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STATEMENT OF THE
NATIONAL VETERANS LAW CENTER

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

OF THE

VETERANS AFFAIRS COMMITTEE
HOUSE OF REPRESENTATIVES

Submitted by:

Lewis M. Milford
Ronald Simon

April 14, 1981

STATEMENT OF THE
NATIONAL VETERANS LAW CENTER

Submitted by:

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Ronald Simon

Mr. Chairman and members of the Subcommittee:

My name is Lewis Milford; at the witness table with me is Ronald Simon. We are lawyers with the National Veterans Law Center (NVLC) in Washington, D.C. The Law Center is a public interest law firm affiliated with The American University School of Law, specializing in the legal problems of veterans. The Law Center is General Counsel to the National Veterans Task Force on Agent Orange, a national coalition of veterans organizations concerned with the Agent Orange issue, and counsel to thousands of Vietnam-era and other veterans in numerous federal class action lawsuits and federal administrative hearings. We are testifying today on behalf of the National Veterans Task Force on Agent Orange. Our testimony will address the health studies and other government efforts related to the Agent Orange controversy.

Veterans Administration Epidemiology Study

The first issue we address is the epidemiology study ordered by P.L. 96-151. Because work to design the protocol has not begun, our comments are necessarily limited. As

everyone knows, a key point in the success and validity of the study will be to determine whether and to what extent veterans were exposed to Agent Orange. Last summer, reports were circulated by the Defense Department and the Inter-Agency Work Group on Phenoxy Herbicides that determining exposure was nearly impossible. We criticized this conclusion as being premature and not based on sufficient efforts to develop adequate exposure data.[1/] We argued then that a conclusion that exposure could not be determined was not acceptable until much more work had been done and all reasonable alternatives presented by the most knowledgeable and thoughtful people had been explored and rejected. After our comments, both the Inter-Agency Work Group (IWG) and the Defense Department embarked on renewed efforts to find exposed populations of veterans. The expertise of the General Accounting Office, which prepared a report on exposure, was also sought by the IWG.

We commend these renewed efforts and await their results. Our concern continues both because the results are unknown and the process has not allowed input sufficient to guarantee that the best efforts to determine exposure are

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1/ See, Agent Orange: Exposure of Vietnam Veterans, Hearings Before the Subcommittee of Oversight and Investigations of the Committee on Interstate and Foreign Commerce, 96th Cong., 2d Sess. 161-175 (Sept. 25, 1980)(statement of National Veterans Law Center).

made. Only one public meeting of IWG has been held and that covered a whole panoply of topics. The process by which DOD is determining what kind of data is available and how it is to be analyzed is still not open to public scrutiny. We stress these agency efforts because the contractor to whom the VA awards the contract to design the mandated study will necessarily be affected, if not bound, by these determinations. This will probably occur because the contract does not contemplate funding for an independent review of exposure data. Thus, the success of the whole study effort depends on work for which the conclusions are still unknown and the process is closed to the public.

We propose that DOD immediately bring together a committee of outstanding scientists from outside the government to review the exposure data. That group should determine whether it is possible to measure exposure data and what standards are appropriate to conduct a meaningful study based on these data. Any conclusion that exposure cannot be measured or that available measurements are not reliable will be unacceptable to the veterans community if veterans are denied an independent review of this process and the data on which conclusions are based. Veterans must be assured that all possible avenues have been explored. Any limitations or difficulties at this stage of the study would necessarily taint any results and further undermine the government's efforts.

Another point about the study is the question about whether it should be expanded beyond a focus merely on Agent Orange. There is much that commends this idea. Yet, a number of doubts remain. The first is that a broader study that looks at all veterans in Vietnam may be epidemiologically suspect and is said by some experts to have an inherent bias toward missing the particular problems that Vietnam veterans complain about. The second problem is that the expansion will serve as an excuse for DOD to avoid the difficult question of attempting to determine usable levels of Agent Orange exposure. As a result, there is a fear that the study will simply ignore health problems that may be caused by Agent Orange. All agree that this must not happen. No level of scientific difficulty should justify an abandonment of the Agent Orange question. This remains the fear of veterans, a fear which has not been removed by the government's actions thus far.

The only way to guarantee that this abandonment does not occur is to insure that veterans participate fully in the study's design and implementation. This question of input and oversight of the study by interested veterans is absolutely essential. As members of this committee are aware, the Task Force filed litigation in the U.S. District Court and a bid protest at the General Accounting Office (GAO) to challenge the way in which the VA was proceeding to choose a contractor. While neither body granted relief

to the Task Force, they did not disagree with many of the points of the challenge. In fact, many of the key points of the challenge were accepted, but the Court and GAO refused relief for other reasons.

Various people have charged the Task Force with delaying, impeding or even attempting to prevent the study. Nothing could be further from the truth. The Task Force wants the study to done -- most importantly that a valid study be done. The Task Force has taken the position and still believes that the VA's lack of credibility and expertise makes it the wrong agency to conduct the study. The Task Force did seek a temporary delay in the courts in the hope that the legal action would create the environment in which the positive suggestions of the Task Force would be implemented. However, the court refused to grant the delay. It should be made clear, however, that the choice not to proceed with the study at that time was made solely by the VA. The agency could have proceeded immediately -- but it chose not to. The VA also could have accepted the various proposals for input and other suggestions offered by the Task Force for participation of veterans, but it chose not to accept those suggestions either. The VA could have discussed these issues with the Task Force and tried to work out their differences -- but it chose not to. The VA could have proceeded with the study either by making these accommodations or by refusing these suggestions and simply going ahead with the study.

No court order, GAO action or other legal barrier ever existed to prevent the VA from going forward with the study. All of these study options were open to the VA -- but it, and it alone, chose delay.

