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aerial spray missions (Operation Ranch Hand). A baseline morbidity study of them and a matched comparison cohort was conducted in 1982, and there were follow-up assessments in 1985, 1987, 1992, and 1997. In accordance with the study protocol, one additional assessment is under way and will be completed in April 2003. A final report will be issued in early 2005 (personal commun., Joel Michalek, Brooks Air Force Base, September 17, 2002).

The AFHS is one of the few primary sources of information on the health of Vietnam veterans known to be exposed to Agent Orange and other herbicides. The study is coming to its scheduled end as the cohorts are reaching the age at which several health outcomes of interest may be expected to manifest, such as cancers and diseases related to aging. The committee recommends continuing the study past its planned completion date to enable further study of those diseases. Given the increased incidence of such diseases as amyotrophic lateral sclerosis, Parkinson's disease, prostatic cancer, and brain cancer in aging populations and the increasing age of the Vietnam-veteran cohort, research should specifically examine those diseases in the Vietnam veterans. Such studies should be conducted with an appropriate control population. Similarly, continued study of other exposed cohorts (for example, the cohort studied by the National Institute for Occupational Safety and Health) could also provide information on diseases of aging.

The committee also recommends retaining and maintaining medical records and samples on the AFHS cohort so that—with proper respect for the privacy of the study participants—they can be available for future research. The federal government should examine how the various forms of data and specimens collected in the course of the AFHS might be maintained and what form of oversight should be established for their future use. Any extension of the research or future use of the records would, of course, have to have the full knowledge and consent of the AFHS population and respect for the privacy of the participants. The committee's judgment is that continued research on the health of the Ranch Hand and comparison veterans is likely to yield important information on the determinants of health and disease in those who served in Vietnam and perhaps in their offspring.

Army Chemical Corps Studies

Members of the Army Chemical Corps constitute the largest cohort of Vietnam veterans exposed directly to herbicides and TCDD. They were involved in the handling and distribution of the compounds in Vietnam. Preliminary studies of this cohort by scientists in the Department of Veterans Affairs (VA) have demonstrated increased TCDD concentrations in Chemical Corps veterans who reported spraying herbicides as part of their duties. Research on the health effects in this population has been and is being conducted. Continued careful and expanded long-term study of the cohort could be a valuable addition to current research on Vietnam veterans. As with all Vietnam-veteran research, the federal government should consider the form of oversight that best facilitates the research effort and ensures the scientific validity of such studies.

Exposure-Reconstruction Study

The committee is aware that an assessment of herbicide exposure of Vietnam veterans, being overseen by the Institute of Medicine Committee on the Assessment of Wartime Exposure to

Herbicides in Vietnam, is nearing completion (see Chapter 5). The assessment should provide more accurate and precise data on the potential exposure of people to herbicides sprayed in Vietnam. The data could be used in epidemiologic studies, such as studies of ground troops, to examine possible associations between health effects and exposure to the herbicide mixtures used in Vietnam. Combining research into the health effects of the herbicides in Vietnam veterans and potential information from this database, might provide better information on the health effects of the chemicals of interest.

Other Studies of Vietnam Veterans

Several other concerns have been raised by veterans that the committee considers worthy of further investigation. A case series of glioblastomas and possibly astrocytomas was brought to the attention of the committee at its public hearing in Seattle. Despite the fact that these tumors are currently classified in the *no* association category, the committee believes that these concerns should be further investigated. These are extremely rare tumors, and the likelihood of detected changes in their rates in occupational cohorts, the AFHS, or the Seveso population is low. Other methods, such as making use of or improving VA databases, might be appropriate first steps toward investigating these concerns. Although more thorough studies of Vietnam veterans are needed if the actual health experience of the veterans is to be adequately understood, recording or monitoring of trends in diseases of aging Vietnam veterans and rare diseases could be especially useful for indicating which diseases might warrant further study.

Studies of the Vietnamese

Another population that has been understudied is the Vietnamese, including those who served in the military during the war and civilians. Anecdotal evidence and studies published in non-English-language journals suggest an array of long-term health effects that could potentially be related to the chemicals used by US troops in Vietnam.

