THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

December 15, 1987

MEMORANDUM TO: Dr. Ralph Bledsoe
Executive Secretary
Domestic Policy Council

FROM : Don Newman, Chairman
Domestic Policy Council
Agent Orange Working Group

SUBJECT : Agent Orange Working Group 1988 Agenda

The plans, programs and policies of the group have remained unchanged since the President established the Group in August 1981. His commitment to give special consideration to the concerns of Vietnam veterans and study the possible adverse health effects of their exposure to Agent Orange while in Vietnam has resulted in some $91 million having been spent on completed studies to date. In 1988 several important ongoing studies will end or will be near completion.

The Centers for Disease Control (CDC) will complete a Vietnam Experience study which began in 1983 of the long term health effects of military service in Vietnam. Significant results are expected from this study which will be released in early summer 1988. The CDC Selected Cancer studies designed to evaluate if Vietnam veterans are at increased risk of any of five specific cancers - soft tissue sarcoma, lymphoma, nasal, nasopharyngeal and liver cancer - will continue through 1988 and 1989 with results due in 1990.

The U.S. Air Force will release its annual Mortality and Morbidity report December 1988, of the Air Force personnel (Operation Ranch Hand), who actually flew spray missions. This epidemiological study continues through the year 2000.

The Veterans Administration will continue its plans to re-examine its data in recent studies released, and to find an acceptable design for a study of Vietnam Women Veterans.

To date exhaustive scientific research on the part of the AOWG and its member scientists have found no cause - effect relationship linking any adverse health effects to Agent Orange exposure in Vietnam. There is no scientific evidence to assume presumptive causation at this time.

cc: Nancy Risque

THE WHITE HOUSE

WASHINGTON

December 11, 1987

MEMORANDUM FOR DON M. NEWMAN

FROM: RALPH C. BLEDSOE Ralph Bledsoe

SUBJECT: 1988 Agenda

Would you please provide me by Wednesday, December 16 with plans, programs and policies for the 1988 agenda, pertaining to the Working Group on Agent Orange. I have attached a memorandum for the Cabinet requesting similar information. As in the request to the Cabinet, items need not be spelled out in great detail. Only a summary paragraph is needed.

monthly mtgs
Attachment
studies

Presumptive — exhaustive sci. invest.
no indication.

cc Liz P.

THE WHITE HOUSE

WASHINGTON

December 10, 1987

MEMORANDUM FOR THE CABINET

FROM: NANCY J. RISQUE

SUBJECT: 1988 Agenda

The President has asked that you submit as quickly as possible all plans, programs, and policies that you would like to be considered by him for the 1988 agenda. This material will be considered for the legislative and administrative message that is being planned in conjunction with the State of the Union.

These submissions should include legislative proposals or legislation that you wish to be enacted next year; legislative proposals that are longer term in nature but that you would like the Congress to begin considering in the next year; other programs and policies to be implemented that do not require legislation; and a list of major reports to Congress that will be due in 1988.

These items do not have to be spelled out in great detail, but a summary paragraph on each is necessary.

Please have this material forwarded to me by noon on Thursday, December 17.

Thank you for your contributions.

THE WHITE HOUSE

WASHINGTON

September 28, 1987

MEMORANDUM FOR NANCY J. RISQUE

FROM: RALPH BLEDSOE

SUBJECT: Agent Orange Follow-up

There are currently three Agent Orange studies remaining in the series of over 100 that have been completed. The Centers for Disease Control (CDC) study will likely be terminated as suggested in the attached memo. The Agent Orange Working Group will discuss this and the other two studies at its October 6 meeting. OSTP will attend, and will likely comment on the status of each of the three. At present, in the opinion of CDC, and Agent Orange Working Group chairman Don Newman, the VA Mortality Study, the second of the studies, does not indicate serious Agent Orange problems. The third study, the Air Force's Ranch Hand study, is not due to be completed until 1988.

This issue is one in which the Federal government has responsibly handled a very difficult health problem by performing extensive studies and tests on veterans who were exposed to the chemical. While there has been a reasonable amount of publicity in the past, it is now receiving only selective attention by groups critical of the process. Especially since the effects of the chemical do not seem to have caused great problems during the period since people were exposed to it. There will likely be continuing news articles about the studies, but they should not draw heavy political rhetoric.

I think the Agent Orange Working Group under the DPC should continue its regular meetings (monthly or bimonthly), so we can point out that the issue is receiving this level of attention. And from time to time a report to the Council is in order. The President will likely not have to become involved, since there is a good process for supporting and reviewing the studies and we have been responsible in reviewing the findings.
As an aside, many years ago the chemical companies reached an out-of-court settlement with veterans groups. Those who feel the science is showing that no effects occurred feel this was a premature decision.

THE WHITE HOUSE

WASHINGTON

September 24, 1987

MEMORANDUM FOR NANCY J. RISQUE
WILLIAM R. GRAHAM

FROM: RALPH C. BLEDSOE Ralph Bledsoe

SUBJECT: Agent Orange

Attached is a letter from Jim Mason of the Centers for Disease Control to several congressmen who wrote him about Agent Orange. Briefly, the letter outlines the reasons for a CDC recommendation to terminate its Agent Orange Exposure Study, and provides comments on the recent VA Mortality Study.

The reason given for terminating the CDC study is that CDC has been unable to identify sufficient numbers of veterans who have been exposed to conduct a specific valid survey.

The comments on the VA study focus on the conclusion that while the study appears to be well executed in mechanics, "there was no indicator of proximity, duration, or intensity of such exposure available to the investigators, (and) one cannot assess the possible effects of exposure to Agent Orange from that study."

The Agent Orange Working Group will meet on Tuesday, October 6. This letter may be discussed at that meeting.

Attachment

9/24 RB -
What about other studies?
Where is this issue going?
What should we be doing?

NR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

SEP 21 1987

The Honorable James Florio
House of Representatives
Washington, D.C. 20515

Dear Mr. Florio

This is in response to your letter of September 15 to the Centers for Disease Control (CDC) regarding the Agent Orange Exposure Study and the Veterans Administration (VA) Mortality Study.

I will address the Exposure Study first. Like you, we would like to provide more clearcut answers to the questions of veterans and their families about the effects of Agent Orange exposure, and I have shared these concerns with Under Secretary Don Newman who is Chair of the Agent Orange Working Group. However, using the best available science to execute methods approved by the Congressional Office of Technology Assessment (OTA) and after rigorous review by several independent scientific panels, we have been unable to identify sufficient numbers of veterans who have been exposed to conduct a scientifically valid study.

We pointed out the presence of difficulties related to Agent Orange exposure early on. The approved protocol, published in November 1983, noted that determining exposure might be difficult. Our concern at that time was made clear to scientific reviewers, to the Congress, and to the national community of veterans. By the end of 1985 it had been confirmed that use of military records alone was an insufficient means of determining exposure in individuals in order to proceed with a scientifically valid study. Chairman Montgomery and Ranking Minority Member Hammerschmidt of the House Committee on Veterans Affairs directed on January 10, 1986, that further work on the Agent Orange Study be suspended.

Dr. Vernon N. Houk and I discussed the difficulties of exposure misclassification while testifying before the House Committee on Veterans Affairs on July 31, 1986. At that time we suggested that a 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) Validation Study--made possible by the development of new laboratory methodology by CDC--would confirm or disprove the potential of misclassification.

A TCDD Validation Study was begun in October 1986 after development of a protocol which, like the initial one, underwent rigorous review by independent scientific groups and was approved by OTA. The study compared measurements of dioxin levels in the blood of over 700 veterans with records-based estimates of their exposure to Agent Orange. Of the veterans participating in this

study, approximately 600 were chosen based on service in areas of Vietnam where spraying of Agent Orange was most intense, during the time period when spraying was the heaviest. We intentionally oversampled men whose records indicated the heaviest likelihood of exposure. The approximately 100 other participants had served in countries other than Vietnam. The findings of the study, reported in July 1987, confirmed conclusively that neither military records nor veterans' personal perception of their exposure to Agent Orange can be used to identify a cohort of exposed ground troops without accepting the likelihood that considerable misclassifications would occur, and hence invalidate any results of the study.

Meanwhile, work on two other components of CDC's investigation of Vietnam veterans' health were begun on schedule and are continuing as planned. Data for our Vietnam Experience Study has been collected on approximately 15,000 health status interviews and 4,500 comprehensive medical and psychological examinations. These morbidity data are now being analyzed; findings will be reported late this year or early next year. A mortality portion of that study has already been reported. Data for the Selected Cancers Study will continue to be collected until late 1988, with publication of findings the following year.

Your letter stated that $63 million had been spent on a study looking at the effects of Agent Orange. That is incorrect. Approximately $40 million has been expended to date, and most of these funds have been spent on the ongoing Vietnam Experience and Selected Cancers studies; both of which show promise of adding significantly to the scientific base of knowledge. From 1983 until now, approximately $7.5 million has been spent trying to develop methods in which military records can be used to predict exposure. The TCDD Validation Study cost approximately $3.5 million.

CDC has aggressively pursued the use of "other methods" for determining exposure of Vietnam veterans to Agent Orange. CDC has for several years measured dioxin in adipose tissue and is currently in the forefront of serum dioxin technology. Ours is the only laboratory in the United States--one of only two in the world--measuring dioxin in serum.

Serum dioxin levels are certainly more valid measurements of dioxin exposure than biomarkers which may be correlated with dioxin levels. CDC has also attempted to find such biomarkers and follows the work of other researchers in this area. Since serum dioxin measurements are quite expensive (about $1000 each in laboratory costs alone) identification of a less expensive screening marker could be very useful. We are familiar with the efforts of the New Jersey Agent Orange Commission and their hopes to eventually find such a marker. We are not familiar with studies in progress to find "biological markers which would indicate that dioxin had been present long after it had left the body of the veteran." Such studies would face significant validity

problems in establishing that exposure to dioxin had, in fact, previously occurred. We would like to be made aware of and review any such studies. In any event, the serum dioxin measurement, as used by CDC in the Agent Orange Validation Study, will remain the most sensitive and specific measurement of exposure to dioxin in Vietnam veterans.

In collaboration with the U.S. Air Force, CDC has determined serum dioxin levels in selected "Operation Ranch Hand" veterans and found high levels of dioxin in some who were involved in the Agent Orange spraying missions. Continued studies are in progress jointly by the CDC and the Air Force to measure serum dioxin levels in all Ranch Hand veterans and a group of control veterans. Thus, the Ranch Hand study, because of the range of serum dioxin levels potentially present in its participants, holds the most promise of determining whether Agent Orange exposure which occurred in Vietnam has caused any adverse health effects. CDC will continue to work with the Air Force in this promising effort.

We have several comments with regard to the findings of the Veterans Administration's (VA) Proportional Mortality Study. The study, as originally designed, cannot conclusively clarify mortality risks for Vietnam veterans, let alone elucidate possible causative factors within, or outside of, the Vietnam experience. Since there was no indicator of proximity, duration, or intensity of such exposure available to the investigators, one cannot assess the possible effects of exposure to Agent Orange from that study. As the authors state, there are several other possible explanations for the increase in certain types of cancer among Marines, not the least of which is chance alone. In fact, the authors suggest that one or more factors distributed differently in Marines and Army troops could be associated with the findings, since mortality excesses were not seen in Army men. A specific example mentioned in the report was the anti-malarial preventive drug Dapsone, the drug of choice in areas where Marines served. If Agent Orange were responsible for the reported excesses, it is hard to believe that there is not even the suggestion of similar risks in Army troops. Thus, the results of the VA study in no way imply that large numbers of military personnel were exposed to Agent Orange in Vietnam. This proportional mortality study appears to be well executed in mechanics. However, the analysis, presentation, and discussion of the results do not provide the necessary caution in interpretation and allow causal inferences to be made where none in fact exist.