Fortunately, we can report some progress in this bleak scenario. Recent discussions with the VA indicate both that the study will go forward and that the VA will accept a committee of scientists to monitor the study on a continuing, on-going basis. This kind of outside review and public involvement can begin to provide the expertise and credibility that the study clearly needs. While the Task Force, along with American Legion and others, still maintains that the study must appropriately be done outside the VA's control, this newly accepted idea of input for veterans groups is a truly encouraging step forward. At the present time, there is still no determination of whether the study will be carried out by the VA. This question is important because the VA lacks the epidemiological expertise to make the difficult decisions that inevitably will come up during the study. These kinds of questions make the creation of a committee of scientists chosen by veterans all the more crucial. This type of continuing involvement of veterans is absolutely essential and the Task Force is quite encouraged that the VA has indicated its willingness to seek credible assistance with the study.

It is important to point out that the thrust of the Task Force's comments has been for increased input and information. Regrettably, these requests are often seen as severe criticism. More unfortunately, it is sometimes said that the demand for more input and participation by veterans implies that VA personnel are incompetent or worse. Some people even have suggested that the veterans are implying that people in the VA would intentionally reach negative results. Again, this inference is not true. The veterans we represent want continuing input because of their concerns for the underlying problems faced by veterans and their understanding of the great complexities of the issues involved. The desire of more veterans' participation is based on an understanding that the Agent Orange issue now raises many more questions than answers. Veterans understand that no one has all the answers -- they only want to participate in developing them.

VA Medical Treatment

The medical treatment received by veterans at VA hospitals is a key concern of the Task Force. This concern raises three separate issues. The first is the adequacy of the treatment veterans now receive. Given the complexity of this issue, it is no surprise that there is no medical protocol which has been developed and accepted by the medical community. On the other hand, the VA's medical expertise is not in the area of environmental and occupational

medicine and toxic substances. We are dealing with an area, therefore, where even the most informed scientists have not agreed on an acceptable medical protocol and where the agency responsible for medical care does not have the sophisticated expertise needed to do the work. In order to be sure that the VA treatment protocol meets the highest possible standards, we believe that the VA should immediately convene a panel of government and private sector medical experts to design the best possible medical protocol. The current protocol is hardly a protocol at all and leaves too much to the discretion of local "environmental physicians" who are in fact not specialists in the area.

A second problem is the implementation of the medical policy the VA has adopted. The VA, as well as the Veterans of Foreign Wars and American Legion, all have done some work to research this problem and the indications are that the delivery of services is highly irregular. A simple example can be seen in a recent VA decision to do some follow-up and inform veterans of the results of the medical tests that were taken concerning Agent Orange. In October, 1980, the VA took a survey of veterans to determine whether they were satisfied with the agency's Agent Orange medical examinations. The results were profoundly disturbing. Of the 55% of veterans who responded, a majority reported that VA physicians did not even discuss the results of the examination with them. And in 80% of the cases, the veteran never received the results of laboratory tests.

Based on these complaints, Chief Medical Director Custis ordered follow-up medical examinations (attached February 11, 1981, memorandum). But the directive appeared to fall far short of providing these veterans with appropriate medical care. Custis ordered only that veterans examined after January 5, 1981, be contacted. This presumably meant that thousands of other veterans who received inadequate care would not obtain laboratory results or have them explained by the agency. The Center complained about this decision (see attached February 23, 1981, letter). The VA in a subsequent letter stated that it was never its intention to exclude persons examined before January 5, 1981, from follow-up activities (see attached March 9, 1981, letter).

But the most recent exchange of correspondence appears to confirm our earlier suspicions about the inadequacy of the follow-up activities. In an April 3, 1981, letter (attached) Dr. Custis, although stating that all veterans would be contacted, suggested that in fact much less would be done. The VA Central Office evidently has left it to the discretion of local hospitals to decide whether to contact veterans examined before January 5, 1981. In a disturbing comment, Dr. Custis stated that veterans examined before that date need not be contacted soon because they are "more likely to have assumed, correctly, that the results of their examinations were negative unless they were informed to the contrary." We wonder if Dr. Custis, or members of

this Committee, would be satisfied with a doctor who did not report laboratory findings because the patient would probably assume nothing was wrong if nothing was said. It is just this kind of indifference to the fears and anxiety of Vietnam veterans that causes people to question whether the VA appreciates the basic human needs of veterans.

The precise nature of these activities should be clarified by this Committee. There is no excuse today, as there was none when the initial examinations were taken, for veterans to be kept in the dark about their health. The results of the VA survey are convincing evidence that veterans' complaints about VA medical care have been well founded. No longer should veterans who complain about the VA's Agent Orange medical program be treated with skepticism, derision, and be made to document each instance of indifference before they are believed. The VA has documented their complaints for them.

The final question about medical treatment is the satisfaction of veterans who go to the VA. Even the VA's informal research shows a very high level of dissatisfaction. Perhaps this is inevitable in light of the lack of scientific and medical knowledge and the VA's absolute policy against compensation. However, this problem cannot be solved by public relations. Better policy both in treatment and compensation has to be the first step to deal with veterans' legitimate health problems. And this improved policy should be formed only with the increased participation

of veterans. The VA's serious lack of credibility can be restored only through real, effective public participation.

VA Compensation Policy

On the issue of compensation, it is clearly time for the VA to finally take a step forward. A compensation policy has to be developed. Both the former head of IWG and its scientific panel agreed that a compensation policy should be developed now because additional science will not change the basic choices that have to be made.

The agency should recognize that there are complex scientific and public policy aspects to a compensation policy. And the agency should acknowledge, as has the IWG, that further science will not prove conclusive. To decide not to develop a policy now is itself a decision to avoid these hard issues.

Inter-Agency Work Group

The Inter-Agency Work Group has represented an important effort by government agencies to work together on the complex issues presented by Agent Orange. Its work has been productive and fruitful both for veterans and for the VA. In an area where there is high concern and even alarm, while clearly obvious and immediate solutions do not appear, it is important that this body and its process for sharing expertise continue. The Work Group has been a forum to discuss issues and to have individual agencies have their work

critically reviewed. It is exactly this process of input and review that must be continued.

