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Item ID Number	05714 ☐ **Not Scanned**
Author	
Corporate Author	
Report/Article Title	Draft Minutes of the Meeting on August 6, 1987, Science Panel of the Agent Orange Working Group (AOWG) and Minutes of the Meeting on August 6, 1987, Science Panel of the Agent Orange Working Group (AOWG)
Journal/Book Title	
Year	1987
Month/Day	
Color	☐
Number of Images	8
Description Notes	

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MINUTES OF THE MEETING ON AUGUST 6, 1987
SCIENCE PANEL OF THE AGENT ORANGE WORKING GROUP

The Science Panel (SP) met from 1:00 pm until 3:50 pm in Room 729G of the Humphrey Building in Washington, D.C. Dr. Ronald W. Hart, Director of the National Center for Toxicological Research and Chairman of the AOWG SP, presided. Members and guests present at the meeting are listed on the attached sign-in sheet (#1). An agenda was distributed and is attached (#2).

Dr. Hart introduced Dr. Anabel Smith, the Acting Deputy Under Secretary, to the SP members and asked each member to introduce themselves.

STATUS REPORT ON VA STUDY AND VVA: Dr. Hart conveyed to the SP that the Vietnam Veterans of America (VVA) had obtained a Discovery Order through the courts for all information pertaining to the VA's submission to JAMA which includes the original manuscript, the journal reviews of the manuscript, the VA's rebuttal to the reviewers' comments, and anything else that could be considered as linked to that study. Dr. Han Kang, VA, said that the reviewers' main objection was that the VA study did not use the general population as the comparison group; however, Dr. Kang indicated that he did not agree with that criticism. Dr. Kang also indicated that a cover memo from Fred Conway of the VA was being transmitted to the VVA along with the subpoenaed documents indicating that the release of any of this material by the VVA would be premature and that the AOWG SP is reviewing the material. Dr. Hart commented that the SP review of the study should strengthen the science and make the study more defensible.

PEER REVIEW OF ALL STUDIES: Prior to the SP meeting, Mr. Don Newman, Chairman of the Domestic Policy Council AOWG, asked of Dr. Hart, "What was the peer review policy of the Science Panel?". Dr. Hart asked if the SP needed to establish a system for peer review and invited discussion. Pandora's box was opened! Dr. Vernon Houk, CDC, stated that a gentlemen's agreement existed for a 48-hour notification to be given to the SP members prior to the public release of Agency studies. Dr. Houk emphasized that he had never brought anything before the SP that had not been leaked publicly. He also stated that the CDC had a system of peer review that included an internal review, a review by the National Academy of Sciences, and the journal review. Dr. Houk also indicated that the SP might not be the best or most appropriate group to conduct the peer review, depending upon the particular study. Colonel George Stebbing, DOD, indicated that they have principal investigators that are very hesitant to present preliminary data before the SP for the same reasons as indicated by Dr. Houk. Dr. Don Barnes, EPA, stated that they are conducting a survey within the EPA to determine how the different offices are conducting their own peer reviews prior to trying to make any Agency-wide policy; he indicated that the SP might wish to follow the same procedure. Dr. Carl Keller, NIEHS, felt that the SP might not be the most appropriate body to conduct peer reviews; he felt that the SP was meant to be advisors to the AOWG, but could accept requests for review of studies from within the SP. Colonel William Wolfe, USAF, said that in addition to internal review, Dr. Miller's AOWG Advisory

Committee reviewed the Ranch Hand reports; it was an effective review system but it took a long time (about 3-4 months). Dr. Marilyn Fingerhut, NIOSH, stated that OMB had requested that the SP review their Dioxin Morbidity Study. Dr. Keller stated that initially the SP was set up to review the protocols and another group was to be set up to review the finished reports; however, this latter group did not get set up except for Dr. Miller's Advisory Committee. Dr. Peter Beach, DHHS, indicated that Dr. Miller's Advisory Committee could review whatever the SP or the AOWG Chair wished it to review. Dr. Houk said that when he was SP Chairman, the SP would not do final report reviews. Dr. Han Kang, VA, was concerned whether the SP had the time to review all of the reports that were being generated. Both Dr. Barnes and Dr. Jeff Lybarger, ATSDR, indicated that the SP review of reports was acceptable to them.