This population provides several opportunities that others do not. First, there is a high probability that the number of exposed persons is substantially larger than the number previously studied. Second, exposures not only were high at the time of application of herbicides, but, because of persistence in the environment, continued long beyond the conclusion of military activities; studies suggest that body burdens and environmental concentrations might still be high in some areas of Vietnam (Verger et al., 1994; Schecter et al., 2002). Third, the establishment of diplomatic relations between the United States and Vietnam and a recent initiative overseen by the National Institute of Environmental Health Sciences (NIEHS), have opened the door for significant scientific collaborations. In March 2002, a US-Vietnamese Workshop on Health and Environmental Effects of the war was held in Hanoi. After the workshop, during a one-day meeting organized by the NIEHS, US and Vietnamese scientists held intensive discussions regarding types of studies that were deemed useful. Although the development of collaborative research between scientists from the two countries presents challenges, the committee believes that the hurdles might be overcome. Careful planning and the strategic building of local capacity in Vietnam through investment in training and infrastructure can lay the foundation for high-quality research. It must be stressed, however, that efforts to conduct research will have to be

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accompanied by efforts to build trust. Because such research has the potential to close a number of gaps in our understanding of the long-term health consequences of exposure to TCDD and herbicides used in Vietnam, the committee supports any further steps that can be taken to develop collaborative programs of research.

The possibility of using the newly established exposure database to assess exposure of the Vietnamese is also worth consideration, although it should be recognized that the explicit purpose of the database was to determine exposures of US service personnel who spent time in Vietnam.

Other Research

As stated previously, the committee has focused its recommendations on studies of human populations. The committee believes, however, that experimental research in the mechanisms that might underlie the human health outcomes can provide information valuable for determining the risk of disease in Vietnam veterans and the interactions between various exposures that lead to disease. For example, experimental studies in animals could examine the interaction of smoking and TCDD exposure with health outcomes of interest to provide better information on potential confounders in epidemiologic studies. The committee recognizes that although it might be difficult to make conclusive links to effects in humans on the basis of such research, those studies could provide information useful for interpreting the results of epidemiologic studies, especially studies in which there might be multiple exposures or other factors that complicate the drawing of conclusions.

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Research Recommendations

As part of their charge, the committees responsible for producing the Agent Orange reports make recommendations concerning the need, if any, for additional scientific studies to resolve uncertainties concerning the health effects of the compounds sprayed in Vietnam—2,4-dichlorophenoxyacetic acid (2,4-D), 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) and its contaminant 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), picloram, and cacodylic acid. This chapter summarizes the present committee's research recommendations.

Although great strides have been made over the last several years in understanding the health effects of exposure to the chemicals sprayed in Vietnam and in elucidating the mechanisms underlying those effects, there are still important gaps in our knowledge. The scope of potential research on these chemical compounds is wide, but information from some kinds of research would be more informative for the committee's charge than information from others. Because of the importance of epidemiologic and other human studies to the committee's conclusions, the focus of these recommendations is on such studies. The lack of discussion of a particular kind of research should not be interpreted as a lack of value in it.

Vietnam-Veteran Studies

As did the previous committees in their reports (IOM, 1994, 1996, 1999, 2000, 2001, 2002), on the basis of its review of the epidemiologic evidence and consideration of the quality of available exposure information, especially from studies of Vietnam veterans, this committee concludes that continuation of epidemiologic studies of veterans could yield valuable information. That is true especially because diseases of aging could emerge as the population grows older, and as a new exposure-reconstruction model is developed and validated.

Air Force Health Study

The Air Force Health Study (AFHS) is an epidemiologic study whose purpose is to determine whether exposure to the herbicides used in Vietnam might underlie any adverse health conditions observed in a cohort of Air Force personnel (termed the Ranch Hands) who conducted

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(1995), and Flesch-Janys (1997); factory workers from the Netherlands studied by Hooiveld et al. (1998); and Austrian production workers studied by Neuberger et al. (1998, 1999) and Jäger et al. (1998). *VAO, Update 1996, Update 1998, and Update 2000* discuss those studies in more detail. No new studies have been published on the IARC cohort or the smaller cohorts that comprise the IARC cohort.