We suggest that the Work Group's role in the Agent Orange matters be increased. The public health agencies in the Work Group have demonstrated a commitment and concern for the sensitivity of the policy issues and the complexity of the scientific issues faced by the government. We would like to see an earlier and more aggressive involvement of the Work Group in all herbicide-related studies conducted by the federal government, particularly the work of the VA and the Defense Department. And we would hope to see a similar invovement in all policy decisions on Agent Orange.

In the last year IWG had one public meeting, which was quite effective. The Task Force believes that all future meetings should be open to the public. Because of its membership and charter, the work of the Group often has the effect of making important policy and this process should not be shielded from public participation.

Ranch Hand Study

For the past year, little information about the Air Force epidemiology study has been made public. No hearings or reports have addressed the status of the study, the design of the protocol, or other important matters.

The only public information about the study is a recent announcement that an advisory committee will be chartered to provide assistance on the study. 46 Fed. Reg.

19602 (March 31, 1981). We were encouraged that the Department of Health and Human Services is the principal sponsor of the advisory committee. We hope that the members of such a committee will be drawn from a wide range of relevant disciplines and be representative of a broad spectrum of opinions. The Task Force believes that it is extremely important for veterans to play an active role in this process.

Center for Disease Control Study -
"Birth Defects and Military Service in Vietnam"

The Center for Disease Control (CDC) has begun an important epidemiological study concerning Vietnam veterans and birth defects. In the development of the study design, CDC has been extremely open and candid about both the limitations and purposes of the study. Given other agencies' record on public participation in Agent Orange matters, we are especially grateful for the Center's willingness to invite the participation of veterans and their advocates in the early stages of the study design.

The Task Force's most important concern is that veterans and the public understand exactly what the study can do and what it cannot do. Because of the increased anxiety and frustration among Vietnam veterans and their families over their reproductive health, the purposes and limitations of the study must be made clear before the study begins. There is no greater danger than reassuring persons with incomplete information. Moreover, any results of the

CDC study are likely not only to be controversial, but also may form the bases for important government decisions on compensation and health care.

With these concerns, the Center submitted to CDC comments on the draft protocol (see attached February 3, 1981, letter). Dr. J. David Erickson, D.D.S., Ph.D., responded with a detailed and extremely helpful reply (see attached March 3, 1981, letter). There are several points about the proposed study which are addressed in the correspondence that deserve this Committee's attention. First, it would be a mistake for veterans and the public to believe that the study will determine whether Agent Orange has caused any reproductive health problems among Vietnam veterans. CDC never has suggested that such specific results could be derived from this study and veterans should understand this basic limitation of the study. At best, the study is designed to assess whether service in Vietnam can be linked to certain serious birth defects among Vietnam veterans; the specific effects of Agent Orange exposure are not the subject of the study. Further, the study has several other inherent limitations that must be emphasized. The CDC Birth Defects study has limited power to determine whether exposure to military phenoxy herbicides has increased a number of reproductive risks that Vietnam servicemen may experience. Indeed, the study's primary

limitation, and one that would likely be acknowledged by CDC, is its scope.

The basic limitation concerns the health risks to be studied. Although evidence suggests that a spectrum of adverse pregnancy outcomes may be associated with dioxin toxicity, the study focuses only on "major structural" birth defects that appear in the first year of a child's life. That is, the study will not determine and is not designed to find out whether veterans suffer from other reproductive health problems not considered "major structural" birth defects. Therefore, the study will not address whether Vietnam veterans and their families suffer an increased incidence of other reproductive risks not covered by the study, such as infertility, spontaneous abortion, mental retardation and others. These other health problems may turn out to be the primary effects of herbicide exposure, a conclusion tentatively suggested by recent research on exposure of males to toxic substances. That the study will concern itself only with "major" malformations both limits the scope of the study and its usefulness for the Agent Orange controversy. Recent scientific evidence suggeststst that veterans may suffer the reproductive health risks left ignored by the study.[2/] Further, because of this

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[2/] We want to make clear that CDC readily acknowledges this limitation; we do not in any way mean to imply that CDC has been anything but candid about the study's purpose. However, we are concerned that certain government officials [footnote continued on page 16]

narrow purview, this study's inherent limitations make any "negative" results particularly equivocal. Certainly, any compensation decisions or further research efforts regarding birth defects should consider carefully these limitations.

a. Limited Scope of Study Misses Reproductive Risks That May Likely Be Elevated by Toxic Exposure of Men

The CDC study relies on data collected through the Metropolitan Atlanta Congenital Defects Surveillance Program, one of the best available U.S. birth defects registries. CDC traditionally uses the registry for population monitoring and to check on reports that drugs and consumer products are acting as teratogens when used by pregnant women.[3/] Yet available toxicologic evidence indicates that the registry data is less well suited to identifying toxic insults to male reproduction, since an increased birth defect rate is one of the least sensitive markers and least likely outcomes of male toxic exposures. Several investigators point out that infertility, sub-fertility, or spontaneous abortion are the most likely

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[footnote continued from page 15]
have suggested publicly that the study will answer questions about the specific reproductive health effects of Agent Orange exposure. Such statements ignore the government's own position on the study, and unfairly raise expectations of Vietnam veterans that the study cannot meet.

3/ Flynt, J.W., Environ. Health Perspect. 18:117-123, 1976.

adverse results expected when men are occupationally exposed to toxic chemicals, while stillbirths, birth defects, or childhood diseases are other plausible, though less likely outcomes.[4,5,6/] The few epidemiologic studies performed to date of men occupationally exposed to reproductive toxicants have by and large reported loss of libido, infertility, or spontaneous abortions to be the characteristic deleterious effects; this includes studies of men exposed to Kepone, DBCP (dibromochloropropane), chloroprene, vinyl chloride, lead, and ethylene dibromide.[7,8,9/] In contrast, reports of birth defects associated with male exposure have been less consistent in repeated studies.

4/ Manson, J.M. and R. Simons. Influence of Environmental Agents on Male Reproductive Failure, Ch. 6 in Work and the Health of Women, V. Hunt (ed.) Boca Raton, FL: CRC Press, 1979.