Dr. Hart observed that the opinions were varied and he would report the same to Mr. Newman. He summarized the discussion into four points:

1) Dr. Barnes's suggestion that we check with the various Agencies and see what is currently being done;
2) Dr. Houk's 48-hour prior notification gentlemen's agreement; Dr. Hart's thought that seven days would be better so that comments could be conveyed back to the PI before the release of the report;
4) Dr. Fingerhut's comment that select members of the SP could form a review panel based on specific expertise; and
5) Dr. Kang's concern that the SP does not have time to review everything.

Dr. Houk commented that the SP needs to keep separate the policy and science issues; if the SP gets too political, it could delay the release of scientific information. Dr. Hart commented that the SP should be limited to science and leave the policy statements to the AOWG. Ms. Hellen Gelband, OTA, stated that the SP does what other groups can not or will not do. Dr. Keller commented that the SP has been asked to provide specific reviews in the past, but the review is often done by a subcommittee of the SP with help from outside experts.

INTERNATIONAL CONFERENCE ON DIOXIN: Dr. Barnes indicated that this meeting would be held October 5-9, 1987 in Las Vegas. There is a good chance that there will not be a NATO meeting as part of this conference. NATO is currently preparing a Dioxin report for a Spring release. The NATO document is being prepared by Dr. David McNelis, University of Las Vegas, and he is sharing the information with Dr. Hart and Dr. John Young (NCTR) for comparison with the SP Status Report. Dr. Hart is planning on attending part of the meeting, but he requested that Dr. Barnes report back to the SP concerning the Dioxin Conference and keep the SP informed concerning the NATO activities. In Dr. Hart's absence from the Dioxin Conference, Dr. Barnes was asked to be the official representative of the SP. Dr. Barnes agreed to do as requested. Dr. Hart suggested that the VA not present the data from their JAMA article at the Dioxin Conference due to the present problems; Dr. Kang agreed. Dr. Fingerhut, Colonel Wolfe and his staff, and some of the CDC staff will attend the Las Vegas meeting.

STATUS REPORT (LIVING DOCUMENT): The Living Document is the computer based access to the AO Status Report. The computer access will be available at the same time as the written report is released. There will be update capabilities within this computer based system. However, Dr. Hart

indicated that there still are discrepancies within the existing Status Report that need to be addressed. The timeliness of this document is also of concern. Dr. Hart asked each of the SP members to do their part and look over the document one more time so that the Status Report can be as complete and accurate as possible.

VALIDATION STUDY: Dr. Houk turned over the presentation of the results to his staff, Drs. Robert Worth, Donald Patterson, Jim Pirkle, and John Karon. Dr. Worth has overall project responsibility. Dr. Patterson presented the analytical methods and detailed the controls, blind sampling procedures, and sensitivity of the procedure (3 ppq from 100 ml serum). Dr. Pirkle presented the half-life data and Dr. Karon updated the information from the Validation Study. Dr. Houk complimented his staff for their excellent work. All of the documentation provided by CDC to the SP members in advance are part of these minutes.

Dr. Fingerhut stated that the body burden data is really the bottom line for this study. Dr. Keller complimented the CDC staff on a good report. Dr. Kang asked if these results were expected. Dr. Worth indicated that he had not expected these results since they had anticipated that they would have a hard time in finding any Vietnam veteran with low TCDD serum levels, but the results indicated that very few Vietnam veterans had anything but low levels. However, Colonel Wolfe indicated that he had felt that the Ranch Handers would have the highest levels, which has turned out to be the case. Dr. Kang asked if the Ranch Handers had been put in exposure categories; Colonel Wolfe indicated that they had not been yet as many still needed to have blood drawn for analysis. Dr. Barnes commented on the low background level of these Vietnam veteran (about 4 ppt) in comparison to the Missouri study (5-20 ppt); differences such as sex and physical health may be part of the reasons. Ms Gelband asked if the 13 Ranch Handers who had the very high levels were being reassesed; there was an indication that they would be. Dr. Barnes brought up the New Jersey study where four persons had high serum levels; a comment was made that three of the four were Ranch Handers.

