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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

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BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

SUBCOMMITTEE ON MEDICAL BENEFITS AND FACILITIES

U.S. HOUSE OF REPRESENTATIVES

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Mr. Chairman and Members of the Subcommittee:

I am Joan Z. Bernstein, General Counsel of Health, Education, and Welfare and Chair of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. I appreciate this opportunity to appear before the Subcommittee in my dual capacity to report on the Federal Government's current and planned efforts to study the possible long-term adverse health effects on humans of exposure to these chemical compounds.

Because of the Subcommittee's concern about health problems experienced by Vietnam veterans, I will review the status of HEW and work group efforts to study the effects on humans of phenoxy herbicides and dioxins, and will focus particularly on our examination of the phenoxy herbicide known as Agent Orange.

With me today are several members of the HEW scientific community who are very much involved in this effort. They are Dr. John Moore, Deputy Director of the National Toxicology Program; Dr. David Rall, Director of the National Institute of Environmental Health Sciences (NIEHS); Dr. Anthony Robbins, Director of the National Institute for Occupational Safety and Health (NIOSH); and Dr. Patricia Honchar, Chief of the Dioxin Study and Registry at NIOSH.

Dr. Moore is the Director of the Scientific Panel of the interagency work group and is being assisted in that endeavor by Drs. Rall and Robbins.

The subject under discussion today is surrounded by controversy and emotion. There is much that is already known about the effects of human exposure to phenoxy herbicides and dioxins, but much that remains in doubt. Accordingly, I believe that we at the Federal level must recognize and fulfill our responsibility to the American people for a thorough, objective, scientifically impeccable, and timely examination of this subject. We must complete such an examination and accounting for the Vietnam veterans, their families, and their offspring because we owe them nothing less. We must complete it, also, because we as a society must face the full impact on our physical environment of the chemicals we use. In the most literal sense, our claim to a healthful environment demands such action.

I believe the Chairman and Members of this Subcommittee share my view concerning the need to avoid emotionalism and alarm, or the creation of false expectations, in connection with the Agent Orange studies. Secretary Harris, my colleagues from HEW and other agencies here today, and I all share your firm commitment to a full examination and a complete and accurate accounting of the truth on this subject. We make this pledge both for the Vietnam veterans and others

who have been working so hard to bring this matter to the country's attention, and for the public at large.

As most of you know, for many years chemical herbicides have been used widely throughout this country and the rest of the world for a variety of farming, forest management, and similar purposes. An important group are the phenoxy acid herbicides. Two of these, 2,4-D and 2,4,5-T, constitute Agent Orange, a herbicide that was widely used for forest defoliation and destruction of crops during the Vietnam conflict.

The chemical reactions that produce 2,4,5-T unavoidably contaminate it with trace amounts of a chemical referred to as TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin), which has been shown in laboratory studies to be one of the most toxic chemicals known. Although TCDD is but one of a family of dioxins, much of the concern as to the alleged health effects of Agent Orange and other dioxins has centered on this contaminant.

In addition to its use in Agent Orange, 2,4,5-T has been extensively applied in the United States. The Environmental Protection Agency temporarily banned major uses of 2,4,5-T in 1979 because of concern as to toxic human effects. Hearings on whether permanently to ban 2,4,5-T are now in progress. Herbicides using 2,4-D are still in wide current use.

The Department of Health, Education, and Welfare and a number of other governmental and private entities and individuals, here and abroad, have been concerned for some years about the potential long-term health effects of exposure to phenoxy acid herbicides and dioxin contaminants. Indeed, HEW has actively conducted or sponsored more than 50 studies relating to phenoxy acid herbicides, TCDD, and other dioxins for more than ten years. The results of this research represent much of our collective current medical and scientific knowledge on this subject.