5/ Barr, M., C.A. Keller, W.J. Rogan, and J. Kline, Ann. NY Acad. Sci. 320: 458-472, 1979.

6/ Strobino, B.R., J. Kline, and Z. Stein. Early Human Development 1 (4): 371-399, 1978.

7/ Sullivan, F.M. and S.M. Barlow. Proc. R. Soc. Lond. (Biol) 205: 91-110, 1979.

8/ Wong, O. H.M.O. Utidjian, and V.S. Karten. J. Occup. Med. 21 (2): 98-102, 1979.

9/ Sanotskii, I.V. Environ. Health Perspect. 17: 35-43, 1976.

Commenting on a smaller CDC study of similar design that evaluated the birth defect risks posed by occupational exposures, Dr. Erickson and his co-authors observed:

> Use of these data from Atlanta should be regarded as nothing more than casting a net with a very coarse mesh. If we are lucky, we may catch some real associations, but most are likely to get away. The numbers involved are small, and the type of pregnancy outcome limited. Therefore this sort of exploration can do virtually nothing to help us in pronouncing an occupation or industry "safe" for reproducing humans. 10/

Much current scientific opinion holds that the type of visible expressions of genetic damage (e.g., birth defects) to a male population, which are the subject of this study, are probably not observable even on the seemingly large scale of the CDC study. In the case of ionizing radiation, an agent whose genetic risks have received extensive scientific attention, current estimates of genetic risks rely on extrapolation from animal experiments, since evidence of genetic damage in exposed human populations has not yet been produced. 11/

10/ Erickson, J.D., W.M. Cochran, and C.E. Anderson. Birth Defects and Parental Occupation: Preliminary Results from Metropolitan Atlanta, in Proceedings of a Workshop on Methodology for Assessing Reproductive Hazards in the Workplace, April, 1978. P.F. Infante and M.S. Legator (eds.) U.S. Dept. of Health and Human Services, National Institute for Occupational Safety and Health, Cincinnati, 1980.

11/ National Research Council, Committee on the Biological Effects of Ionizing Radiations. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. Washington, D.C.: National Academy of Sciences, 1980.

In sum, although an elevated incidence of structural birth defects may be one of the potential results of the veterans' exposures, experience warns us that it is probably one of the least observable effects. This problem points up the basic issue with Agent Orange scientific research - its intended use in compensation and health care decisions. The government has still not explained how much, and what type of, data will be needed for policy decisions. And until it does, any truly informed debate on the application of the research results is impossible.

b. Pregnancy Histories Obtained During Interviews Should Be Explored

Although the study focuses on structural defects, it will also ascertain family histories of spontaneous abortion, childhood "problems" and cancers. These outcomes should be examined to identify any suspicious associations with Vietnam service. Such exploratory analysis could provide clues that would stimulate further, more refined investigations.

c. Inherent Limitations Of Epidemiologic Methods

The imprecision and bias that plague all epidemiologic studies affect this one as well. In particular (i) the lack of firm herbicide exposure criteria, and (ii) the possibility of systematic respondent bias, will temper any negative results.

With regard to exposure data, CDC should conduct an independent investigation of DOD exposure records. Stratification of the veterans into herbicide exposure categories would be enhanced by CDC's direct review of the available troop movement and herbicide spray records. Since development of exposure indices from rough, incomplete historical data is a standard epidemiologic problem, it is advisable that CDC independently review these service records to ensure development of the best feasible exposure index that the records support. CDC's involvement in the dabate over the appropriate standard of exposure for these studies might prove helpful. Our earlier suggestion about an independent panel to review DOD exposure data would be important in this effort.

One source of systematic bias that would tend to hide any actual association is the probable low response rate from out-of-wedlock fathers. The proportion of out-of-wedlock births is several times higher among the black population than the white population, and blacks were also more likely to have served in Vietnam and seen combat there.

d. A Single Epidemiologic Study is Rarely Convincing - More Studies of Veterans' Reproductive Experience Are Needed

In the few instances in which a single epidemiologic study has provided convincing evidence that an exposure heightened disease risk, e.g., maternal rubella with cataracts and deafness, thalidomide with limb reduction deformities,

or in-utero exposure to DES with vaginal cancer, the agent caused a striking, singular defect, uncommon in the unexposed population.[12/] There is no biologic evidence to suggest that a toxic exposure to males will cause a singular birth defect or defect syndrome. In situations such as this, observations must be repeated in different populations, using different methods before conclusions can be drawn. The CDC study will be most interpretable if it can be evaluated alongside several other studies using alternative designs.

e. Public Review of Underlying Data

To insure the credibility of the study's results, the study's underlying data should be made available to independent researchers for analysis, immediately following CDC's publication of its results.

f. Use of Study Results

That the study will at most determine any health problems associated with Vietnam service only, not Agent Orange, raises an important question about the use of these scientific results. We understand that some scientific studies such as the CDC effort have been prompted in part by the Veterans Administration service connection scheme for

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12/ MacMahon, B. Strengths and Limitations of Epidemiology, in The National Research Council in 1979: Current Issues and Studies. Washington, D.C.: National Academy of Sciences, 1979.

compensation for military related disabilities. Agencies such as CDC understandably but uncritically accept the VA's repeated assertions that the actual cause of disabilities possibly related to Agent Orange is not needed to award service connected disability compensation. Without an elaborate analysis of the practical application of this standard in disability cases, we suggest that these agencies not rely on this reason to influence their scientific efforts.

The VA standards of proof in disability cases are so vague, ill-defined, inconsistent in practice and generally inapplicable to latent diseases that reliance on these standards to guide scientific inquiry is misplaced. Because the agency's individual benefit decisions are not subject to judicial review, there has not developed a clear body of law on the standards of causation needed to establish a service-connected disability. This has left the line between causality in latent and non-latent disease cases blurred. Indeed, the agency never has articulated the actual compensation standards and levels of proof that would be required to establish service connection for Agent Orange related diseases. The VA position that it cannot compensate for genetic damage further complicates the compensation question. The basic flaw with the VA's approach is that it ignores the reality of agency decision making. The agency has always required proof of causation but it just has never explained or articulated the level

of proof required to establish service connection. Research agencies should not be misled to believe that health risks associated with Vietnam service will be enough for veterans to succeed on Agent Orange claims.