CDC and our parent organizations, the Public Health Service and the Department of Health and Human Services, are awaiting whatever actions may result from recommendations made to the Congress by the OTA Agent Orange Advisory Panel, and to the White House Domestic Policy Council by the Agent Orange Working Group. We are open to suggestions for other scientific approaches and ready, provided resources are available, to undertake whatever alternate studies may be designed to effectively resolve the concern of veterans and their families about Agent Orange exposure. This, however, will still require some means of separating exposed from unexposed veterans.

An identical letter is being sent to the nine other Members of Congress who co-signed your September 15 letter.

Sincerely yours,

James O. Mason

James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General
Director

Identical Letter sent to:

The Honorable David E. Bonier
House of Representatives
Washington, D.C. 20515

The Honorable John W. Bryant
House of Representatives
Washington, D.C. 20515

The Honorable Don Edwards
House of Representatives
Washington, D.C. 20515

The Honorable Lane A. Evans
House of Representatives
Washington, D.C. 20515

The Honorable James Florio
House of Representatives
Washington, D.C. 20515

The Honorable James M. Jeffords
House of Representatives
Washington, D.C. 20515

The Honorable Marcy Kaptur
House of Representatives
Washington, D.C. 20515

The Honorable Joseph P. Kennedy II
House of Representatives
Washington, D.C. 20515

The Honorable Leon E. Panetta
House of Representatives
Washington, D.C. 20515

The Honorable Harley O. Staggers, Jr.
House of Representatives
Washington, D.C. 20515

cc:
The Honorable G. V. Montgomery
The Honorable John P. Hammerschmidt

bc:
Mr. Thomas K. Turnage, VA
Dr. John A. Gronvall, VA
Dr. John H. Gibbons, OTA
Dr. Ralph C. Bledsoe ←
Mr. Gary Bauer
Dr. Peter Beach
Under Secretary Newman

Ralph-

THE WHITE HOUSE
WASHINGTON

August 28, 1987

MEMORANDUM FOR NANCY RISQUE

FROM: RALPH BLEDSOE

SUBJECT: Agent Orange Issue

This is the Agent Orange issue I spoke of at the staff meeting this morning. Don Newman would like this to be presented to the DPC. I will discuss it with Steve Galebach.

cc: Steve Galebach

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

August 27, 1987

The Honorable Edwin Meese
Chair Pro Tem
Domestic Policy Council
The White House
Washington, D.C. 20500

Dear Mr. Meese:

As you are aware, this Department has the lead in the Agent Orange Working Group, which reports to the Domestic Policy Council. Members are limited to the Department of Defense (DOD), the Office of Management and Budget (OMB), and the Veterans Administration (VA).

In January 1979, Congress enacted P.L. 96-151, which directed the VA to investigate the health effects of Agent Orange. The authorization was expanded in November 1981 by P.L 97-72 to include other factors of the Vietnam Experience. Congress called for the transfer of Agent Orange studies to the Centers for Disease Control (CDC), which in turn proposed three separate, but complimentary epidemiological studies of the health of Vietnam veterans, in September 1982:

1. A Vietnam Experience study which is nearing completion;
2. A Selected Cancer study which is due for completion in mid-1989; and
3. The Agent Orange Exposure study which has proved far more difficult. The problem has consistently been that of identifying exposed versus non-exposed ground troops.

In repeated attempts, the Science Panel of the AOWG, the Advisory Committee of Office of Technology Assessment, and a sub-panel of the Science Panel chaired by Office of Science Technology Policy, were unable to endorse any exposure index based on military records. All three groups recommended that a method to verify exposure must be attempted before a scientifically valid Agent Orange Exposure Study could be performed.

A new method using blood sera was developed by CDC to establish body burden of dioxin in order to indicate past exposure to dioxin-containing substances such as Agent Orange. A study of Vietnam veterans to verify exposure based on

military records has recently been completed by CDC. From these results, it has been concluded, that military records cannot support a valid epidemiological study of the health effects of Agent Orange exposure on Vietnam veterans.

Comparisons of exposed ground troops, non-exposed ground troops and veterans who did not serve in Vietnam, reveal almost identical dioxin levels in their blood sera (3.8-3.9 parts per trillion). Exposure was determined from extensive review of military records as well as self-assessments of exposure by the veterans themselves. A study of Air Force Ranch Hand Volunteers who were known to have been exposed to Agent Orange is now well underway and may provide leads for other studies.

The Science Panel's August 14, 1987 report to me as chair of the AOWG (copy attached) unanimously concluded that the Agent Orange exposure component of the Vietnam Veterans Health Studies currently underway at the Centers for Disease Control cannot be scientifically conducted. The members of the AOWG concur in this conclusion.

I advise you to recommend to the Domestic Policy Council that the Agent Orange exposure study be cancelled.

We are prepared to inform Congress and veterans service organizations through appropriate channels if you deem this advisable.

Please call me should you require additional information.

Sincerely,

Don M. Newman
Under Secretary
Chair Pro Tempore
Domestic Policy Council
Agent Orange Working Group

Enclosure

cc: Gary Bauer DPC/HPWG
Dr. Ralph Bledsoe, DPC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date August 13, 1987

From Ronald W. Hart, Ph.D.
Chairman, AOWG Science Panel

Subject Recommendation to Cancel the Vietnam Veteran Agent Orange Exposure Study

To The Honorable Don M. Newman
Chairman, Agent Orange Working Group / Domestic Policy Council

Following the Science Panel review of CDC's TCDD serum level study, it is the unanimous recommendation of the AOWG Science Panel that the Agent Orange Exposure Study, the cohort epidemiological study of Vietnam veteran ground troops exposed to Agent Orange, can not be scientifically conducted and therefore should be canceled.

The recent report by the CDC at the AOWG Science Panel on August 6, 1987 entitled "Comparison of serum levels of 2,3,7,8-TCDD with indirect estimates of Agent Orange exposure in Vietnam veterans" documented that none of the various methods, including a self-perception of exposure, were able to identify Agent Orange exposed and non-exposed Vietnam veterans. In addition, the TCDD serum level comparisons between the Vietnam Veteran and the non-Vietnam Veteran controls indicated that there was no difference in TCDD serum levels (about 3.8 ppt) between these two groups.

The TCDD half-life study of the Ranch Handers indicated a 7-8 year median half-life in this group of Vietnam veterans. This long half-life value coupled with the 3.8 ppt serum level in the CDC AO Exposure Study indicates that little exposure occurred in this group of ground troops in Vietnam. These ground troops were selected from military records as the most likely individuals exposed from the battalions which were most heavily potentially exposed from the area of Vietnam that had the highest amounts of Agent Orange used and from the years when its use was the highest.

All of this data taken together provides solid scientific data that a valid cohort Agent Orange Exposure Study can not be conducted.

Ronald W. Hart, Ph.D.

cc: Dr. Peter Beach

Flash: Not to be released unless Dr Bledsoe indicates.

HHS NEWS

May be re-written as coming from Mr Meese.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE

CONTACT: Campbell Gardett
(202) 245-6343

HHS Under Secretary Don M. Newman stated today that one of the government's studies of possible health effects of Agent Orange has proved unfeasible due to difficulties in measuring levels of exposure to the herbicide among Vietnam-era veterans.

Serving as chairman of the Agent Orange Working Group of the Domestic Policy Council, Newman reported the group's recommendation to terminate the proposed Agent Orange Exposure Study in a letter to Attorney General Edwin Meese, chairman of the DPC. Newman's statement follows a year-long study of the problem by HHS' Centers for Disease Control.

Several other studies of Vietnam-era veterans, however, are either complete or will be continued, Newman said. Since 1979, about $150 million has been spent by the federal government on Agent Orange-related studies, although so far no health effects have been conclusively shown to result from exposure among Vietnam veterans.

"This study was intended to evaluate possible health effects of Agent Orange by comparing the health of a group of Vietnam veterans exposed to herbicides with the health of Vietnam veterans not exposed," Newman said in making the statement.

- More -

"To be valid, the study would have to be able to identify a group of those who were most likely to have been heavily exposed, and another group who were not exposed. But it is now clear from CDC's work that we will not be able to determine exposure with sufficient accuracy on a large group of men who served as ground troops in Vietnam, and thus a valid study cannot be carried out," the Under Secretary said.

The study was first delayed last year when it was found that exposure to Agent Orange could not be determined from military records alone. Seeking an alternative means of verifying exposure, CDC utilized a new method for measuring dioxin in blood in order to verify significant past exposure to dioxin-containing substances, including Agent Orange. CDC's laboratory is finding elevated levels of dioxin in people with definite occupational or environmental exposure 20 or more years ago.

However, on a sample of Vietnam veterans categorized into exposure groups by military records and also by the veteran's own estimate of his exposure, CDC found almost identical dioxin levels in the blood (about 3.9 parts per trillion) in the "exposed" and "non-exposed" groups. This same level was found in a non-Vietnam veteran comparison group. Approximately one-half of 1% of the Vietnam veterans showed modest elevations of dioxin in their blood.

"CDC was working at the forefront of technology in developing a method that accurately measures these traces of dioxin in the blood," Under Secretary Newman said. "However, the nearly-identical dioxin levels found among those who were thought to have had very different exposure levels to Agent Orange means that the necessary step of identifying large groups of exposed and non-exposed men for a study of health effects is not feasible in a general population of Vietnam veterans, so the proposed exposure study cannot go forward as originally planned."

CDC is also carrying out two other Agent Orange-related studies:

-- The Vietnam Experience Study, examining long-term health effects of military service in Vietnam through interviews of more than 15,000 veterans and medical examinations of some 4,500. This study is nearing completion.

-- The Selected Cancers Study, investigating the risk in Vietnam veterans of five cancers which have been identified as possibly associated with industrial or occupational exposure to phenoxy herbicides, including Agent Orange, and their dioxin contaminant. The study is on schedule for completion in 1989.

CDC also completed a Mortality Assessment Study last year, investigating and comparing the causes of death of 446 Vietnam and non-Vietnam veterans who died since leaving active military service.

Several other studies have been completed or are underway in the Department of Defense and the Veterans Administration.

"We are disappointed that it has not proved possible to carry out the proposed exposure study," Newman said. "However, we will continue to investigate the possible health effects of Agent Orange exposure through other ongoing studies, including the Ranch Hand study which is being performed by the Air Force, with the assistance of the CDC laboratory for measuring dioxin levels in men who were involved heavily in spraying Agent Orange in Vietnam. Another study has recently been started by the National Institute of Occupational Safety and Health on civilian workers in chemical plants producing Agent Orange in the 1950s and 1960s.

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THE WHITE HOUSE

WASHINGTON

September 4, 1987

9-8: Ralph follows up with NR

MEMORANDUM FOR NANCY J. RISQUE

FROM: WILLIAM R. GRAHAM WRG

SUBJECT: Agent Orange Working Group

As noted in the attached newspaper articles (Tab A), the subject of Agent Orange and our Vietnam veterans continues to be of major interest to the public. Unfortunately, the articles imply that the Administration is doing little to clarify the issue. This false impression is due to lack of leadership of the DPC Agent Orange Working Group.