In January, 1978, concern about the long-term health hazards of TCDD and other dioxins led to the Department's co-sponsoring, with the International Agency for Research on Cancer of the World Health Organization (WHO), the development of a report that assessed available knowledge on the effects of dioxins and future needs for information. Much of the current research in this field is designed to address the major recommendations developed at that meeting. Further, the Department established a group in the summer of 1979 to coordinate its research activities germane to the Agent Orange and dioxin issues.

From a government-wide perspective, during the past two years, the Administration has given increasing attention to the potential adverse human health effects resulting from exposure to the phenoxy herbicides and dioxins. Various

Federal agencies have been involved in the collection of scientific information, the review and evaluation of existing animal and human exposure data on the toxicity of dioxins (especially TCDD), and the support of related research.

The Administration is supporting studies to be conducted by the Department of Defense, by the Veterans Administration, by the Center for Disease Control and the National Institutes of Health, both within HEW, and by other Federal agencies. In addition, members of the Domestic Policy Staff and the Office of Science and Technology Policy of the White House have reinforced the efforts of various agencies to conduct well-designed, valid, objective, and peer-reviewed laboratory and epidemiological studies concerning the potential toxic and adverse health effects of dioxins.

The Air Force has made a commitment to conduct a study of possible health effects in Air Force personnel who were involved in aerial herbicide missions in Vietnam (the RANCH HAND study). This commitment has led to the development of a protocol which has incorporated the recommendations of outside expert peer review groups. This revised protocol has been transmitted to a Committee of the Assembly of Life Sciences of the National Academy of Sciences for their review. This study, to be elaborated on and discussed further by the Air Force, is one of several epidemiological studies which are being planned, currently in progress, or nearing completion.

On December 11, 1979, the President's Assistant for Domestic Affairs and Policy, Stuart Eizenstat, asked the Secretaries of Defense and Health, Education, and Welfare, and the Administrator of Veterans Affairs, to establish an interagency work group to facilitate, coordinate, and monitor agency studies of the possible long-term health effects of phenoxy herbicides and their contaminants. This work group, chaired by HEW, is charged with assuring that the protocols and methodology of current and proposed federally funded research and studies are scientifically sound. This interagency group also will ensure that all relevant research findings, whether publicly or privately financed, are promptly made available to the public and the Congress, in a comprehensible and comprehensive manner.

Although the formal work group held its first meeting on February 1, 1980, the real interagency effort began two years ago. Thus, the work group represents the formalization of a number of informal working relationships among the various agencies involved in dioxin studies rather than the starting point of such efforts.

This same concern about phenoxy herbicides and dioxins is clearly shared by the Congress and has resulted in the passage of legislation to spur adequate research and to assure its quality and objectivity. As you know, one of these bills, S. 2096, was disapproved by the President.

It was the President's conviction that one provision of the bill encroached on functions vested by the Constitution in the Executive Branch and that the activities it required were already under way.

No doubt the members of this Subcommittee and I could spend several interesting hours in debate over the separation of powers issues presented by the disapproval. However, rather than engage in such a dialogue, I would rather focus on the salient point of the veto message: the President's strong support of the effort to investigate the health effects of dioxin exposure and his commitment to continue and complete that investigation.

With that in mind, I'd like to discuss where we are and where I believe we are going in this investigation. HEW's own research over the past decade has encompassed a combination of laboratory investigations and studies of people who have been exposed to TCDD or phenoxy acid herbicides in their occupational environment or by accidental exposures.

Research with animals has indicated that TCDD, a dioxin contaminant in Agent Orange, is one of the most toxic agents known. These animal studies have already established that TCDD can cause cancer, birth defects and fetal toxicity when pregnant female animals are exposed, and can also cause depressions of the immunological systems and increased susceptibility to infectious agents.



Animal toxicity tests have served us well in reliably predicting toxic effects in man. Thus, the animal studies which show TCDD to be highly toxic are extremely important. Epidemiologic studies will help to define the full nature and expression of the toxicity of TCDD and other dioxin contaminants in man.