The CDC should be especially mindful of this problem. Dr. Caldwell's study of participants in nuclear test shot "Smoky" has shown an increased incidence of leukemias appearing in that population of veterans. Yet the VA has not changed its basic compensation policy to meet these new study results. There is no reason to believe that Agent Orange results will be treated with more official interest.

Conclusion

In conclusion, the Task Force and the Center have few new developments to report to this committee. Although we commend the VA's consideration of more input for veterans on the study, many underlying policy issues have not been adequately addressed. Important decisions concerning compensation and treatment require the full participation of veterans that has been sorely missing.

Finally, the Task Force along with the NVLC is sponsoring a national conference on Agent Orange over Memorial Day weekend at American University in Washington, D.C. This conference will address the relevant medical, legal and scientific issues. The Task Force would like to invite members of the Committee, its staff, government agencies

and the public to learn about this issue not from the government's perspective, but from the perspective of veterans and their families.

Department of Medicine and Surgery
Washington, D.C. 20420

Veterans Administration

IL-10-81-5

February 11, 1981

CHIEF MEDICAL DIRECTOR'S LETTER

TO: Directors, VA Medical Centers, Medical and Regional Office Centers, Domiciliary, Outpatient Clinics and Regional Offices with Outpatient Clinics

SUBJ: Follow-Up Activities Related to Agent Orange

1. Last October, at the request of the Administrator, I asked the Office of Environmental Medicine to initiate a sample survey of veterans' satisfaction with the Agent Orange examination process. By the end of November we had received answers from approximately 55% of the 643 veterans to whom the questionnaire was distributed. For the most part these were randomly selected veterans who had been examined in seven VAMC's.

2. An analysis of the survey suggests that in the majority of cases a VA physician did not discuss the results of the physical examination with the veteran, and that in about 80% of cases the veteran did not receive the results of his/her laboratory tests. Even if this is not a totally representative sample, the survey does suggest that we need to make some improvements in our Agent Orange examination procedures.

3. DM&S Circular 10-81-12 which was distributed by teletype on January 15, 1981, provided guidance which when implemented should accomplish some of these needed improvements. I am attaching two recommended sample letters referred to in paragraph 1.B. of the circular. These letters are meant to serve only as a guide. It is likely that in some cases a modification of the sample letter should be made. It is urged that the appropriate follow-up letter be sent to all veterans who have been examined since January 1, 1981. It is recommended that the letter be signed by the environmental physician as the staff member charged with the responsibility of coordinating the Agent Orange Program in your facility.

4. Questions concerning follow-up procedures should be directed to Dr. Barclay M. Shepard, Special Assistant for Environmental Medicine, or to staff members Layne Drash or Nancy Zanis (FTS 389-5412/13).

DONALD L. CUSTIS, M.D.
Chief Medical Director

Attachments

In Reply Refer To:

Distribution: COB: (10) only plus (102) 30
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(STATION LETTERHEAD)

Positive Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve veterans, such as yourself, who are concerned about the possible adverse health effects of exposure to Agent Orange.

A review of the results of your examination indicates that _____
(Use this space to briefly describe any positive findings.)
_____
_____

In view of the above findings, we suggest that you contact the Outpatient Admissions Office at extension _____ to schedule a follow-up examination. This will provide us with an opportunity to personally discuss these findings with you and to suggest or provide any essential medical treatment.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Chief of Staff

(STATION LETTERHEAD)

Negative Findings -- Recommended Format

Dear Veteran:

We sincerely appreciate your recent participation in the Veterans Administration's Agent Orange Registry. This effort should prove to be very helpful in assisting us to better serve you and your fellow veterans who are concerned about the possible adverse health effects of exposure to Agent Orange.

The results of your examination and laboratory tests suggest that you are presently in good health and that you have no reason at this time to be concerned about possible adverse health effects resulting from exposure to Agent Orange. However, if in the future you have a medical condition about which you are concerned, I would encourage you to seek the help and advice of your nearest Veterans Administration Medical Center.

The results of your examination will be maintained by the Veterans Administration and will be available for future use as needed.

Again, your participation in the registry is appreciated.

Sincerely,

(NAME)
Chief of Staff

614851-P

NATIONAL VETERANS LAW CENTER
4900 MASSACHUSETTS AVENUE NW
WASHINGTON, DC 20016
(202) 686-2741

February 23, 1981

Dr. Donald L. Custis
Chief Medical Director
Veterans Administration
Central Office
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Dr. Custis:

We understand that you sent a February 11, 1981, letter to VA medical facilities concerning Agent Orange screening examinations. The letter (IL-10-81-5)(attached) noted the failure of VA facilities to discuss the results of Agent Orange screening examinations with veterans and the failure in 80% of the examinations to send the results of laboratory findings to veterans.

In what we hope is a mistake, you suggest that follow-up on examinations be done only with regard to veterans examined after January 1, 1981. This appears to ignore the thousands of Vietnam veterans examined before that date, just those veterans who complained in the recent VA survey about not receiving laboratory results.

We urge you to contact all veterans who have been examined since the screening program began, inform them of laboratory results and have VA officials discuss thoroughly the results with them. Anything short of this would not only be a breach of the VA's official duty to these veterans, but may be legally actionable should the results suggest health problems that deserve medical attention.

We would expect a prompt reply to this letter. Any questions about this matter should be addressed to me.

Sincerely,

Lewis M. Milford, Esq.

encl.

cc: Dr. Barclay Shepard

Department of Medicine and Surgery
Washington, D.C. 20420

Veterans Administration

MAR 9 1981

Mr. Lewis M. Milford, Esquire
National Veterans Law Center
4900 Massachusetts Avenue, N.W.
Washington, D.C. 20016

Dear Mr. Milford:

Thank you for your letter of February 23, 1981, requesting clarification of IL 10-81-5, dated February 11, entitled "Follow-up Activities Related to Agent Orange."