In early May, this office contacted the Chair of the DPC and advised him of the need to evaluate results of key studies and identify appropriate follow-on activities prior to the public release of federal Vietnam veteran-health studies (Tab B). However, the AOWG has not met. In the interim, results have been released to the Congress, Office of Technology Assessment, veterans groups, and the press. Consequently, the public is getting an inaccurate picture of the implications of these studies while interagency policy deliberations have not yet begun.

For the past six years this Administration has developed and executed an in-depth research program designed to answer the scientific concerns related to Agent Orange. It is of great concern to me that as we now complete these studies, we are failing to provide to the veterans and the public an understanding of the magnitude of our concerns, our efforts, the scientific results, and their implications. This is a direct result of the circumvention of the DPC process.

I recommend that the DPC Agent Orange Working Group be reconstituted under a new chairman: an individual who will take an active interest in the DPC process. Because of his competence and interest in this area, I recommend that Dr. Ralph Bledsoe become the AOWG Chairman. I understand that the DPC may discuss the topic of Agent Orange in September. It is important that the AOWG review the issue prior to the Cabinet-level meeting in order to consider the technical issues.

Attachments
Tab A - Newspaper articles
Tab B - Berger/Newman letter, May 7, 1987


A

Agent Orange suspect again in vet deaths

By Dan Sperling
USA TODAY

Marine veterans of Vietnam have died of some cancers at a much higher rate than other vets — and Agent Orange is a suspect — says the largest study ever done on the topic.

The Veterans Administration study said those Marines:

■ Had a 58 percent higher rate of lung cancer than Marines who didn't go to Vietnam.

■ Had a 110 percent higher rate of non-Hodgkin's lymphoma (a category of cancers of the lymph system).

The study, released Thursday, examined deaths among 49,920 Marine and Army veterans who had served as ground troops in Vietnam and elsewhere between 1965 and 1973.

Though not designed to determine causes of death, the report states, "exposure to Agent Orange may be suspected."

Most Marines served in the northern part of South Vietnam — which "was the area sprayed by Agent Orange," says Michael Leaveck of Vietnam Veterans of America.

"There shouldn't be any doubt left in anyone's mind about the link between Agent Orange and adverse health effects," says Leaveck. "For years the government's been denying that there's a link. And the VA has yet to pay compensation to even one veteran."

His group has sued the VA to get compensation for those sprayed by Agent Orange.

The higher cancer rates were not found among Vietnam veterans who had served in the Army — most of whom served in other parts of Vietnam than the Marines.

Agent Orange is suspect in several ailments, including cancer and birth defects in veterans' children. Dioxin, an ingredient, is highly toxic.

The VA declined comment until its Advisory Committee on Environmental Hazards gets the study next month.

Other findings:

■ Higher homicide rates among Vietnam veterans with combat-related military jobs.

■ More drug-related deaths among Vietnam veterans.

USA TODAY
Page 1, Friday
Sept. 4, 1987.

VVT A 10 9/4/87

Cancer Deaths High for Some Veterans

By PHILIP M. BOFFEY
Special to The New York Times

WASHINGTON, Sept. 3 — The largest mortality study of Vietnam veterans yet conducted has found that former Marine ground troops died of lung cancer and certain lymph cancers at a significantly higher rate than marines who did not serve in the war, the Government reported today.

The study, performed by the Veterans Administration, was not intended to determine the cause of the higher cancer death rates and thus did not clarify what role, if any, might have been played by the herbicide Agent Orange.

The study cited such other possible causes for the excess cancer among marines with Vietnam service as antimalaria drugs, diseases and statistical chance. No similar increases in cancer deaths were found in Army troops who served in Vietnam.

The V.A. researchers examined the death records of more than 52,000 veterans who served in the Army or the Marine Corps from 1965 to 1973. Slightly less than half the group served in Vietnam; the rest served elsewhere. The group accounted for about a third of all deaths among veterans who served in Vietnam, thus providing a far greater statistical sweep than any previous study of mortality among these veterans.

'Proportional Mortality' Study

The study dealt with "proportional mortality," comparing the percentage of veterans dying of specific causes among the group that served in Vietnam compared with the group that served elsewhere. It found that marines in Vietnam had a 58 percent higher rate of death from lung cancer, the most common form of cancer, than would be expected and a 110 percent higher rate of death from non-Hodgkin's lymphomas, a category embracing several types of rare cancers of the lymph system.

The finding that is expected to prove the most controversial is the excess in non-Hodgkin's lymphomas. At least two civilian studies have suggested a link between these cancers and phenoxy herbicides, the family of chemicals that includes the ingredients of Agent Orange. But other studies have linked the lymphomas to arsenic compounds, which were used in other herbicides sprayed in Vietnam; to dapsone, an anti-malaria drug, and to certain viruses. The V.A. study noted that "the men who served in Vietnam had the potential for exposure to all of these agents."

> A study cites lymphoma and lung rate in Vietnam marines.

The study also noted that most of the marines in South Vietnam served in I Corps and in the central highlands, northern regions where malaria was present and dapsone was administered widely. The V.A. said it would not analyze the data to determine whether Army troops in those specific areas also suffered an excess of lymphomas.

The areas most heavily sprayed with Agent Orange, according to the Defense Department, were closer to the capital, Saigon.

The puzzling findings come at a time when the Centers for Disease Control, another Government agency, has said that it cannot carry out a major study that some had hoped would determine whether Agent Orange was a cause of health damage among ground troops in Vietnam. The agency said it could not locate enough veterans with high exposures to dioxin, the dangerous contaminant of the herbicide.

In another finding that will further cloud the question of Agent Orange, the V.A. study found no excess of deaths in Vietnam veterans from soft tissue sarcomas, a rare type of cancer that has been associated in some studies with exposure to herbicides comparable to Agent Orange. Some state studies have suggested that Vietnam veterans have an excess of soft tissue sarcomas, but all such studies have been much smaller than the one whose findings were issued today.

The study gave no explanation for the elevated lung cancer mortality among the marines who served in Vietnam as compared with marines who did not serve there. A similar elevation in lung cancer had been found in a study of veterans from New York, although the increase was not large enough to be statistically significant.

No Histories on Smoking

Tobacco is the most commonly cited cause of lung cancer, but the V.A. said it had no smoking histories of the marines in the study. Nor is it known whether smoking rates differed among the marines who suffered excess lung cancer and the Army troops, who had normal rates of lung cancer. A state study in Wisconsin has found that veterans as a whole smoke at twice the rate of men in the civilian population, but this should have increased lung cancer among the Army troops as well as the marines, the V.A. said. Lung cancer has also been associated with exposure to chemicals such as the phenoxy herbicides and arsenic, the V.A. noted.

The finding of an elevated rate of non-Hodgkin's lymphomas among marines who served in Vietnam was reported Tuesday by The New York Times. Lawrence B. Hobson, director of the V.A.'s Agent Orange office, said then of the lymphoma finding: "I wouldn't say it's terribly worrisome. If I were a Vietnam veteran, I don't think I'd be the least bit disturbed about it."

The study's findings were issued today only because the key finding had been reported in The Times, an official said. Bonner Day, a spokesman for the agency, said today that the V.A. would have no comment until the study is presented next month to an advisory committee of experts for their scientific evaluation.

Lack of Military Data Halts Agent Orange Study

By PHILIP M. BOFFEY
Special to The New York Times

WASHINGTON, Aug. 31 — Federal scientists have concluded that they cannot proceed with a major Congressionally mandated study on the effects of Agent Orange on American ground soldiers in Vietnam because they are unable to find enough soldiers who were exposed to significant levels of the herbicide.

The finding, which appears to contradict the popular image that ground troops were in frequent contact with chemicals used to defoliate the jungle, has been relayed by the Centers for Disease Control in recent weeks to key Agent Orange advisory committees in the Administration and Congress. Neither the Reagan Administration nor Congress has taken a position yet on what to do about the study.

The centers' conclusion is based on a pilot study to determine whether troops with high exposure to Agent Orange could be identified from military records for a large-scale study.

"This study has demonstrated that, for most of the ground troops, the exposure was not significant," Dr. Vernon Houk, director of the Center for Environmental health at C.D.C., said in an interview. "I'm quite sure there were some individuals, such as chemical corps workers, who were exposed. But this study shows it is not possible to get a sufficient number of exposed people through military records to do a meaningful study of ground troops."

The centers' conclusion is sure to provoke anger and disbelief among veterans who are convinced that Agent Orange caused a wide range of illnesses that appeared after they returned home, including cancers, birth defects in their offsping and other serious ailments.

Other studies, such as of Air Force

Continued on Page C5, Column 1

C.D.C. Wants to Abandon Agent Orange Study

Continued From Page A1

personnel who directly handled Agent Orange, are under way. But none of these studies, or the one that may now be aborted, will affect the court settlement in which companies that manufactured Agent Orange have contributed more than $200 million to a fund to be distributed among veterans who say they were injured by the herbicide. The distribution is based on the disabilities suffered, not on whether those disabilities were caused by Agent Orange.

Dioxin, a chemical contaminant of Agent Orange, has been found to be highly toxic to some animal species. It is known to cause skin disorders in humans and experts suspect it may cause other diseases, but the risks of high exposure levels have not been determined.

The conclusion that the study cannot go forward as planned has been endorsed by scientific advisers to the Government but challenged by veterans' leaders and the New Jersey Agent Orange Commission.

The president of the Vietnam Veterans of America Foundation, John Terzano, contends that the Centers for Disease Control has proved only that the methods it explored for doing the study will not work, not that the study was impossible by other methods. If the study is now abandoned, he said, there will be "some very, very real problems, political problems."

Effort Criticized as 'Pitiful'

Mr. Terzano acknowledged that the number of troops believed to be exposed "has been on a downward curve" for the past eight years, but he suggested that the planned study should be replaced by other research, including smaller-scale studies or a large study of ground troops using methods not yet explored.

Similarly, Peter C. Kahn, a biochemist at Rutgers University who is a member of the New Jersey Agent Orange Commission, charged, "The Federal effort has been pitiful in this whole business." He said that New Jersey was trying a different method of finding troops who were highly exposed to Agent Orange that may in turn make a study of health effects possible.

The Federal study was intended to be the largest and most important investigation of whether ground troops in Vietnam suffered health damage from exposure to Agent Orange, a chemical that was sprayed from aircraft, helicopters and hand-held dispensers to kill vegetation that might hide the enemy.

Other studies are examining whether Agent Orange harmed the Air Force personnel who conducted the spraying missions or caused specific cancers or birth defects among a broad group of veterans. Still other studies are examining whether service in Vietnam, regardless of exposure to Agent Orange, had adverse long-term health effects. Thus far the other studies, most of which are well under way, have turned up little evidence of serious problems.

Possibly Troublesome Finding

The only potentially troublesome finding, Government scientists say, has emerged in a Veterans Administration study of mortality records that has not yet been made public. Scientists familiar with the findings said the V.A. study found an unexplained excess of deaths from non-Hodgkin's lymphomas, an unusual form of cancer, among marines who served in Vietnam.

> Veterans' leaders suggest that Federal scientists explore other methods for the research.