Other Chemical Plants

Studies have reviewed health outcomes among chemical workers in the UK exposed to TCDD as a result of an industrial accident in 1968 (May, 1982, 1983; Jennings et al., 1988), production workers in the former Soviet Union involved in the production of 2,4-D (Bashirov, 1969), factory workers in Prague who exhibited symptoms of TCDD toxicity 10 years after occupational exposure to 2,4,5-T (Pazderova-Vejlukova et al., 1981), 2,4-D and 2,4,5-T production workers in the United States (Poland et al., 1971), white men employed at a US chemical plant manufacturing flavors and fragrances (Thomas, 1987), and US chemical workers engaged in the production of PCP, lower-chlorinated phenols, and esters of chlorophenoxy acids (Hryhorczuk et al. 1998); the long-term immune-system effects of TCDD in 11 industrial workers involved in production and maintenance operations at a German chemical factory producing 2,4,5-T (Tonn et al., 1996); and immune effects in a cohort of workers formerly employed at a German pesticide-producing plant (Jung et al. 1998). *VAO, Update 1998, and Update 2000* detail those studies. No studies at other chemical plants have been published since *Update 2000*.

Agricultural and Forestry Workers

Cohort Studies

Agricultural Workers *VAO, Update 1996, Update 1998, and Update 2000* detail a number of cohort studies examining health effects in people involved in agricultural activity. They include studies of proportionate mortality among Iowa farmers (Burmeister, 1981) and among male and female farmers in 23 states (Blair et al., 1993), cancer mortality among Danish and Italian farmers (Ronco et al., 1992) and among a cohort of rice growers in the Novara Province of northern Italy (Gambini et al., 1997), cancer incidence among farmers licensed to spray pesticides in the southern Piedmont area of Italy (Corrao et al., 1989) and among female Danish gardeners (Hansen et al., 1992), sperm abnormalities among Argentine farmers (Lerda and Rizzi, 1991), cancer birth defects among the offspring of Norwegian farmers (Kristensen et al., 1997), the incidence of spontaneous abortion in couples living on family farms in Ontario, Canada (Arbuckle et al. 1999), and immunologic changes in 10 farmers who mixed and applied commercial formulations containing the chlorophenoxy herbicides (Faustini et al., 1996). In addition, a set of Canadian studies, called the Mortality Study of Canadian Male Farm Operators, evaluated the risk to farmers of death and specific health outcomes, including non-Hodgkin's lymphoma (NHL) (Wigle et al., 1990; Morrison et al., 1994), prostatic cancer (Morrison et al., 1992), brain cancer (Morrison et al., 1993), multiple myeloma (Semenciw et al., 1993), leukemia (Semenciw et al., 1994), and asthma (Senthilselvan et al., 1992). On the Basis of data from the

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Department of Veterans Affairs

Report

REPORT TO TO SECRETARY OF THE DEPARTMENT OF VETERANS AFFAIRS

ON THE ASSOCIATION BETWEEN ADVERSE HEALTH EFFECTS

AND EXPOSURE TO AGENT ORANGE

CLASSIFIED

CONFIDENTIAL STATUS (1)

As Reported by Special Assistant

Admiral E.R. Zumwalt, Jr.

May 5, 1990



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1. INTRODUCTION

On October 6, 1989 I was appointed as special assistant to Secretary Derwinski of the Department of Veterans Affairs to assist the Secretary in determining whether it is at least as likely as not that there is a statistical association between exposure to Agent Orange and a specific adverse health effect.

As special assistant, I was entrusted with evaluating the numerous data relevant to the statistical association between exposure to Agent Orange and the specific adverse health effects manifested by veterans who saw active duty in Vietnam. Such evaluations were made in accordance with the standards set forth in Public Law 98-542, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act and 38 C.F.R. 1.17, regulations of the Department of Veterans Affairs concerning the evaluation of studies relating to health effects of dioxin and radiation exposure.

Consistent with my responsibilities as special assistant, I reviewed and evaluated the work of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards and commissioned independent scientific experts to assist me in evaluating the validity of numerous human and animal studies on the effects of exposure to Agent Orange and/or exposure to herbicides containing 2,3,7,8 tetrachlorodibenzo-para-dioxin (TCDD or dioxin). In addition, I reviewed and evaluated the protocol and standards employed by government sponsored studies

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to assess such studies' credibility, fairness and consistency with generally accepted scientific practices.

~~After reviewing the scientific literature related to the health effects of Vietnam Veterans exposed to Agent Orange as well as other studies concerning the health hazards of civilian exposure to dioxin contaminants, I conclude that there is adequate evidence for the Secretary to reasonably conclude that it is at least as likely as not that there is a relationship between exposure to Agent Orange and the following health problems: non—Hodgkin's lymphoma, chloracne and other skin disorders, lip cancer, bone cancer, soft tissue sarcoma, birth defects, skin cancer, porphyria cutanea tarda and other liver disorders, Hodgkin's disease, hematopoietic diseases, multiple myeloma, neurological defects, auto—immune diseases and disorders, leukemia, lung cancer, kidney cancer, malignant melanoma, pancreatic cancer, stomach cancer, colon cancer, nasal/pharyngeal/esophageal cancers, prostate cancer, testicular cancer, liver cancer, brain cancer, psychosocial effects and gastrointestinal diseases.~~

I further conclude that the Veterans' Advisory Committee on Environmental Hazards has not acted with impartiality in its review and assessment of the scientific evidence related to the association of adverse health effects and exposure to Agent Orange.