It is widely accepted, though obviously unfortunate, that occupational groups often are instructive populations in which to explore questions about the effect of a particular chemical or substance upon human health. Workplace exposures to particular materials are often well documented, and records are frequently available describing the work histories of industrial populations. Documented incidents of heavy exposure to dioxin due to industrial accidents have produced some information about its immediate effects in humans, but less is known about its long-term effects. In this setting, NIOSH has initiated an epidemiologic study designed to examine long-term effects of human exposure to TCDD.

NIOSH is assembling a registry of all workers in the United States who have been involved in making 2,4,5-T, one of the components of Agent Orange which is contaminated with TCDD. This study is designed to monitor the health of workers who have been exposed to dioxins. Because 2,4,5-T has been synthesized in this country since the 1940s by a number of industries, there may be a large enough group

of workers who have been exposed to dioxin for a long enough period of time, to answer questions about the long-term effects of dioxins on humans. The study should assist in answering key questions about dioxins posed by Vietnam veterans and others.

Assembling the registry and determining how well it will answer questions or confirm animal toxicity results will take time. The first step, already completed, has been to ascertain which U.S. industries have ever made 2,4,5-T. Through confirmation of lists of suppliers and registrants of 2,4,5-T provided by the Air Force and the Environmental Protection Agency, a final list of the industries which have synthesized this material has been compiled. Contacting each industry to explain the NIOSH study and the information needed from them is under way.

Also in progress is the collection of worker records and other information from the industrial users. To determine precisely how long ago and for how long workers have been exposed to 2,4,5-T, NIOSH must gather the work histories of the people involved. Together with detailed information about the exact process used to manufacture 2,4,5-T, this approach will allow the best determination of exposures which the workers have received. Additionally, any medical records which employers have maintained for their workers may provide more clues about the effects of exposure.

A critical step in this study will be tracing the health of workers exposed to 2,4,5-T. To do this, demographic information such as name, Social Security number, and last-known address for each individual must be obtained from the industry. Through Social Security records, a determination can be made of the vital status of each 2,4,5-T worker. For those no longer living, the cause of death will be determined through State death certificates.

Ascertaining vital statistics and cause of death may require some time past the point when all records are accumulated from the industries. The final data analysis then will aim at determining, by total time of exposure, whether the mortality experience of these 2,4,5-T workers differs significantly in any way from that of the general population.

Because the records of 2,4,5-T workers are currently being collected, it is still not possible to say with certainty just how definitive results from the NIOSH registry will be. The ultimate value of the registry in answering questions about health effects will depend on the number of workers registered, the adequacy of the records obtained from the industries, and the success of tracing these workers historically.

All of these activities are time consuming, but HEW believes that the NIOSH dioxin registry is a pursuit which holds promise for providing reliable information about the

effects of exposure to dioxins on the workers who have been involved in the manufacture of 2,4,5-T, and on other groups such as Vietnam veterans exposed to Agent Orange. At a minimum, the registry should make possible an objective evaluation of morbidity and mortality patterns, including cancer incidence.

Another current occupational study involves a health examination of workers at a Nitro, West Virginia, plant that has been involved in the production of 2,4,5-T since the 1940s. Heavy exposure of some of these workers to TCDD occurred in 1949 from an industrial accident. Other studies involving workers exposed to 2,4,5-T and TCDD are under way in Arkansas and New York. Additionally, studies of workers exposed to other dioxins are under way in Illinois and Kentucky. Taken together, these studies represent one part of an overall effort to gather the data most relevant to the specific concern that Agent Orange exposure may have caused long-term adverse health effects in Vietnam veterans.

Another part of the scientific effort that is directly relevant to the veterans' concerns is the group of studies being conducted to ascertain whether TCDD, 2,4-D or 2,4,5-T produce genetic damage or induce alterations in males that may result in their fathering malformed offspring. This is especially important because research is clearly establishing that other members of the dioxin family of chemicals can

produce toxic manifestations that are indistinguishable from those produced by TCDD. Studies of some occupationally exposed populations are consistent with these laboratory findings. Thus, what is learned about one dioxin is extremely important in adding to our knowledge about them all.