No one knows what caused the increase — the study was not designed to make this determination — or whether it is a significant development, the scientists said.

A cause for concern, some scientists said, is that an excess of non-Hodgkin's lymphomas has been found in at least two studies of agricultural and forestry workers who used herbicides similar to Agent Orange. However, the V.A. study found no excess lymphomas among Army troops who were presumably exposed to Agent Orange as much as the marines were, or more. "I wouldn't say it's terribly worrisome," said Lawrence B. Hobson, director of the V.A.'s Agent Orange office. "If I were a Vietnam veteran, I don't think I'd be the least bit disturbed about it."

The inability to perform the central epidemiological study of the impact of Agent Orange on ground troops comes after eight years of efforts to devise a scientifically sound approach. The study was ordained by Congress in 1979 in an effort to determine whether the illnesses suffered by veterans were indeed caused by Agent Orange or were instead simply the normal illnesses that would occur in any large group of people over a long period of time.

Transferred From the V.A.

The study has been repeatedly delayed by political and scientific problems. It was first assigned to the Veterans Administration, but after veterans' groups charged that the V.A., which would have to pay their health benefits, could not be impartial, the study was reassigned to the Centers for Disease Control. There it has been repeatedly delayed by difficulties in finding a way to determine which troops had been exposed to Agent Orange.

Those difficulties were explored in a small "validation study" of more than 600 men, just completed by the centers. The study sought to determine if military records of the movements of ground troops and of the locations of herbicide spraying missions could be used to pick out the military personnel most likely to have been exposed to Agent Orange, so that those people could then be examined for adverse health effects.

Using newly devised measurement technologies, scientists compared the levels of dioxin, the most dangerous contaminant of Agent Orange, in the blood of ground troops who were believed, on the basis of records, to have the greatest likelihood of exposure in Vietnam, with the blood levels of veterans who did not serve in Vietnam.

The two groups were virtually identical. According to nearly complete results presented last week, both groups had a median blood dioxin level of 3.8 parts per trillion, which falls within the range generally expected in the American public. Only three men had a dioxin levels above 20 parts per trillion, the upper end of the normal range, and even their levels were not considered very high by scientists.

A 'Perceptual Gap'

Two of the scientists involved in the study have measured their own blood dioxin at 6 parts per trillion and 4.8 parts per trillion. The highest level ever reported, after a chemical accident at Seveso, Italy, was above 1,800 parts per trillion.

The scientists calculated, on the basis of dioxin measurements in Air Force chemical personnel taken in 1982 and 1987, that dioxin has a "half-life" of about seven years and would still be found today at elevated levels in the blood of individuals exposed to the herbicide in Vietnam in the late 1960's.

The Centers for Disease Control warned in a provisional report of its findings that there is a "perceptual gap" between the beliefs of the veterans and the realities of what happened to them in Vietnam.

The conclusion that the study cannot proceed as planned was endorsed by most members of the Agent Orange Advisory Panel of the Congressional Office of Technology Assessment at a meeting last Thursday. The panel is monitoring the study on behalf of Congress. Instead of classifying the exposure of ground troops to Agent Orange as high, medium and low, as the Centers for Disease Control did, "you almost want to say low, lower and lowest," said Richard Remington, chairman of the panel who is vice president for academic affairs at the University of Iowa.

Another panelist, Lewis Kuller, an epidemiologist at the University of Pittsburgh, urged that "we should abandon this craziness" of trying to do a study that amounts to "a great fishing expedition" without knowing who was exposed or what diseases to look for.

Various panelists suggested that a limited number of troops, perhaps 20,000 to 60,000 from among the 2.9 million who served in Vietnam, might have received significant exposure to Agent Orange. But the C.D.C. argues that except for a few thousand people who regularly sprayed the chemicals, no practical means exists to find most of those with higher exposures. Testing all Vietnam veterans' blood would be prohibitively costly and would overwhelm laboratory capacity, Federal scientists say.

The panel's judgment is presented as advice to the Office of Technology Assessment, which must now frame its own recommendation to Congress.

Earlier this month the scientific panel of the Reagan Administration's Agent Orange Working Group also agreed that the study could not proceed as planned, according to Carl A. Keller, a member of the panel and its former chairman.

"The general evidence is that there was not massive exposure in Vietnam," he said. "Nobody is saying that nobody was exposed. But the kind of massive exposure of great concern to all Vietnam veterans does not seem to have occurred." The panel's advice to abort the study is expected to be influential as the Administration makes a final decision, perhaps at the level of the Domestic Policy Council, on its position.

The WASHINGTON POST
Pg A-6, TUESDAY, SEPT 1, 1986

Agent Orange Study Lacks Subjects

Associated Press

ATLANTA, Aug. 31—Federal health officials say they can't find enough Vietnam veterans who were exposed to Agent Orange to do a scientifically valid study of the herbicide's effects on humans.

However, Dr. Vernon Houk, director of the Center of Environmental Health at the national Centers for Disease Control, said any decision to terminate studies of Agent Orange in veterans would have to be made "at a higher level."

Dr. Stephen Thacker, assistant director of the center, in a recent study found levels of Agent Orange in 519 veterans were "well within the range we've found in the general population, who have had no known exposure."

Houk said, "We looked at three different kinds of exposure: short-term, long-term, and exposure from being in an area of Vietnam where the herbicide was used. In none of these groups was there any difference in the level of Agent Orange in the blood."

Agent Orange, used in Vietnam between 1965 and 1970 to defoliate the jungle, contains dioxin, which causes cancer in some animals.

Tests of 444 Vietnam Veterans Find Average Dioxin Levels

ATLANTA, July 24 (AP) — Preliminary results of a study of 444 Vietnam veterans who may have been exposed to the herbicide Agent Orange show that very few veterans have unusually high levels of dioxin, the potentially harmful chemical in the herbicide, researchers said today.

Blood tests were performed on 444 combat veterans who served in areas where Agent Orange was sprayed. The chemical was used widely in Vietnam to destroy jungle plant cover that concealed enemy troop movements from the air.

Only one of the veterans tested showed a dioxin level higher than the expected range for Americans with no known exposure, the Centers for Disease Control reported. That veteran showed a dioxin level of 25 parts per trillion. The expected range for Americans with no known exposure is from zero to 20 parts per trillion, researchers said.

The report said the median level of dioxin exposure in the veterans was 3.8 parts per trillion, meaning that half the veterans had higher levels and half had lower levels. This was virtually identical to the median level of 3.9 parts per trillion found in the blood of people of the same general age who did not serve in Vietnam.

Researchers have not determined the exact level at which exposure to dioxin causes health problems in humans.

Researchers emphasized that the report drew no conclusions on the health effects of dioxin and did not mean that no Vietnam veterans were exposed to harmful levels of dioxin.

"This study really wasn't designed to do that," said Dr. Steve Thacker, assistant director for science at the agency's Center for Environmental Health.

The blood tests are the result of a law passed by Congress in 1979 amid bitter dispute over whether some veterans suffered health damage from exposure to Agent Orange.

The veterans whose blood was tested served in at least one of 65 battalions from October 1966 to March 1969. The results made public today involved veterans who served in the military region round Saigon.

The Centers for Disease Control, based here, asked 979 veterans to participate, of whom 665 gave blood for the study. Today's results are based on the blood samples from the first 444 veterans tested, as well as samples from 75 people who did not serve in Vietnam, officials said.


B

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

May 7, 1987

Dear Mr. Newman:

Recently I had the opportunity to discuss some of the research issues associated with Agent Orange with your Deputy, Robert Raclin and Dr. Peter Beach, Director, Office of Veteran Affairs and Military Laison. I was pleased to learn of the fine progress made by your Agent Orange Working Group.

It appears that late this summer the results of three major research programs will be ready for publication and release. These are the Air Force Health Study, the Veterans Administration's Mortality Study and the Morbidity Phase of the Centers for Disease Control's Vietnam Experience Study. The culmination of such significant studies provides an opportunity to jointly evaluate the government's progress in understanding the possible effects of Agent Orange. This also is the time to look at all the available information and consider appropriate follow-on activities.

Accordingly, I would like to request that you convene a special session of the Agent Orange Working Group Principals and the Principal Investigators of these three health studies so we all shall have an opportunity to receive in-depth briefings on the studies and participate in developing future research plans. This meeting will also provide the opportunity for Dr. William Graham, Science Advisor to the President, to get an overview of the important results of these health studies. Conversations with Ralph Bledsoe, OPD, Stephen Galebach, DOJ, and Deborah Steelman, OMB, indicate their interest in participating.

We are pleased to make available Room 476, of the Old Executive Office Building, as a meeting place for 9:45 a.m. on June 1, 1987, if this will be convenient.

Sincerely,

Beverly Berger

Beverly J. Berger
Assistant Director

Honorable Don M. Newman
Under Secretary of Health and
Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

THE UNDER SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

August 27, 1987

The Honorable Edwin Meese
Chair Pro Tem
Domestic Policy Council
The White House
Washington, D.C. 20500

Dear Mr. Meese:

As you are aware, this Department has the lead in the Agent Orange Working Group, which reports to the Domestic Policy Council. Members are limited to the Department of Defense (DOD), the Office of Management and Budget (OMB), and the Veterans Administration (VA).

In January 1979, Congress enacted P.L. 96-151, which directed the VA to investigate the health effects of Agent Orange. The authorization was expanded in November 1981 by P.L 97-72 to include other factors of the Vietnam Experience. Congress called for the transfer of Agent Orange studies to the Centers for Disease Control (CDC), which in turn proposed three separate, but complimentary epidemiological studies of the health of Vietnam veterans, in September 1982:

1. A Vietnam Experience study which is nearing completion;
2. A Selected Cancer study which is due for completion in mid-1989; and
3. The Agent Orange Exposure study which has proved far more difficult. The problem has consistently been that of identifying exposed versus non-exposed ground troops.

In repeated attempts, the Science Panel of the AOWG, the Advisory Committee of Office of Technology Assessment, and a sub-panel of the Science Panel chaired by Office of Science Technology Policy, were unable to endorse any exposure index based on military records. All three groups recommended that a method to verify exposure must be attempted before a scientifically valid Agent Orange Exposure Study could be performed.

A new method using blood sera was developed by CDC to establish body burden of dioxin in order to indicate past exposure to dioxin-containing substances such as Agent Orange. A study of Vietnam veterans to verify exposure based on

military records has recently been completed by CDC. From these results, it has been concluded, that military records cannot support a valid epidemiological study of the health effects of Agent Orange exposure on Vietnam veterans.

Comparisons of exposed ground troops, non-exposed ground troops and veterans who did not serve in Vietnam, reveal almost identical dioxin levels in their blood sera (3.8-3.9 parts per trillion). Exposure was determined from extensive review of military records as well as self-assessments of exposure by the veterans themselves. A study of Air Force Ranch Hand Volunteers who were known to have been exposed to Agent Orange is now well underway and may provide leads for other studies.

The Science Panel's August 14, 1987 report to me as chair of the AOWG (copy attached) unanimously concluded that the Agent Orange exposure component of the Vietnam Veterans Health Studies currently underway at the Centers for Disease Control cannot be scientifically conducted. The members of the AOWG concur in this conclusion.

I advise you to recommend to the Domestic Policy Council that the Agent Orange exposure study be cancelled.

We are prepared to inform Congress and veterans service organizations through appropriate channels if you deem this advisable.