I have been advised that Dr. Barclay M. Shepard, my Special Assistant for Environmental Medicine, spoke to you on March 2 concerning the purpose of this latest VA Agent Orange communication to the field. As explained to you at that meeting, this information letter transmits sample follow-up letters which can be utilized to advise veterans of the results of their initial examination. It was not our intent to suggest that follow-up be done only for veterans examined after January 1, 1981. Future VA directives will address the need for our field facilities to initiate a program to follow-up all registry participants. Prior to this effort, we will be attempting to contact these individuals for the purpose of updating address information and questioning them on their health status relative to their initial examination.

May I assure you that we are vitally concerned with the need to serve these individuals as fully as possible. Your expression of interest in their behalf is appreciated.

Sincerely,

DONALD L. CUSTIS, M.D.
Chief Medical Director

In Reply Refer To: 102

Department of Medicine and Surgery
Washington, D.C. 20420

Veterans Administration

APR 3 1981

Mr. Lewis M. Milford, Esquire
National Veterans Law Center
4900 Massachusetts Avenue, N.W.
Washington, D.C. 20016

Dear Mr. Milford:

Thank you for your letter of March 18, 1981, requesting additional clarification about our Agent Orange follow-up activities.

You are correct that it is our intention to contact all veterans who have participated in our registry. We will not, however, necessarily reexamine all of these individuals. Our future follow-up program will depend on the availability of resources and cannot be planned in detail at present. We will provide you with copies of directives on this subject when available.

January 1, 1981, was not intended to be a cut-off date for writing to veterans who did not receive results from their examinations. Stations were urged to send letters to all veterans examined since January 1. This did not imply that letters could not or should not be sent to veterans examined prior to that date. Veterans examined during the period 1978-1980 are more likely to have assumed, correctly, that the results of their examinations were negative unless they were informed to the contrary. Thus, the veterans examined most recently were chosen for the more intense effort.

We hope this information is helpful to you, and we appreciate your interest in our program.

Sincerely,

Donald L. Thompson

DONALD L. CUSTIS, M.D.
Chief Medical Director

In Reply Refer To: 102

NATIONAL VETERANS LAW CENTER
4900 MASSACHUSETTS AVENUE NW
WASHINGTON, DC 20016
(202) 686-2741

February 3, 1981

Dr. J.D. Erickson
Department of Health, Education,
and Welfare
Center for Disease Control
Atlanta, Georgia 30333

Dear Dr. Erickson:

Since we were given the CDC birth defects protocol, Birth Defects and Military Service in Vietnam, some time ago, we solicited comments from several interested acientists. Their comments about the protocol have been incorporated into this letter. We trust that we are not too late and that these comments will be of assistance in the development of a scientifically valid protocol and study. The comments are divided according to the following sub-headings: (a) lack of exposure stratification, (b) power and sample size, (c) exclusion of "minor" defects, (d) other considerations, and (e) specific recommendations.

a. Lack of Exposure Stratification

The draft design fails to address in any detail how veterans' exposure categories will be defined or analyzed. Section 4.9, p. 16 indicates that an attempt will be made to "segregate veterans into categories reflecting probability of exposure", by comparing DOD information with unit(s) of service reported by veterans and their wives during the phone interviews. It is crucial that this effort be undertaken. The draft design would devote a great deal of interview time and data analysis to identifying potentially confounding risk factors such as parental drug use, occupational exposures, and familial histories. At the very least, a comparable effort should be made to assess exposure probabilities with the same exactitude.

If exposure categories are <u>not</u> delineated (based on unit and spray records, MOS, combat experience) and the analysis proceeds to use Vietnam service <u>per se</u> as the only exposure

criteria, serious misclassification errors and diminution of study power could result. This is alluded to, but not addressed, on p. 8, section 4.3. For example, if 1/4 (one-quarter) of all Vietnam veterans in the study population received toxic doses of Agent Orange that doubled their risk of fathering children with major birth defects (the suggested end-point proposed for this study), an analysis without exposure stratification would dilute that doubling to a 25% increased tisk in the overall veteran population. Moreover, the power of the study in this event drops to 70% (i.e., the probability of failing to find a statistically significant difference when in fact there is one, is 30%), instead of the 99% power to detect a doubled risk of all defects shown in Figure 1. Given the current design and analysis, risk among that hypothetical target 1/4 of the veteran population would have to be triple that of the general populace in order to be detected with good sensitivity - and it would be reported as a 50% increase in defects, rather than a 300% increase.

Any epidemiologic study of this population will suffer from reduced power due to misclassification bias, since any Agent Orange exposure index will be necessarily imprecise, but lumping all veterans into a single "exposed" category creates more bias and a greater power reduction than would a reasonably-wrought exposure index.

b. Power and Sample Size

The power computations (p. 26) seem to have been computed on the basis of a 5% background prevalence rate for all defects (in live and stillbirths). However, the study includes among cases only "major" defects in live births, which have about a 2-3% background rate (p. 7). These power computations do not apply to the study described.

c. No Justification Offered for Exclusion of "Minor" Defects

This study sets out to determine whether Vietnam veterans are at increased risk of siring babies with birth defects (p. 1). Yet it is designed only to determine if Vietnam veterans are at increased risk of siring babies with "major" birth defects. That is, it should have set out and been designed to determine whether Vietnam veterans exposed to Agent Orange experienced any reproductive dysfunction above background rates. No scientific justification is offered for limiting cases to the diagnostic rubrics noted on p. 7. Perhaps this is because the protocol never defines what hypothesis(es) are being tested.