Dr. Houk said that the conclusion from this study was that it was not possible to do the AO Exposure Study since a cohort study of exposed vs non-exposed ground troops can not be set up; not enough exposed troops can be found. Therefore, based on all of the data taken in total, it must be concluded that the Exposure Study must be canceled. Dr. Fingerhut asked if one could exclude workers such as chemical core or combat engineers and then obtain cohorts. Dr. Houk indicated that the few potentially high exposure individuals might be identified; however, he pointed out that their were nearly 3 million troops in Vietnam that would need to be screened. At the present rate of 35-36 unknown samples per week, it would take an extremely long time with this level of effort which includes over $4 M in equipment, $0.5 M per year in maintenance costs, and 16 dedicated persons. This does not seem to be a feasible approach. The assessment of the health effects due to potential exposure to Agent Orange of the Vietnam veteran lies with the Ranch Hand study; the assessment of the health effects of the civilian population lies with the NIOSH Dioxin Morbidity Study.

RECOMMENDATION: It is the unanimous recommendation of the AOWG SP that the Agent Orange Exposure Study, the cohort epidemiological study of Vietnam

veteran ground troops exposed to Agent Orange, cannot be scientifically conducted and therefore should be canceled.

Dr. Houk inquired as to whether it would be appropriate to send a copy of the CDC results to the appropriate House and Senate committees. Dr. Beach felt that it would be appropriate and to coordinate the delivery to coincide with Ms. Gelband's distribution to her OTA review committee. Dr. Hart agreed with this distribution plan.

OLD/NEW BUSINESS: Colonel Stebbing said that his office had been requested to help with a movie based on Admiral Zumwalt's book, "My Father, My Son". MGM wants to use Navy ships as backdrops for the movie; the script is just a tad biased and blames the government. Colonel Stebbing said that the script was written by Jacqueline Feathertone and David Seidler. Dr. Hart indicated that the SP, or even the full AOWG, may not be the right forum to decide this question; this is a DOD call, especially after hearing Colonel Stebbing's comments about the script. Perhaps the public affairs office at the White House should be informed of the request. Dr. Houk suggested that perhaps the SP's services might be offered to review the script and comment on the technical accuracy. Dr. Lybarger stated that this is one man's story with its accuracies and inaccuracies; what would be our impact? Since the movie is not a documentary and our impact would probably be nill, it will be best to stay away from any endorsement in any form. Dr. Keller stated that perhaps it would be dangerous for the SP to even assess the validity of the script as it would mean a heavy involvement and indirect endorsement and our own credibility would be tested. Dr. Fingerhut wondered if we became involved would not the emphasis be on the government "endorsement" rather than the movie itself. Dr. Hart summarized the SP concerns into four issues: (1) if the SP became involved, we might be inflaming an already sensitive issue based on a less than complete data base; (2) this movie is not a SP issue, but one for the DOD; (3) it would be a courtesy to notify the Public Affairs at the White House; and (4) if MGM is interested in the current state-of-the-art scientific data base, the SP could supply them with the information.

Dr. Fingerhut stated that Phase II of the NIOSH Dioxin Morbidity Study had been approved by OMB and the staff has begun its training. The examinations of the participants will begin next month. From the analytical results of serum from 14 persons from Phase I, the mean value from the six controls was 9.5 ppt (range of 4.7 to 17.1 ppt) and from the eight workers was 254.5 ppt (range from 10 to 717 ppt). The three low values (10, 28, and 33 ppt) from the worker group were from chemists who worked less than two months in the plants.

Dr. Hart thanked everyone for their participation and apologized for the length of the meeting. The meeting was adjourned at 3:50 pm.

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Executive Secretary
AOWG Science Panel

Approved by Ronald W. Hart, Ph.D. _____
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STATUS REPORT ON VA STUDY AND VVA: Dr. Hart conveyed to the SP that the VA was requested to provide to the Vietnam Veterans of America (VVA) all published and unpublished documents concerning herbicide or dioxin in the possession of the VA under the Discovery Request and this may include all information pertaining to the VA's submission to JAMA which includes the original manuscript, the journal reviews of the manuscript, the VA's rebuttal to the reviewers' comments, and anything else that could be considered as linked to that study. Dr. Han Kang, VA, said that the reviewers' main objection was that the VA study did not use the general population as the comparison group; however, Dr. Kang indicated that he did not agree with that criticism. Dr. Kang indicated that the VA maintained the position that the document linked to the mortality study might be subject to a claim of priviledge and therefore beyond the scope of the Discovery Request while the documents were being peer-reviewed, including the AOWG SP review. Dr. Hart commented that the SP review of the study should strengthen the science and make the study more defensible.

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