Please call me should you require additional information.

Sincerely,

Don M. Newman
Under Secretary
Chair Pro Tempore
Domestic Policy Council
Agent Orange Working Group

Enclosure

cc: Gary Bauer DPC/HPWG
Dr. Ralph Bledsoe, DPC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date August 13, 1987

From Ronald W. Hart, Ph.D.
Chairman, AOWG Science Panel

Subject Recommendation to Cancel the Vietnam Veteran Agent Orange Exposure Study

To The Honorable Don M. Newman
Chairman, Agent Orange Working Group / Domestic Policy Council

Following the Science Panel review of CDC's TCDD serum level study, it is the unanimous recommendation of the AOWG Science Panel that the Agent Orange Exposure Study, the cohort epidemiological study of Vietnam veteran ground troops exposed to Agent Orange, can not be scientifically conducted and therefore should be canceled.

The recent report by the CDC at the AOWG Science Panel on August 6, 1987 entitled "Comparison of serum levels of 2,3,7,8-TCDD with indirect estimates of Agent Orange exposure in Vietnam veterans" documented that none of the various methods, including a self-perception of exposure, were able to identify Agent Orange exposed and non-exposed Vietnam veterans. In addition, the TCDD serum level comparisons between the Vietnam Veteran and the non-Vietnam Veteran controls indicated that there was no difference in TCDD serum levels (about 3.8 ppt) between these two groups.

The TCDD half-life study of the Ranch Handers indicated a 7-8 year median half-life in this group of Vietnam veterans. This long half-life value coupled with the 3.8 ppt serum level in the CDC AO Exposure Study indicates that little exposure occurred in this group of ground troops in Vietnam. These ground troops were selected from military records as the most likely individuals exposed from the battalions which were most heavily potentially exposed from the area of Vietnam that had the highest amounts of Agent Orange used and from the years when its use was the highest.

All of this data taken together provides solid scientific data that a valid cohort Agent Orange Exposure Study can not be conducted.

Ronald W. Hart, Ph.D.

cc: Dr. Peter Beach

THE WHITE HOUSE

WASHINGTON

September 15, 1987

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM: RALPH C. BLEDSOE Ralph Bledsoe

SUBJECT: Meeting on September 16, 1987

Attached are an agenda and materials for the Domestic Policy Council meeting scheduled for Wednesday, September 16, 1987 at 2:00 p.m. in the Roosevelt Room. The topics to be discussed include Family and AIDs.

AIDS

The Health Policy Working Group will report on the prevalence survey to be done by the Public Health Service. Planning for this effort has been delayed because of disagreements over the scope and types of surveys to be conducted. The Council will be asked for comments and approval of the approach to be presented. A paper describing the approach is attached. If time permits, the working group will also discuss AIDS policies pertaining to Federal agencies and employees.

Family

Gary Bauer, who chaired the Council's Family Working Group, will describe the recent Executive Order on the Family. A copy of the Executive Order is attached.

THE WHITE HOUSE

WASHINGTON

DOMESTIC POLICY COUNCIL

Wednesday, September 16, 1987

2:00 p.m.

Roosevelt Room

AGENDA

1. AIDS Testing -- Secretary Bowen

   Gary L. Bauer
   Assistant to the President for
   Policy Development
   The White House

2. Family -- Gary L. Bauer
   Assistant to the President for
   Policy Development
   The White House

THE WHITE HOUSE

WASHINGTON

September 15, 1987

MEMORANDUM FOR THE DOMESTIC POLICY COUNCIL

FROM THE HEALTH POLICY WORKING GROUP

SUBJECT The National Epidemiological Survey
To Determine The Extent Of HIV Infection

In response to the President's decision of May 27, 1987, the Department of Health and Human Services has proposed to carry out the national epidemiological survey with a program composed of three, discrete, processes:

1. Statistical Survey -- The Centers for Disease Control, and the Center for Health Statistics, will survey all raw data which shall have been accumulated by November 30, 1987, and analyze these data statistically in order to provide the best possible estimate of the number of infected individuals in this report. This will provide the base line on which public policy decisions may be made.

2. Continuing Targeted Survey -- This survey will continue certain current programs, and initiate new ones, all of which are to survey the level of infection in targeted groups of individuals known to be at high risk. This will provide information on incidence (new infection), and on the dynamics of the virus. Because the targeted groups are not representative of the American public, they will not give us information on prevalence (the extent of infection).

3. National Household Survey -- This will be performed by an outside contractor, and will include the largest possible sample size, in order to provide the most accurate estimate of the extent of the infection. This will update the statistical survey due on November 30, 1987.

These surveys will be performed with as much speed as may be consistent with accuracy. The Health Policy Working Group will work with HHS to identify every possible roadblack which impedes these processes, and will remove, or recommend the removal of the same, to this Council.

A draft of the HHS proposal is attached to this memorandum.

DRAFT

DATE: September 14, 1987

FROM:

TO:

SUBJECT: Plan to Determine the Incidence, Prevalence, and Risk Factors for HIV Infection in the United States

I. Background

In June 1987, the President directed HHS "to carry out a comprehensive program to determine the nationwide incidence of the HIV virus and to predict its future occurrence and to initiate epidemiologic studies to determine the extent to which the HIV virus has penetrated the various segments of our society." Accurate information on HIV infections is needed at the local, State, and national levels in order:

- To determine the number of persons currently infected with HIV in the United States (prevalence). The number infected and asymptomatic far exceeds those with AIDS disease and AIDS related complex.
- To determine the number of new infections occurring each year in the United States (incidence).
- To determine the relative importance of various modes of transmission (e.g., the extent of heterosexual transmission).
- To identify the size and location of populations at greatest risk of infection.
- To appropriately target prevention efforts, including testing, counseling and education/information.
- To evaluate the impact of prevention efforts upon HIV transmission.
- To project the number of HIV infections and cases of AIDS in the future in order to determine the needs for health-care and social services.

On July 7, 1987, 40 CDC staff and consultants met to discuss approaches, design, and implementation of a national HIV prevalence survey to estimate the <u>overall prevalence</u> of HIV infection in the United States. Major consensus points from the discussions were as follows:

- o A national household survey to determine the overall prevalence of HIV infection is technically feasible. However, this type of survey may not reach a high proportion of certain high risk groups (e.g., IV drug users not living in sampled households) and other high-risk persons may refuse to cooperate by not allowing surveyors to draw blood. Thus, the survey may underestimate the prevalence of infection in persons who perceive they may be infected.

  - An optimal survey should provide estimates for the total population, for males and females, for broad age groups, for whites, blacks and hispanics and for major geographic areas.

  - The survey would be household-based, supplemented by smaller surveys of other populations not reachable through households (particularly IV drug abusers who are homeless, the institutionalized and the imprisoned).

- o Risk factor data (e.g., sexual orientation and behaviors, IV drug use, etc.) should not be included in the study.

  - It is unlikely that valid risk behavior data (sexual orientation, IV drug abuse, etc.) can be gathered as part of the survey since such questions may have a negative impact on participation by persons in high risk groups. Also, persons at increased risk may fail to provide accurate risk information in a household setting where several persons may be present at the time of the interview.

  - A misclassification of risk (with no way to validate) would overestimate the level of infection in the "low risk" population (by classifying persons as "low risk" when they are really at high risk). This would confuse, rather than clarify the extent to which HIV has spread outside recognized risk groups.

- o In order to achieve maximal public participation, the survey must assure anonymity and the perception of anonymity to the extent possible.

- o Procedures should be in place to allow participants to obtain the results of the HIV antibody test (e.g., the use of code name or number given by the respondent).

- o Pilot studies (pretest) should be undertaken prior to conducting a major national survey.

- A large survey necessarily involves pretesting of methods before launching the actual survey. Pilot studies, in different geographical areas, are essential to test feasibility and the best means of assuring high levels of participation. A national HIV seroprevalence survey will require new approaches (anonymous blood collection, logistics unfamiliar to most survey organizations, motivation and public participation in an emotionally charged subject area, credibility of anonymity procedures, etc.).

- Many of the issues in the pilot studies would have broader applicability to future studies of special populations.

o The national survey of 50,000 or larger including developmental work and pilot studies would take a minimum of 2 to 2 1/2 years to complete.

- At least 4 months will be required for the contracting process.

- In order to have a reasonable study proposal developed, potential contractors must be allowed a minimum of 2 months to prepare a proposal.

- Following award of a contract, approximately 11 months would be needed for the pilot studies (including planning, training, trials, analysis, and readjustments). An additional 12 months minimum would be required for the actual household survey and the initial estimation. Detailed analysis of the data should take place concurrently, to the extent possible.

o In order to assure trust and maximum participation of subgroups most likely to be infected, representatives of key groups (especially homosexual men, and black and Hispanic minorities) must be involved in the development and implementation of the survey.

To meet the President's directive of carrying out a comprehension program to determine the national incidence of AIDS virus infection and to determine the prevalence of infection in the various segments of our society, we propose a) a nationwide seroprevalence survey and b) a comprehensive family of surveys. Because of the unknown influence of factors which may affect the validity of a nationwide survey we propose that pilot studies in two or more metropolitan areas be undertaken before the national survey is initiated in the field. A description of the surveys follow.

A. Nationwide seroprevalence survey

A household-based survey of 50,000 participants is proposed to be conducted by an outside contractor selected by a competitive bidding process. Appropriate pilot studies would be incorporated in the developmental phase during the first year after the contract is awarded.

The minimum range of prevalence estimates based on a sample size of 50,000 is illustrated in Tables 1 and 2. The relative size of sampling error depends on the level of overall participation in the survey (preliminary data from the National Center for Health Statistics (NCHS) Household Interview Survey suggests the participation level may be approximately 65%) as well as the observed total prevalence of infection. Because of the sensitivity of the data to be collected, lower participation by persons with risk factors or by those who know they are infected with HIV can be anticipated and its extent cannot be measured. This will result in response bias. Response biases and other nonsampling errors may be several times larger than the sampling error.

Participation rates and sampling and response biases should be carefully analyzed during pilot studies and adjustments made to predict and deal with them during the national survey. The sample size of 50,000 participants would provide the most precise national estimates with more limited precision for estimates in women, social/ethnic groupings and geographic subunits.

Additional FTE's and cost (FY 88): 5.25, 5-10 million; (FY 89) $20 - 25 million.

Table 1
Range of Prevalence Estimate by Subgroup
(assumes 75% participation) with sample size of 50,000

	Range of Estimate, in Millions (95% confidence intervals)				
Observed Total Prevalence[1]	All Persons	Males[2]	Females[2]	White[3]	Black[3]
2,500,000	2.28-2.72	1.79-2.21	0.39-0.61	1.32-1.68	0.53-0.72
1,500,000	1.32-1.68	1.03-1.37	0.22-0.38	0.76-1.04	0.29-0.46
1,000,000	0.86-1.14	0.67-0.93	0.13-0.27	0.49-0.71	0.19-0.31
500,000	0.40-0.60	0.31-0.49	0.04-0.16	0.22-0.38	0.08-0.17

1 if observed total is lower, confidence intervals widen

2 assumes 80% of infections are in males, 20% in females; range would be wider for females if less than 20% of infections occur in females

3 assumes distribution of infection is proportional to distribution of AIDS cases

Table 2
Range of Prevalence Estimate by Subgroup
(assumes 50% participation)

Observed Total Prevalence[1]	Range of Estimate, in Millions (95% confidence intervals) All Persons	Males[2]	Females[2]	White[3]	Black[3]
2,500,000	2.23-2.76	1.74-2.26	0.37-0.63	1.28-1.71	0.51-0.74
1,500,000	1.29-1.71	1.01-1.39	0.20-0.40	0.74-1.06	0.29-0.46
1,000,000	0.82-1.18	0.64-0.96	0.12-0.28	0.46-0.74	0.18-0.32
500,000	0.38-0.62	0.28-0.52	0.03-0.17	0.21-0.40	0.07-0.18

1 if observed total is lower, confidence intervals widen

2 assume 80% of infections are in males, 20% in females, 60% white, 25% black; range would be wider for females if less than 20% of infections occur in females

3 assumes distribution of infection is proportional to distribution of AIDS cases

A sample size of 50,000 is proposed, which would yield reasonable precision (at least in terms of sampling error) on infection levels for the overall population, for men and women and for whites and blacks.

