,4,5-T and 2,4-D.

6. Item d: Barnes will gather toxicological information and regulatory information on the levels of 2,4,5-T, 2,4-D, and 2,3,7,8-TCDD which might be of concern.

7. Item e: Bricker distributed a draft paper which addresses this issue, although bioavailability may not have been directly addressed. Some felt that if the levels resulting from such an analysis were lower than the levels of toxicological or regulatory concern, then there would relatively little concern. Others felt that the concern was already present (e.g., an Act of Congress) and that that constituted a prima facia need to proceed in any case.
   We should come prepared to discuss Bricker's paper at the next meeting.

8. Item f: It was suggested Christian's folks use their data and expertise to examine the question of how dispersed the troops within a company might be.
   Further, it was suggested that by making some estimates of the dispersion of the troops and coupling that with the time-distance criteria for exposure opportunity, a statistician or Monte Carlo highroller should be able to generate some estimate of the probability of misclassification. Apparently, we already have in hand an analysis of the effect of misclassification on the proposed study. Comparing these two results should give guidance on the likelihood of the ground troops study resolving the health issue.

9. Item g: Fingerhut reported that there was little in the way of useful guidance in the published literature.

10. The group expressed interest in the existence of a population of 800 back pack sprayers. Perhaps these would be a good cohort. Using US studies in which exposure doses were determined for such workers, we could get some quantitative estimate of exposure.

11. Given the limitations of the exposure opportunity index approach, there is a need to validate the index by some means. The possibility of adipose tissue analyses looks reasonably promising at this point. There would be problems in interpreting such results, but if everything worked out in the right direction, we might gain added confidence in our approach.
    Also, we could explore the possibility of checking veteran recalls of exposures (obtained in the Birth Defects Study and the Vietnam Experience Study) against the Exposure Opportunity Index determination from the military records. Again, this would certainly not be definitive, but it could possibly provide some comforting insights.

12. As a status report, Christian informed the group that he is completing record examinations for 7 battalions (30 companies). This pilot study should be completed on schedule by the end of April. There was concern expressed about development and "approval" of a CDC study protocol which did not have the benefit of the pilot study results. The lines, kinds, and levels of communication within and outside HHS regarding this study are beyond the kin of this observer.

13. The next meeting will be held on March 10 at 9:30 in Christian's office. By that time, the various assignments should have been completed, principally General Murray's examination of the perimeter spray records.

3/10/86 Don Barnes

SUMMARY OF THE AO SCIENCE PANEL SUBCOMMITTEE
ON EXPOSURE ASSESSMENT
Meeting No. 2

Present:
Dick Christian
Jerry Bricker
Aaron Blair
Don Barnes
Dana Flanders
Marilyn Fingerhut
Barclay Shepard
Al Young
MG John Murray

1. Murray and Christian gave the group an update on their assignments from the previous meeting.
   a. The 23 chemical units have been identified as well as the personnel within those units.
   b. Efforts are underway to collect cohorts of folks who were involved in backpack and/or helicopter spraying.
   c. Within the next couple of weeks, we should have data on the "chemical handlers" within the Ranch Hand cohort, so that stratification might possibly be made on some measure of likelihood of exposure, in addition to officers vs. enlisted men.
   d. A summary of the status of the pilot study was distributed (attached).
   e. It appears that it will be possible to obtain information on the dispersion of elements within a company. See next item.

2. In another of his patented prestidigitations of military records, Christian graphically displayed dispersion of company elements in three arbitrarily chosen units (one infantry, one artillery, and one air cavalry) on six arbitrarily selected dates.

   The differences were dramatic. The artillery and the cavalry tended to be more dispersed than the infantry, in some cases over 10s of kilometers. Even the infantry elements often spanned 6-10 kilometers. Some of the distant elements within a unit may have consisted of only a few individuals. In no case would it be possible to assign names of individuals to the dispersed elements. Therefore, the possibility of misclassification appeared to be great.

   Some folks pointed out that there were times when even the most dispersed units (e.g., artillery) were concentrated (e.g., at a base camp, like Bearcat). One approach might be to include only those situations (days) during which the entire unit (i.e., all elements) were together. That is, consider only the "one pinners".

Others pointed out that we could use more situations (days) in which a rational judgment could be made that an outlying element was likely to be small relative to the main body of the unit; e.g., a reasonable assumption might be that a small element had been sent out on ambush detail. In such a case, either the small element could be ignored, or, alternatively, the probability of exposure for the main unit could be reduced. For example, if 7 men of a 150 man unit were out on ambush duty, then the exposure probability index of the main body could be multiplied by 143/150 for that one day.

In summary, it is important to note that under current practice if <u>any</u> element of the unit met the criteria for a "hit" then <u>every</u> member of the unit would be accorded a "hit". Coupled with the fact that there is no obvious way to link individual names to individual elements of the unit, the opportunity for misclassification under this current practice is great if the dispersion is great -- as it often appears to be.

3. Christian's group is <u>planning to develop this dispersion information for each of the units within the pilot study</u>. These elements locations will then be matched against the Service Herbs Tapes in order to assess likelihood of exposure.

Note that the Service Herbs Tapes include perimeter sprays, as well as Ranch Hand sprays. In fact, the Tapes may contain in excess of 2500 missions.

We will also be getting information on the locations of fire support bases, landing zones, main base camps/posts, and a master list of the perimeter sprays.

4. There was a <u>growing feeling within the group that the likelihood of significant exposure was less via direct Ranch Hand sprayings than it was via perimeter spraying</u>; either directly to the applicators (buffalo sprayers compared to RH pilots) or inadverently to unintended humans (e.g., base camp sunbathers compared to combat infantryman).