Little clinical, laboratory, or epidemiological research has been done to date investigating the mechanisms or outcomes of reproductive toxicity in males; particularly little is known about what reproductive dysfunctions might ensue in the decade following chronic exposures to lipid-soluble compounds that accumulate in the body's fat depots. To assume that only certain categories of congenital anomalies will ensue from chronic reproductive roxicity in males is unfounded, based on our current limited knowledge. This is the standard approach used to determine whether a teratogen to which women were exposed during pregnancy has increased the frequency of a "marker" defect. Where male reproductive toxicity is suspected, a wide spectrum of effects, including infertility, spontaneous abortion, stillbirth, low birth weight, congenital and developmental abnormalities, neonatal and infant mortality, and childhood cancer, should be investigated. Otherwise, we are simply conducting research that gives the "right" answer to the wrong question.

The protocol's only suggestion of a plausible biological mechanism (p. 14, section 4.8) is curious. It proposes a search for a "fresh dominant mutation"; presumably this refers to a perceptibly increased frequency of single-gene dominant disorders caused by an increased mutation rate. First, if one were to conduct this search, it would be senseless to exclude single-gene dominant disorders such as polydactyly and mental retardation from the cases, as the protocol now requires. Secondly, according to current theories, (based on follow-up studies of A-bomb survivors) the sample size of 280,000 live births (and at most 25,000 live births to exposed individuals) is insufficient to detect an increased mutation rate if it existed.

d. Other Considerations

A major question with the study is whether fathers of out-of-wedlock (OOW) births are to be included in the phone survey. If not, this could introduce serious bias: black OOW births probably exceed white OOW births in the metropolitan area covered; there is reason to believe that blacks were at greater risk of Agent Orange exposure since they had a greater chance of combat experience. Neglecting OOW births might mean missing much of the target population.

Another question is the validity of this case-control design in the event that infertility or abortion has reduced the number of offspring born to the exposed cohort.

e. Specific Recommendations

If the study is conducted as described in the draft protocol it is virtually guaranteed to discover no service-associated risk. Because of the study's design limitations, that negative finding will not be interpretable, i.e., it will not be "of substantial value in easing the concerns of a great many veterans" (p. 16). To accomplish that goal, innovative research programs that make a serious effort to stratify exposure cohorts, investigate the full reproductive histories of those cohorts, and perform systematic karyotyping of veteran's offspring would have to be conducted. Costs of these programs need not "far exceed the cost of the present study" (p. 9) since power would be appreciably enhanced by more accurate delineation of exposure and outcome variables, based on plausible mechanisms of male reproductive toxicity.

Since this study is being conducted, the following are some changes and additions that could be incorporated into the present design to improve its interpretability:

1. Include questions in the father's phone interview to shed light on Agent Orange exposure, e.g. Were you in combat? Did you ever have a skin rash following field work? Did you ever drink the surface water? Did you eat local fish or shellfish? local food? (Other questions might be suggested by veterans.)

2. Expand the case population to include all recorded birth defects except those clearly associated with maternal factors, e.g. congenital rubella. This means expanding beyond ICDA 740-759, to include congenital neoplasms, cretinism, disqrders, dento-facial anomalies; this may not be possible if only 74-759 are included in the MACDSP.

3. Expand the case population to include all still-births.

4. Retrieve reproductive histories and birth weights for cases and controls from hospital and state vital records and assess risks of abortion and small-for-date births.

5. Retrieve infant and childhood mortality data for these populations from state vital records and snalyze the current design neglects survival, childhood cancer of veterans' offspring not chosen as index births. Include linkage to state specialized registries also, if possible, to trace developmental abnormalities not noted at birth.

6. Follow up fathers of out-of-wedlock births.

7. Clarify the hypotheses to be tested and recalculate study power assuming various exposure rates in the veteran population.

8. Establish a background rate for adverse reproductive outcomes based on Vietnam-Era veterans who did not serve in Vietnam; this would address the problem of selection of a healthy subset of the population, i.e., "health veteran effect."

9. Analyze temporal patterns and secular trends with respect to time lapsed since Vietnam service, e.g., years until first birth, taking marriage date into account. This could suggest early infertility problems.

I also would like to know the stage of peer review, assuming it has not been completed, and the identity of persons who served on the review panel.

If you have any questions about these comments, please feel free to contact us. Again, I apologize for the delay, but trust that the comments will be useful.

Sincerely,

Lewis Milford

Lewis M. Milford, Esq.

cc: Les Platt
John Moore
Patricia A. Honchar

LMM:bas

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

March 3, 1981

Lewis M. Milford, Esq.
National Veterans Law Center
4900 Massachusetts Ave. N.W.
Washington, D.C. 20016

Dear Mr. Milford:

Thank you for your thoughtful letter of February 3, 1981 in which you gave us comments and suggestions about our draft protocol. Our responses are set forth under the same headings you used in your letter.

a. "Lack of Exposure Stratification"

We were aware that our draft protocol required strengthening in the area of delineating exposure to Agent Orange. Indeed, my letter of protocol transmittal to your organization (September 23, 1980; addressed to L. Golinker) indicated that we were most interested in veteran's suggestions on this matter. We will be improving the telephone interviews as a result of suggestions which we have already received. In addition, we will be developing a mail questionnaire which will be sent to case and control fathers who are identified as Vietnam veterans during the telephone interviews. This mail questionnaire will include a map of Vietnam and be designed to elicit times and areas of service. During analysis we will try to correlate these data with other data (eg. "Herbs" tapes or other information that may be available) to derive more sensitive and objective indicators of a veteran's exposure probability. This approach was suggested to us by one of the veteran's groups. We are hopeful that these steps will help to minimize the power reduction problems that often accompany exposure misclassification.

b. "Power and Sample Size"

The power computations which we used to obtain protocol Figures 1 and 2 do apply to the study as described. As was pointed out in the 3rd paragraph of section 4.3, the calculations were done from the perspective of a case-control study. Thus the major determinants of power are the numbers of cases and controls, and the exposure rate. The rate of defect occurrence (whether it be 2% or 5%) is nearly irrelevant to the computations; this would not hold, of course, if this was to be a cohort study. A technical explanation of the very small effect of defect rates on power in this case-control study is explained in Attachment #2. From another point of view, however, one might hold that the defect rate has a major impact on power--power is dependent on the number of cases and the number of cases is determined by the number of births and the defect rate. Thus power could be improved if we had a source of cases in addition to the Atlanta registry.