If a much larger size is selected, increasing both the cost and the time necessary for the survey, more precise date could be available by further subgrouping (eg. black females, males in the Northeast, Hispanics in the Southwest, sex by age group, etc.)

Timetable. The following outlines the time requirements for contract development, pilot studies, and the conduct of the national household based seroprevalence survey.

The contract process will begin the week of September 14, 1987. Following award of the contract, 12 months will be devoted to conducting pilot studies. Using the knowledge gained in the pilot survey a national survey will be designed and implemented, if indicated. The projected completion data is December 30, 1989.

6

Timetable

	Date Completed
A. PROTOCOL DEVELOPMENT (14 days)	9/28/87
B. CONTRACTING PROCESS (135 days)	
o Initiate Privacy Act Clearance	9/30/87
o RFC Development	10/2/87
o Release of Solicitation	10/9/87
o Proposal Preparation by Prospective Contractors (60 days)	12/9/87
o Evaluation by Government (concurrent)	
--Technical evaluation (14 days)	
--Cost evaluation (21 days)	12/30/87
o negotiations	1/13/88
o EEO Clearance (14 days)	1/13/88
o Best and Final Review and Selection (14 days)	1/27/88
o Legal Review and Award (7 days)	2/3/88

C. PILOT STUDIES (11 months beginning 2/3/88)

- Develop study design, survey instruments and consent form (30 days) — 2/3/88
- Human subject clearance (14 days) — 3/17/88
- OMB Clearance (7 days) — 3/24/88
- List sample (2 months) — 5/24/88
- Recruit and train teams (2 months) — 5/24/88
- Conduct trial surveys, sequentially (6 months) — 11/30/88
- Complete design for national survey — 12/30/88

D. NATIONAL SURVEY (16 months beginning 8/30/88)

- Recruitment and training (4 months) — 12/30/88
- List sample (4 months) — 12/30/88
- Final survey instrument (1 month) — 1/30/89
- Conduct survey (6 months) — 7/30/89
- Analyze specimens (1 month) — 8/30/89
- Preliminary analysis and report (4 months) — 12/30/89

II. Comprehensive Family of Surveys

In order to obtain complete estimates of the extent of the HIV problem nationally, PHS will conduct a comprehensive family of surveys. HIV prevalence data from the national survey described above will be compared with national data obtained annually from 700,000 military recruits, 7,000,000 blood donations, and 60,000 Job Corp entrants (see below). To provide more comprehensive data, extensive additional surveys will be conducted in sentinel hospitals, sexually-transmitted disease clinics, drug treatment centers, and family planning clinics in 30 standard metropolitan statistical areas (SMSA's). These areas will be chosen carefully to represent high, moderate, and low prevalence communities by using known data on reported cases of AIDS and prevalence of HIV infections in military recruits and blood donors. The 20 areas with highest rates will survey more than one STD clinic each. Those metropolitan areas selected for pilot studies for the national survey will be among the 30 SMSA's targeted for extensive surveys.

These surveys are the components of a comprehensive program. Some are already underway while others are in planning stages. Taken together, they will provide the information needed to best measure the prevalence and incidence of HIV infection in the United States as well as the focused data needed for good public health management..

1. Sentinel Hospital Based Surveillance System -- By May 1988, expand sentinel hospital surveillance system to include 30 metropolitan areas. Forty hospitals each will be testing 300 anonymous "non-AIDS" patients per month (7 hospitals will be providing seroprevalence results by November 1987).

Thus far, with 7,545 specimens tested, representing an average of 7 months' partial to full sampling per hospital, 20 infections were detected, giving an overall prevalence of 2.8 per 1,000. Prevalence ranged by hospital from 1.0 to 6.5 per 1,000. The rate per 1,000 for males was 4.0, and for females 1.3. The rate per 1,000 whites was 1.9 and for blacks 6.1.

Total survey target: 144,000 per year.

Additional FTEs and cost (FY-88): 3 FTEs, ($4 million requested in Amendment to President's Budget)

2. Survey of Sexually Transmitted Disease Clinics -- By November 1987, initiate surveys of both HIV prevalence and risk behaviors in patients attending sexually-transmitted disease (STD) clinics in 10 SMSA's throughout the country (1,000 patients surveyed per clinic per year). Up to 100 STD clinics in 30 SMSA's will be providing seroprevalence data by May 1988. Repeating these surveys annually at the same sites will allow the estimation of incidence (new infections) and for monitoring the prevalence and incidence of heterosexual infection.

Total survey target: 100,000 per year.

Additional FTEs and cost (FY-88): 6.5 FTEs, $ 10 million

3. Survey of Drug Abuse Treatment Clinics -- Expand HIV seroprevalence surveys in drug abuse treatment clinics (200 patients surveyed per clinic) from 15 SMSA's currently to 30 SMSA's by May 1988 (with Alcohol, Drug Abuse and Mental Health Administration [ADAMHA]). Seroprevalence studies will monitor the prevalence and incidence of HIV infection in these populations throughout the country.

Total survey target: 10,000 per year.

Additional FTEs and cost (FY-88): 0.5 FTEs, $3 million, CDC; additional FTEs at ADAMHA

4. Survey of Family Planning Clinics -- Obtain seroprevalence data from 2 family planning clinics by November 1987. Initiate HIV seroprevalence surveys in family planning clinics in 30 SMSA's by May 1988 (with Office of Population Affairs). This survey will monitor prevalence and incidence of HIV infection in these populations of women 15-44 years of age (1,000 patients per clinic each per year).

   Total survey target: 20,000 per year (up to 50 clinics), initially; 50,000 per year once enrollment is complete.

   Additional FTEs and cost (FY-88): 4 FTEs, $ 5 million

5. Survey of Childbearing Women -- Continue/expand surveys of HIV antibody in newborns through surveys of phenylketonuria (PKU) screening program filter paper specimens (with NIH and State of Massachusetts currently). This survey will measure the prevalence of HIV infection in women delivering live births (since the antibody detected in the newborn is passively transferred from the mother). Plans are now in progress for surveys to be continued and expanded in at least six States.

   In Massachusetts, the first place where a preliminary State-wide survey has been done, 2.3 of every 1000 specimens tested have been found positive.

   Total survey target: 300,000 minimum per year.

   Additional FTEs and cost (FY-88): 3.5 FTEs, $4 million

6. Survey of Military Recruit Applicants -- Continue to monitor prevalence rates in military recruit applicants (with Department of Defense (DOD) by specific demographic subgroup and geographic area and over time to compare with data from surveys described in 1-5 above. Data on risk factors for infection, obtained through follow-up interviews of HIV positive recruits, will be available by May 1988. At the same time, incidence data will be determined by DOD for active duty personnel who have been serologically tested more than once.

   For the first 21 months, with over 1,000,000 tested, the level of infection is 1.5 per 1,000 (1.1 per 1,000 when adjusted by sex). Infection level increases with age, peaking in the 30's, and varies by sex (males more likely to be infected than females), race/ethnicity (blacks and Hispanics more likely to be infected than whites, as well as by geographic region). No significant increase or decrease in level of infection has been observed over 21 months for the group as a whole, or when analyzed by age group, sex, race/ethnicity or geographic region.

   In the two limited follow-up interview studies underway thus far, approximately 90% of the seropositive recruits have acknowledged traditional HIV risk factors, primarily homosexual contact.

Total survey target: 700,000 military recruit applicants per year.

Additional FTEs and cost (FY-88): 0.75 FTE

7. Survey of Job Corps Applicants -- Monitor prevalence and incidence of HIV infection in disadvantaged youths, aged 16-21, through analysis of data from testing program conducted by the Job Corps, Department of Labor. Summary seroprevalence data from 8 months of testing will be available in November, 1987. Specific seroprevalence data by age, sex and race will be available by May 1988.

   Thus far, with over 25,000 tested, the overall level of infection for incoming Job Corps members has been 3.3 per 1,000 tested.

   Total survey target: 60,000 applicants per year.

   Additional FTEs and cost (FY-88): 0.5 FTE

8. Surveys of Incidence, Prevalence, and Risk Factors in United States Blood Donors -- Continue to monitor infection rates in American Red Cross blood donors and expand surveillance activities to other blood collection agencies; monitor infection rates over time and by specific geographic area to compare with results of other surveys (1-8). Seroprevalence data will be available on 12,000,000 donations by November 1987.

   Risk behaviors associated with HIV infection will be assessed and monitored in this highly self-deferred population (i.e., excludes most homosexual men, IV drug abusers, and hemophiliacs) in order to monitor current trends in mode of HIV transmission, especially heterosexual transmission. Seroprevalence data according to risk factors will be available by May 1988. Data on incidence of HIV infection will be obtained from tests on repeat donors.

   The level of infection in Red Cross donors nationally has declined from 0.35 per 1,000 in early 1985 to the current 0.14 per 1,000. This decline is due to the progressive elimination of infected individuals from the pool of repeat donors. First-time donors have a level of 0.4 per 1,000.

   Total survey target: 6 million donors per year currently for seroprevalence monitoring, targeted for expansion to 9 million by 1988.

   Additional FTEs and cost (FY-88): 1.25 FTE, ($2 million requested in Amendment to President's Budget)

9. Survey of U.S. Prisons -- Initiate anonymous testing in a sample of incoming prisoners in 10 state prison systems by May 1988 in collaboration with the National Institute of Justice.

Total survey target: 5,000 prisoners per year

Additional FTEs and cost (FY-88): 0.25 FTE, $ 0.7 million

10. Serosurveys among college students.

    By May 1988, seroprevalence will be determined in 2,000 - 3,000 randomly selected students seen for other routine health exams at each of 6 colleges in scattered geographic areas in the United States.

    Total survey target: 12-18,000 students per year.

    Additional FTE's and costs. 0.5, $0.3 million

11. Incidence and prevalence of HIV infection in cohorts of homosexual men -- PHS is funding prospective followup studies in 8 cohorts of homosexual men in 7 cities in the United States. The incidence rate of new infections is continuously monitored in each of these cohorts with comparisons made by age, race, city and reported behaviors.

12. NHANES -- The third National Health and Nutrition Examination Survey (NHANES-III) is scheduled to begin in September, 1988 after extensive developmental work. The objective is to provide extensive information on the health and nutritional status of the U.S. population. NHANES is based on household interviews, direct physical examinations and clinical and laboratory tests administered to a representative sample of persons.