In addition to providing evidence in support of the conclusions stated above, this report provides the Secretary with

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a review of the scientific, political and legal efforts that have occurred over the last decade to establish that Vietnam Veterans who have been exposed to Agent Orange are in fact entitled to compensation for various illnesses as service-related injuries.

II. AGENT ORANGE USAGE IN VIETNAM

Agent Orange was a 50:50 mixture of 2,4-D and 2,4,5-T. The latter component, 2,4,5-T, was found to contain the contaminant TCDD or 2,3,7, 8-tetrachlorodibenzo-para-dioxin (i.e. dioxin), which is regarded as one of the most toxic chemicals known to man.¹

From 1962 to 1971 the United States military sprayed the herbicide Agent Orange to accomplish the following objectives: 1)

¹ See CDC Protocol for Epidemiologic Studies on the Health of Vietnam Veterans (November, 1983), p. 4 (The CDC Protocol also contains a literature review as of 1983 of the health effects on animals and humans exposed to herbicides and dioxin, pp. 63-78. The literature review documents health problems such as chloracne, immunological suppression, neurological and psychological effects, reproductive problems such as birth defects, carcinogenic effects such as soft tissue sarcomas, lymphomas and thyroid tumors, and various gastrointestinal disorders) ; See also General Accounting Office, "Report by the Comptroller General: Health Effects of Exposure to Herbicide Orange in South Vietnam Should Be Resolved," GAO-CED-79-22 at 2 (April 6, 1979) (hereinafter GAO Report, 1979).

Dioxin is a family of chemicals (75 in all) that does not occur naturally, nor is it intentionally manufactured by any industry. The most toxic dioxin is called 2,3,7,8 — TCDD. Dioxins are produced as byproducts of the manufacture of some herbicides (for example, 2,4, 5—T), wood preservatives made from trichlorophenals, and some germicides. Dioxins are also produced by the manufacture of pulp and paper, by the combustion of wood in the presence of chlorine, by fires involving chlorinated benzenes and biphenyls (e.g. PCBs), by the exhaust of automobiles burning leaded fuel, and by municipal solid waste incinerators

defoliate jungle terrain to improve observation and prevent enemy ambush; 2) destroy food crops; and 3) clear Vegetation around military installations, landing zones, fire *base* camps, and trails²

Unlike civilian applications of the components contained in Agent Orange which are diluted in oil and water, Agent Orange was sprayed undiluted in Vietnam. Military applications were sprayed at the rate of approximately 3 gallons per acre and contained approximately 12 pounds of 2,4-D and 13.8 pounds of 2,4,5-T.³

Although the military dispensed Agent Orange in concentrations 6 to 25 times the manufacturer's suggested rate, "at that time the Department of Defense (DOD) did not consider herbicide orange toxic or dangerous to humans and took few precautions to prevent exposure to it." Yet, evidence readily suggests that at the time of its use experts knew that Agent Orange was harmful to military personnel.⁵

² See Bruce Myers, "Soldier of Orange: The Administrative, Diplomatic, Legislative and Litigatory Impact of Herbicide Agent Orange in South Vietnam," 8 *B. C. Env't. Aff. L. Rev.* 159, 162 (1979).

³ See GAO Report, 1979 at 2, 3 n.1; See also Myers, 8 *B.C. Env't Aff. L. Rev.*, at 162. In contrast, civilian applications of 2,4,5-T varied from 1 to 4 pounds per acre.

⁴ General Accounting Office, "Ground Troops in South Vietnam Were in Areas Sprayed with Herbicide Orange," FPCD 80-23, p.1 (November 16, 1979).