Animal toxicity studies have predicted and occupational studies have confirmed that skin lesions (chloracne) in humans are associated with TCDD exposure. There is also evidence of other toxic effects in humans, including: liver effects as indicated by enlargement and abnormalities in clinical tests of liver function; alterations in lipid (fat) metabolism; and, more recently, a modest decrease in the ability of peripheral nerves to transmit impulses.

Despite the great amount of insight that we already have, important gaps in our knowledge still exist. The symptoms that are known to be associated with dioxins or phenoxy acids often have not been shown to represent a unique disease pattern. Therefore, studies to determine whether there is a relationship between these chemicals and a specific disease pattern in veterans exposed to them are imperative.

The interagency work group has appropriately begun by focusing on scientific information that is already available or under development about health effects in order to establish an action agenda for getting done that which remains

undone. We must, however, recognize some of the problems involved in this scientific effort.

Despite all the current and contemplated research, it may be that although Agent Orange is the cause of some disease, the disease is also attributable to other agents. If so, the most that a study can tell us is that exposure to the chemical increases the disease's frequency. This limitation is especially acute in studying the effects of Agent Orange on the health of American troops in Vietnam. The time and concentration of their exposure is not known. Also, it is already known that the more serious illnesses claimed to be caused by phenoxy herbicides and dioxins can be caused by a variety of agents.

In the face of these problems, the work group has decided to set the following priorities for the gathering of information:

- ° First, to attempt to correlate the incidence of illness and disease among Vietnam veterans with their exposure in Vietnam to Agent Orange, in part by determining, insofar as practical, if Vietnam veterans as a class are as healthy as other relevant population groups.

- ° Second, to study the broader implications for public health in the United States and elsewhere raised by the continued use of substances containing dioxins.

The mission of the work group is essentially scientific. It may discover that members of the Armed Forces who served in Vietnam run a greater risk than other groups of contracting serious diseases. But it may also find that the origin of any such diseases is not peculiar to a given chemical or to the Vietnam experience.

- ° If these are the findings, they will not tell us at what elevation of risk a veteran's illness should be deemed service-connected, or if the United States should assume responsibility for compensating the Vietnam veteran or his survivors for illness should the increased risk be very small.

- ° They will not assist us in adjusting the equities between those Vietnam veterans and non-Vietnam veterans who contract similar ailments, or between veterans and other members of the public.

- ° Finally, they will give only tenuous guidance on the role that government should play in ameliorating the adverse consequences of dioxins to the health of the public at large.

I do not raise these difficult questions in order to answer them. I raise them because I am concerned that the intense public discussion to date about the design, objectivity and timeliness of research on this subject may be creating

or contributing to an erroneous impression. Because of the controversy, many may have come to believe that once an optimal research agenda is established and carried out, the research results will provide definitive, incontrovertible scientific information about the health effects of phenoxy herbicides and their contaminants.

I believe this is an unfortunate view because even the best effort of which our scientists are capable may not produce such conclusive results. In short, we may be left, after the research is done, with many of the same social policy issues we face today. Nevertheless, we believe the research being carried out or planned is important and valuable. We hope it will help all of us formulate a fair and humane social policy. But it will not and cannot by itself answer questions that seem to us to be fundamentally ones of broad social policy that both the Administration and the Congress must soon confront.

The timetable for a definitive report by the work group and the development and review of its scientific findings will be established within the relatively near future. In the coming months, as the work group holds additional meetings, we will keep this Subcommittee apprised of current or planned research. We will also try to keep you and the public fully informed on our progress at each stage along the way.



In that regard, I have attached to this statement, and ask that it be considered a part of my testimony, a copy of the work group's first report to Stuart Eizenstat. The report provides additional details on a number of points I have discussed briefly and explores many additional and related features of the overall effort. We will be happy to answer any questions the Subcommittee may have. Thank you.