    Currently the survey proposal includes anonymous HIV testing and is under review at the Office of Management and Budget. Pilot testing is scheduled to begin in September, 1987. NHANES will involve a randomly selected population-based sample of 60,000 persons two months of age and older with over-sampling of the black and Hispanic populations. From past experience, about 45,000 persons are expected to participate in the clinical examinations, which include a variety of blood tests designed to measure health and nutritional status.

    Because of the time-consuming nature of such an examination survey, data collection will take place in two phases over a period of six years. Results from the first phase will be available in 1991. Information from NHANES-III will facilitate interpretations of the ongoing, more specific surveys outlined above and will provide an estimate of the overall level of HIV infection in the country.

13. Health Interview Survey - By November 30, 1987, data will be available from 12,000 persons on knowledge of AIDS and AIDS virus infections. Depending on public acceptance determined from pretesting, appropriate questions, information on self-reported risk factors will be available in May 1988.

14. Clinical Specimens - The feasibility of testing sera from anonymous "non-AIDS" patients from laboratories serving private physicians is under investigation. Such sera may be particularly useful in those SMSA's where data may not otherwise be available.

Table 3
HIV Serosurveys/studies underway or planned (11/30/87 - 12/39/89)

	Data available or projected accomplishments		
Surveys/studies	11/30/87	5/31/88	12/30/88
National Seroprevalence	RFP out	Pilots begun	Pilots completed National survey begun*
Family of Surveys			
1. Sentinel Hospital	7 SMSA'S*	30 SMSA's	continued
2. Sexually transmitted disease clinics	10 SMSA'S	30 SMSA's	continued
3. Drug abuse clinics	15 SMSA'S	30 SMSA's	continued
4. Family Planning clinics	2 SMSA'S	30 SMSA's	continued
5. Childbearing women/ newborns	1 State	6 States	20 States
6. Military recruits	24 months (1,800,000)	30 months age/race/sex	continued
Military active duty		incidence	continued
7. Job Corps	8 months (40,000)	12 months age/race/sex	continued
8. Blood donors	24 months (14,000,000)	30 months age/race/sex risk factor incidence	continued
9. Prisons	1 State/ Federal	10 States continued	continued
10. College students		6 colleges	expand
11. Homosexual/biosexual Cohort	7 SMSA's incidence	10 SMSA's	continued
12. NHANES	pilot begun	pilot continued	survey underway***
13. HIS	knowledge about AIDS	knowledge and self-reported risk factors	continued
14. Clinical specimens	under investigation		

*Projected completion data 12-30-89
**Standard Metropolitan Statistical Area (SMSA)
***Results of first phase willb be available in 1991

Table 4
Summary of additional funds for HIV serosurveys/studies (FY 88)

Surveys/studies	Funds ($ millions)	FTE's
Total needs	48 - 58	26.0
1. National seroprevalance	25 - 35	5.25
2. Sentinel hospitals	0	3
3. Sexually transmitted disease clinics	10	6.5
4. Drug abuse clinics	3	0.5
5. Family planning clinics	5	4
6. Childbearing women/ newborns	4	3.5
7. Military recruits	-	0.75
8. Job Corps	-	0.5
9. Blood donors	-	1.25
10. Prisons	0.7	0.25
11. Colleges	0.3	.50

III. Forecasting

Models are being developed and utilized to project the future incidence of AIDS and HIV infection and to assess the potential impact of prevention efforts, vaccines and therapies.

Modelling efforts have already served to focus epidemiologic inquiry by highlighting key factors which influence infection levels in a community. Dr. Peter Denning has described the construction of a mathematical model for the spread of a sexually transmitted disease as encompassing five critical steps.

1. Define the states of the system, which are the possible combinations of population classes and disease stages. The population is divided into classes that reflect sexual habits of their members. The progress of the disease is characterized as a series of stages with associated infectiousness and death rates.

2. Define the rates of flow between the states; for example, the rate of formation of pairs of partners and the rate of transmission of the disease from an infected to an uninfected partner. The flow rates are parameters that must be measured or estimated before the model can be used.

3. Associate a variable with each state, representing the number of entities in that state; for example, the number of single heterosexuals or the number of married couples.

4. Construct a set of equations that specify the increases and decreases in the variables due to changes in neighboring states.

5. Evaluate the equations to trace the evolution of the variables over time.

Methods for developing models include:

1. Empirical or data-driven. These models capture information on observed increases in the rate of disease and assume that these increases will continue on into the future. These statistical models are most useful for projecting short term (1 to 5 year) trends. As the projections are extended farther

out, the confidence bounds become wide. Empirical models may not accurately reflect the processes generating the disease, but they may serve as approximations. The PHS estimate (May 1986) of 270,000 diagnosed AIDS cases by the end of 1991 is based on an empirical model which has accurately predicted the increase in AIDS cases to date (Figure 1).

Epidemiologic models (including mathematical, deterministic and computer simulation models). These models not only use empirical information on the spread of infection and disease, but also information on the size of populations at risk, interactions between groups quantitative risk behaviors, transmission rates of infection, incubation period, survival rates, and other factors. (Table 5)

CDC is continuing to develop empirical and time-series models for short-term projections of AIDS incidence. A contract will be awarded by September 30, 1987 for the development of mathematical models for transmission of HIV infection.

NIDA (ADAMHA) held a workshop in August, 1987 to select methods for modelling HIV transmission among IV drug users.

The National Academy of Science/Institute of Medicine is conducting a workshop October 15-17, 1987 to discuss strategies, data needs, and priorities for methods to make projections.

The Johns Hopkins School of Public Health has announced a modelling workshop in November 1987 to discuss methods and data needs.

University and corporate scientists known to be involved in AIDS modeling include:

- Princeton University, Dept. of Biology (Dr. Robert May)
- Johns Hopkins School of Public Health (Dr. Ron Brookmeyer)
- University of Georgia, Dept. of Entomology (Dr. John Pickering)

- Harvard University, School of Public Health (Dr. Stephen Lagakos)
- Imperial College, London, England (Dr. Roy Anderson)
- University of Tubingen, West Germany (Dr. Klaus Dietz)
- Los Alamos National Laboratories
- Rand Corporation
- AIDS Spread Simulation Project (ASSP), Karlsborg, Sweden (Dr. Michael G. Koch)

Table 5
Factors to be Considered in Epidemiologic Models for HIV infection and AIDS

A. Size of populations at-risk for infection and quantitative information about at-risk behavior

1. Homosexual/bisexual men
   a. Geographic distribution
   b. Frequency of sexual contact by type of contact
   c. Duration of relationships

2. Intravenous drug users
   a. Geographic distribution
   b. Frequency of needle sharing

3. Persons with hemophilia or other coagulation disorders

4. Heterosexuals
   a. Rates of contact with others at risk
   b. Duration of relationships

5. Transfusion recipients

B. Efficiency of HIV transmission

1. By type of homosexual contact

2. By needle sharing

3. By type of heterosexual contact

C. Incubation time (time from infection until onset of disease)

1. AIDS

2. Other serious HIV morbidity

3. Possible role of cofactors

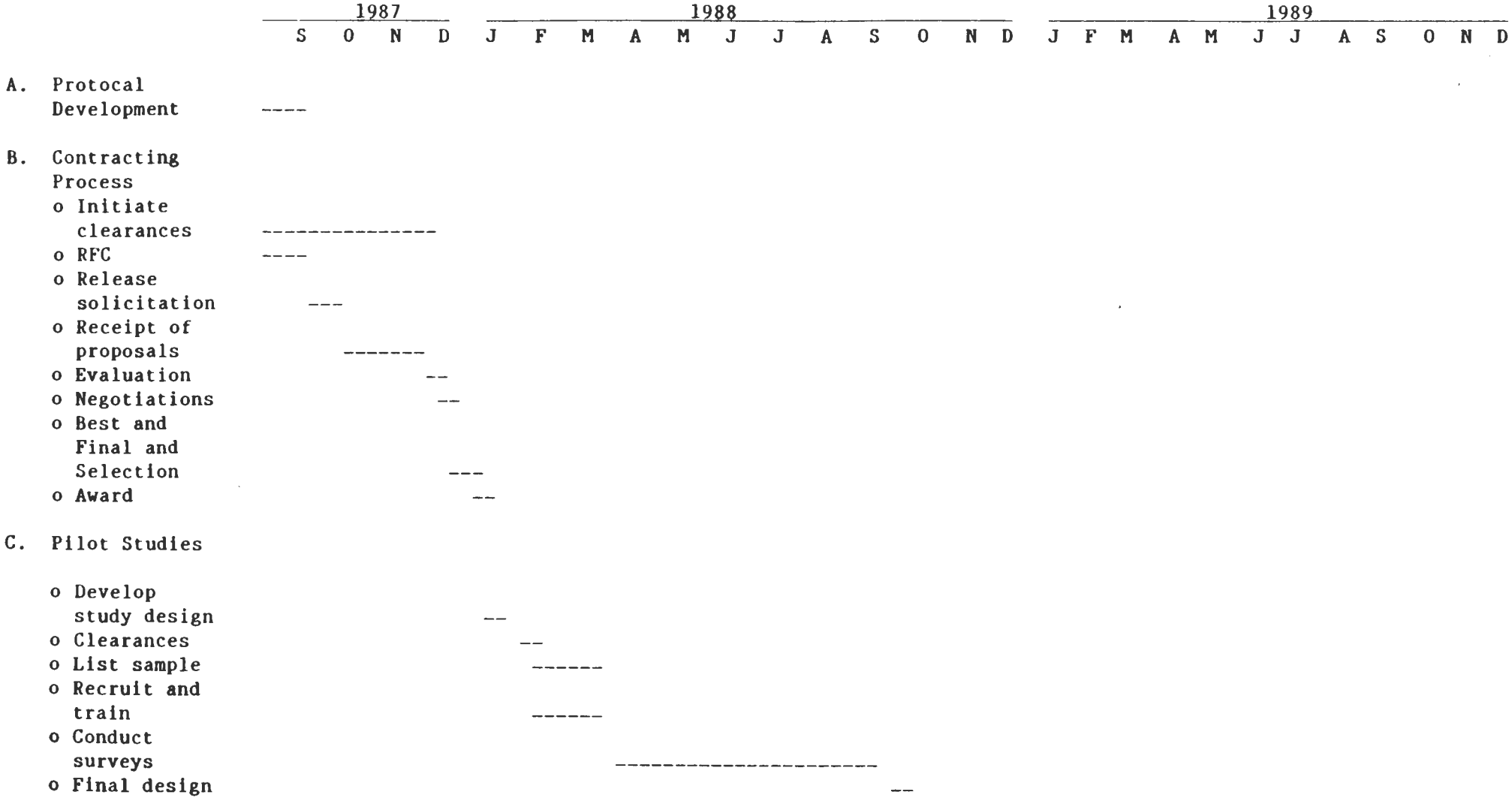
4. Efficacy of therapevtic agents such as AZT in preventing disease