This sense was predicated on a number of considerations:

a. The "cleanliness" of the spray operation; buffalo sprayers were graphically more exposed than RH pilots.
b. The application rates; purportedly higher for perimeter spraying.
c. The proximity to the spray; perimeter spraying seemed to be an unheralded event, while RH missions were often announced so that troops could move clear of anti-personnel ordinance that was laid down to suppress ground fire.
d. The attire during an encounter; potential sunbather inside the perimeter vs. full battle gear near the RH spray.
e. Frequency and duration of exposure; every 5 weeks and a static location at the bases vs. a few times per year and movement into and out of RH sprayed areas.

f. The likelihood of spray drift toward the troops; circumnavigating the perimeter essentially guaranteed drift onto the population of concern vs. problematic drift in the case of the ground troops.

5. Since most of the base camps experienced perimeter spray, there was concern that it might not be possible to identify a "comparably stressed" (read "active combat") population with which to compare the AO exposed folks in AO-sprayed base camps. It may be possible to find such a "control" group in I Corps. The subcommittee was long on exhortations related to this effort. That is, if we don't have a control group, we may not have a study; or, more correctly, we may have already done the study as a part of the Vietnam experience study.

6. The group chatted about worst case vs. realistic cases of exposure from Ranch Hand spraying, comparing their notes, calculations, and assumptions. These two cases seemed to differ by as much as 1000X.

7. The following tox data were discussed:
   a. ADI (acceptable daily intake -- roughly, an estimate of an amount which could be consumed daily for a lifetime without adverse effects) for 2,3,7,8-TCDD = 1-10 pg/kg-d
   b. 2,4,5-T = 3 mg/kg-d
   c. 2,4-D = 1-12 mg/kg-d

8. There is some suggestion of a correlation between the results of the exposure opportunity index and the self recall of "skin contact with spray material" and of "observation of spraying operations".

9. Reference was made to a $1M oversight study being conducted by the NAS on the CDC effort.

10. The "gut issues" for this subcommittee seem to be
   a. Is the possibility of misclassification in this study so great that utility of the study should be questioned? Stated with a slightly different twist, what is the best way to approach the exposure issue so as to lead to the most useful study?
   b. Is the magnitude of any possible exposure so low that the utility of the study should be questioned?

   At a more specific level, the questions might be
   a. Can we clearly and cleanly identify field-exposed people?
      i. Compare the spray track with the dispersed unit information. (This will be done for the next meeting.)
      ii. Estimate levels of exposure
   b. Can we clearly and cleanly identify base-exposed people?
      i. Look at the perimeter spray information vis a vis based units
      ii. Estimate levels of exposure
   c. Compare the number of field vs. base encounters. One type

may clearly outweigh the other.

11. Earlier attempts to identify "hits" may not have adequately taken base camp and/or fire base camp information into account. Contextual reading of the records could lead to marked increases in the number of "hits".

12. The subcommittee will be notified of the next meeting once Christian's folks have completed their work; estimated 3-4 weeks.

DEPARTMENT OF THE ARMY
US ARMY & JOINT SERVICES ENVIRONMENTAL SUPPORT GROUP
1730 K STREET N.W. ROOM 210
WASHINGTON, DC 20006

REPLY TO
ATTENTION TO

10 MARCH 86

AGENT ORANGE PILOT STUDY - UPDATE

STATUS REPORT

BATTALION STATUS

BATTALION 2	GAPS FILLED - SENT TO BE KEYPUNCHED
BATTALION 6	GAPS FILLED - SENT TO BE KEYPUNCHED
BATTALION 10	GAPS FILLED - INITIAL KEYPUNCH COMPLETE INITIAL QC BEING PERFORMED BY ESG PERSONNEL
BATTALION 20	GAPS FILLED - SENT TO BE KEYPUNCHED
BATTALION 22	GAPS FILLED - SENT TO BE KEYPUNCHED
BATTALION 43	GAPS FILLED - INITIAL KEYPUNCH COMPLETE INITIAL QC BEING PERFORMED BY ESG PERSONNEL
BATTALION 50	GAPS FILLED - INITIAL KEYPUNCH COMPLETE INITIAL QC BY ESG PERSONNEL COMPLETE - SENT BACK TO JDSSW FOR CONSOLIDATION OF PRINTOUTS FOR FINAL QC BY ESG PERSONNEL

ARPERCEN MORNING REPORT NAME ABSTRACTIONS STATUS

BATTALION 20	NAMES BEING TAKEN FROM MORNING REPORTS
BATTALION 43	NAMES BEING TAKEN FROM MORNING REPORTS
BATTALION 50	NAMES BEING TAKEN FROM MORNING REPORTS

MORNING REPORTS ON ORDER

BATTALION 2	1966
BATTALION 6	COMPLETE IN HOUSE
BATTALION 10	1966
BATTALION 20	1969
BATTALION 22	COMPLETE IN HOUSE
BATTALION 43	COMPLETE IN HOUSE
BATTALION 50	1967, 1969

PERSONNEL QUALIFICATION STATUS

BATTALION #	PERS QUALIFIED PRIOR TO PILOT	PERS QUALIFIED SINCE PILOT BEGAN	PERS IDENTIFIED FOR QUALIFICATION
2	879	11	590
6	596	206	0
10	697	86	0
20	17	0	0
22	319	27	1514
43	37	0	0
50	2	0	0
TOTAL	2547	330	2104

THE PERSONNEL RECORDS IN COLUMN 3 (PERS IDENTIFIED FOR QUALIFICATION) WILL BE FORWARDED FROM CDC TO ESG. THE RECORDS WILL THEN BE PULLED AT NARA AND SENT TO ESG FOR QUALIFICATION OR DISQUALIFICATION.

Maxie M. Tenberg

MAXIE M. TENBERG
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