c. "No justification offered for exclusion of 'minor' defects"

Your observation that this exclusion does not have a scientific basis is generally correct, although there are a few exceptions which will be noted below. Our protocol reflects emphasis on "major" structural birth defects. Pragmatic concerns are the basis for this design. CDC is uniquely situated to do a study of structural birth defects because of its Atlanta registry and we proposed our study because we believed that structural birth defects were a major concern of Vietnam veterans. We are aware that veterans have other concerns about reproductive health (eg. infertility, spontaneous abortion, mental retardation, cerebral palsy, etc.). However, CDC does not have case registries for these problems which would facilitate their study. Within the class of problems included in the registry (ie. those, and only those, set forth in Table 1 of the protocol), we decided to study only "major" malformations because 1) we percieved that veterans were concerned about "major" malformations, and 2) we felt we should devote limited resources to problems which cause premature mortality, require substantial medical care, or result in serious physical or mental handicap.

The babies in our registry who will be excluded from the study are those who have only defects noted in part 3 ("exclusion class"). This class has roughly 3 subclasses, "minor" defects (eg. accessory auricle-usually no more than a skin tag), defects with known maternally related cause (eg. rubella syndrome) and defects where the diagnosis is imprecise (eg. unspecified anomalies of the ear).

Polydactyly deserves special mention. Although this is usually classed as a "minor" defect it might seem reasonable to include these babies in a search for dominant mutations, particularly because it is non-lethal. But as you suggest the studies of the A-bomb survivors in Japan would not augur well for such an approach. Moreover, most polydactyly (at least in blacks) is inherited as a mendelian dominant disorder--it does not usually occur sporadically. Parenthetically, it may be mentioned that the same reasoning applied to our exclusion of the inborn errors of metabolism, most of which are inherited as mendelian recessives.

We agree that little is known about male contributions to reproductive problems (other than infertility) and concur that this may only be because it has received little study. A good example of this is Down syndrome. Because of the marked association of this defect with advanced maternal age, maternal risk factors have received the majority of scientific attention in the past. However, it has become apparent within the last 5 years or so that roughly 20-30% of cases arise because of an error in the father's gametogenesis.

d. "Other considerations"

We will attempt to interview all parents of all cases and controls except for those who have been legally adopted and whose original birth certificates have been changed (we think this will be about 1%). Thus we will attempt to reach virtually all natural fathers regardless of separation, divorce, or illegitimacy. It is obvious, however, that our ability to reach the father of an illegitimate child will usually depend on the willingness of the mother to reveal the identity of the father. We do not know at this time how

successful we will be in obtaining interviews from fathers, be they still married, out-of-wedlock, divorced or separated, but we think that we will succeed in interviewing a higher proportion of mothers than fathers. It is for this reason that we will be asking mothers questions about the fathers' military service.

e) "Specific Recommendations"

Your opening paragraph in this section deals with a very important issue. Among other things you say the study "... is virtually guaranteed to discover no service-associated risk". You then go on to propose that a much more sweeping study of the range of adverse reproductive studies is required. The reasons for limitation to structural malformations is the uniqueness of the Atlanta registry. After setting aside the issue of relatively limited types of outcomes which we will be able to study, we cannot agree that the study is doomed to failure. Whether we find an effect in our study depends on many factors; most importantly it depends on whether there really is an effect on the occurrence of structural defects and whether the effect is substantial in terms of the increase in risk and in terms of the number of veterans affected.

Our comments about the numbered suggestions in this section follow:

1) As we have discussed earlier, we are incorporating suggestions received from veterans groups and other consultants to improve exposure discrimination.

2) This study is focused on structural birth defects because of the availability of CDC's Atlanta defect registry. Testing of hypotheses related to other adverse reproductive outcomes is not within our present capabilities.

3) An earlier version of the protocol included the study of a sample of stillbirths. It was strongly suggested by CDC's peer-review group that this aspect be dropped. This suggestion was seconded by the university-based consultants who reviewed the protocol. This suggestion was made primarily because many stillbirths are known to be associated with factors which are very unlikely to be the consequence of service in Vietnam. For example, in metro Atlanta during 1968-1976 about 24% of white stillbirths and 35% of black stillbirths were twins. Note, however, that stillborn babies who had structural malformations will be included in the study. This will amount to about 14% of white stillbirths and 7% of black stillbirths.

4) Information about birth weights for cases and controls will be available from state vital records and from study interviews; information about reproductive histories will also be gathered during the study.

5) Linkage of cases and controls with state vital records or specialized registries for purposes of assessing mortality or developmental abnormalities not included in the Atlanta birth defects registry would be very difficult and would require additional resources. However, some relevant information will be gathered during parents interviews.

6) As noted above, we will try to interview out-of-wedlock fathers.

7) As noted in the protocol, the major study objective is to determine if Vietnam veterans are at increased risk of siring babies with birth defects and the power curves were generated to aid us in determining how many controls should be studied in order to achieve that objective. We also noted in the protocol (p17) that "For rare defects and low increases in risk or for increases in risk which are limited to those veterans with prolonged and/or heavy exposure to Agent Orange, the study will have low power." We also said that "... if the increase is limited to very rare categories of defects or to special veterans, then the study still has the utility of putting some boundary on the scope of the problem for most veterans." We still think that this is a valid and important point.

8) A portion of case and control fathers will be Vietnam-era veterans who did not serve in Vietnam and "background rates" can be obtained from them.

9) Our analysis will include consideration of temporal patterns, secular trends, and many other factors.

Because of your question about peer-review I am enclosing a copy of my September 23, 1980 letter to your organization. The university based scientists who served as CDC's outside consultants are listed on page 2, #2; the CDC scientists who did the "in-house" review are unknown to me because it was done anonymously.

Again, thank you for your thoughtful review. I'll keep you informed of our progress.

Sincerely yours,

J. David Erickson, D.D.S., Ph.D.

Enclosure

cc:
Dr. Moore
Mr. Platt