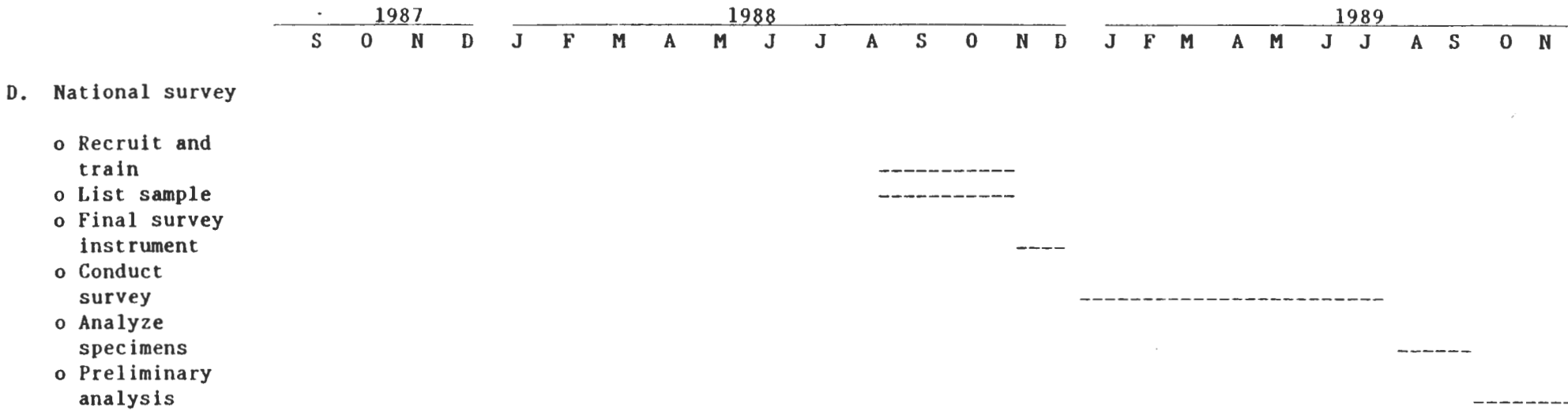
D. Survival time (from onset of disease until death)

1. By individual opportunistic infectious or other AIDS-associated diseases

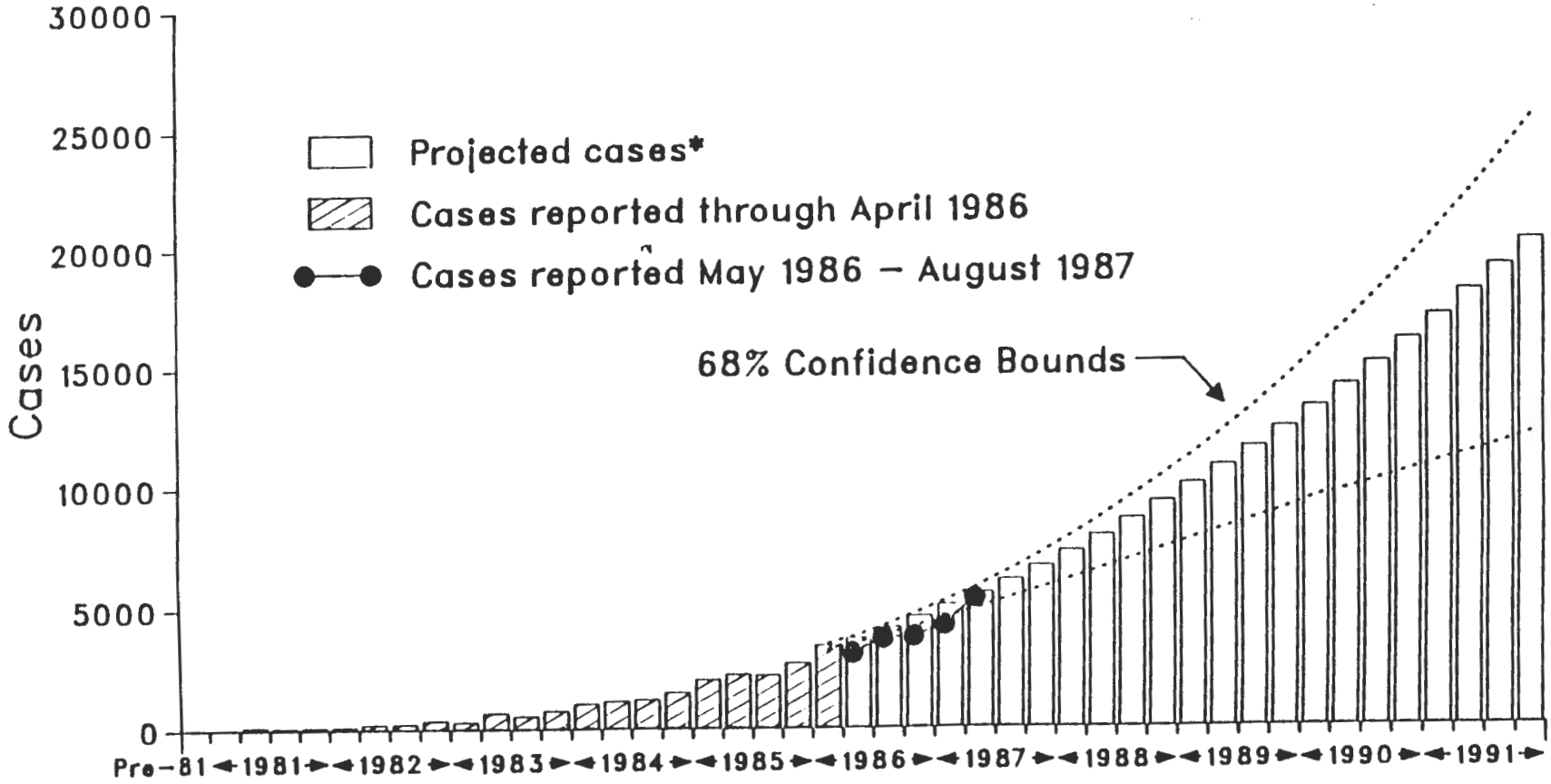
2. Efficacy of therapeutic agents such as AZT in prolonging survival

NATIONAL SEROPREVALENCE SURVEY




1987
1988
1989
S O N D J F M A M J J A S O N D J F M A M J J A S O N
D. National survey
o Recruit and train
o List sample
o Final survey instrument
o Conduct survey
o Analyze specimens
o Preliminary analysis

Cases of AIDS in the United States, by Quarter of Diagnosis Projected from Cases Reported as of April 30, 1986 and Shown with Cases Reported as of August 31, 1987



*Note: projected cases are by quarter of diagnosis; reported cases are by quarter of report to CDC, lagged two months to account for reporting delays

CENTERS FOR DISEASE CONTROL

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MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Epidemiologic Notes and Reports

Trends in Human Immunodeficiency Virus Infection Among Civilian Applicants for Military Service — United States, October 1985-December 1986

Since October 1985, the U.S. Department of Defense has routinely tested civilian applicants for serologic evidence of infection with human immunodeficiency virus (HIV) as part of their preinduction medical evaluation (*1*). Results from the first 6 months of testing have been reported previously (*2,3*). Results for the first 15 months provide the opportunity to observe trends of infection in this population.

Between October 1985 and December 1986, 789,578 civilian applicants for military service were screened. Of these, 1,186 were confirmed as HIV-antibody positive by enzyme immunoassay and Western blot immunoelectrophoresis, for an overall rate of 1.5/1,000 individuals tested. Seroprevalence per 1,000 varied by age, sex, race and ethnicity, and region of residence. By age, it was 0.6 for 17-20 year-olds, 2.5 for 21-25 year-olds, and 4.1 for those ≥ 26 years of age. By sex, it was 1.6 for males and 0.6 for females. By race and ethnicity, seroprevalence per 1,000 was 0.8 for whites, 4.1 for blacks, 2.3 for Hispanics, 1.0 for American Indians or Alaskan Natives and Asian or Pacific Islanders. Table 1 shows the seroprevalence among civilian applicants by region of residence.

TABLE 1. Prevalence of HIV antibody* among civilian applicants for military service, by age group and region of residence — October 1985-December 1986

Region†	Age Group (Years)			
	17-20	21-25	≥26	All Ages
New England	0.4	1.0	3.8	0.9
Middle Atlantic	0.7	4.6	10.0	2.9
EN Central	0.4	1.8	1.9	0.9
WN Central	0.2	1.0	1.8	0.6
South Atlantic	0.9	3.4	5.4	2.1
ES Central	0.4	1.9	1.3	0.9
WS Central	0.6	2.7	3.0	1.6
Mountain	0.3	1.5	1.9	0.9
Pacific	0.8	1.5	4.0	1.5
US Territories	1.6	6.3	12.3	5.8
All Regions	0.6	2.5	4.1	1.5

*Repeatedly reactive enzyme-linked immunosorbent assay (ELISA) test confirmed by Western blot immunoelectrophoresis, reported as the number of antibody-positive applicants per 1,000 tested.

†Defined in notifiable diseases table (Table III).

THE WHITE HOUSE

Office of the Press Secretary
(Santa Barbara, California)

For Immediate Release September 3, 1987

EXECUTIVE ORDER

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THE FAMILY

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to ensure that the autonomy and rights of the family are considered in the formulation and implementation of policies by Executive departments and agencies, it is hereby ordered as follows:

Section 1. Family Policymaking Criteria. In formulating and implementing policies and regulations that may have significant impact on family formation, maintenance, and general well-being, Executive departments and agencies shall, to the extent permitted by law, assess such measures in light of the following questions:

(a) Does this action by government strengthen or erode the stability of the family and, particularly, the marital commitment?

(b) Does this action strengthen or erode the authority and rights of parents in the education, nurture, and supervision of their children?

(c) Does this action help the family perform its functions, or does it substitute governmental activity for the function?

(d) Does this action by government increase or decrease family earnings? Do the proposed benefits of this action justify the impact on the family budget?

(e) Can this activity be carried out by a lower level of government or by the family itself?

(f) What message, intended or otherwise, does this program send to the public concerning the status of the family?

(g) What message does it send to young people concerning the relationship between their behavior, their personal responsibility, and the norms of our society?

Sec. 2. Governmentwide Family Policy Coordination and Review.

(a) Executive departments and agencies shall identify proposed regulatory and statutory provisions that may have significant potential negative impact on the family well-being and provide adequate rationale on why such proposal should be submitted. The head of the department or agency, shall certify in writing that, to the extent permitted by law, such measure has been assessed in light of the criteria in Section 1 of this Order and how such measures will enhance

more

family well-being. Such certification shall be transmitted to the Office of Management and Budget. Departments and agencies shall give careful consideration to family-related concerns and their impact in notices of proposed rulemaking and messages transmitting legislative proposals to the Congress.

(b) The Office of Management and Budget shall, to the extent permitted by law, take action to ensure that the policies of the Executive departments and agencies are applied in light of the criteria set forth in Section 1 of this Order.

(c) The Office of Policy Development shall assess existing and proposed policies and regulations that impact family well-being in light of the criteria established by Section 1 of this Order, provide evaluations on those measures that have significant potential impact on the family to the Office of Management and Budget, and advise the President on policy and regulatory actions that may be taken to strengthen the institutions of marriage and family in America.

Sec. 3. Report. The Office of Policy Development shall submit preliminary reports including specific recommendations to the Domestic Policy Council and shall submit a final report to the President no later than 180 days from the date of this Order. Each year thereafter, a report, including recommendations shall be submitted, through the Domestic Policy Council to the President.

Sec. 4. Judicial Review. This Order is intended to improve the internal management of the Executive branch and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

RONALD REAGAN

THE WHITE HOUSE,
September 2, 1987.

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