⁵ Letter from Dr. James R. Clary to Senator Tom Daschle (September 9, 1988). Dr. Clary is a former government scientist with the Chemical Weapons Branch, BW/CW Division, Air Force Armament Development Laboratory, Eglin AFB, Florida. Dr. Clary was instrumental in designing the specifications for the A/A 45y-1 spray tank (ADO 42) and was also the scientist who prepared the

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The bulk of Agent Orange herbicides used in Vietnam were reportedly sprayed from "Operation Ranch Hand" fixed wing aircraft. Smaller quantities were applied from helicopters, trucks, riverboats, and by hand. Although voluminous records of Ranch Hand missions are contained in computer records, otherwise known as the HERBS and Service HERBs tapes, a significant, if not major source of exposure for ground forces was from non-recorded, non Ranch Hand operations.⁶

Widespread use of Agent Orange coincided with the massive buildup of U.S. military personnel in Vietnam, reaching a peak in

final report on Ranch Hand: Herbicide Operations in SEA, July 1979. According to Dr. Clary:

When we (military scientists) initiated the herbicide program in the 1960's, we were aware of the potential for damage due to dioxin contamination in the herbicide. We were even aware that the 'military'⁶ formulation had a higher dioxin concentration than the 'civilian' version due to the lower cost and speed of manufacture. However, because the material was to be used on the 'enemy', none of us were overly concerned. We never considered a scenario in which our own personnel would become contaminated with the herbicide. And, if we had, we would have expected our own government to give

assistance to veterans so contaminated.

See also notes 13, 73-75 and accompanying text *infra* for additional information of the manufacturer's awareness of the toxicity of Agent Orange.

⁶ Combat units, such as the 'Brown Water Navy,' frequently conducted "unofficial" sprayings of Agent Orange obtained from out of channel, and thus unrecorded sources. Additionally, as Commander, U.S. Naval Forces, Vietnam, I was aware that Agent Orange issued to Allied forces was frequently used on unrecorded missions.

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1969 and eventually stopping in 1971. ⁷ Thus, according to an official of the then Veterans Administration, it was "theoretically possible that about 4.2 million American soldiers could have made transient or significant contact with the herbicides because of [the Ranch Hand Operation]." ⁸

A. REASONS FOR PHASE OUT

Beginning as early as 1968, scientists, health officials, politicians and the military itself began to express concerns about the potential toxicity of Agent Orange and its contaminant dioxin to humans. For instance, in February 1969 The Bionetics Research Council Committee ("BRC") in a report commissioned by the United States Department of Agriculture found that 2,4,5-T showed a "significant potential to increase birth defects." ⁹ Within four months after the BRC report, Vietnamese newspapers began reporting significant increases in human birth defects ostensibly due to exposure to Agent Orange. ¹⁰

⁷ GAO Report 1979, *supra* note 1, at 29. See also note 82 and accompanying text *infra* for a discussion of the correlation between the spraying of Agent Orange and the hospitalization of Vietnam soldiers for disease and non-battle related injuries.

⁸ House Comm. on Veteran's Affairs, 95th Cong., 2d Sess., Herbicide "Agent Orange". Hearings before the Subcommittee on Medical Facilities and Benefits, (Oct. 11, 1978) (Statement of Maj. Sen. Garth Dettinger USAF, Deputy Surgeon General USAF at 12).

⁹ Myers at 166.

¹⁰ *Id* While birth defects did significantly increase in Saigon, critics contend that Saigon was not an area where the preponderance of defoliation missions were flown and argue that such increases were due primarily to the influx of U.S. medical personnel who kept better records of birth defects. Subsequent

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By October, 1969, the National Institute of Health confirmed that 2,4,5-T could cause malformations and stillbirths in mice, thereby prompting the Department of Defense to announce a partial curtailment of its Agent Orange spraying.¹¹

By April 15, 1970, the public outcry and mounting scientific evidence caused the Surgeon General of the United States to issue a warning that the use of 2,4,5-T might be hazardous to "our health".¹²

On the same day, the Secretaries of Agriculture, Health Education and Welfare, and the Interior, stirred by the publication of studies that indicated 2,4,5-T was a teratogen (i.e. caused birth defects), jointly announced the suspension of its use around lakes, ponds, ditch banks, recreation areas and

studies in Vietnam confirm the incidence of increased birth defects among civilian populations exposed to Agent Orange. See e.g. Phuong, et. al. "An Estimate of Reproductive Abnormalities in Women Inhabiting Herbicide Sprayed and Non-herbicide Sprayed Areas in the South of Vietnam, 1952-1981" 18 Chemosphere 843-846 (1989) (significant statistical difference between hydatidiform mole and congenital malformations between populations potentially exposed and not exposed to TCDD); Phuong, et. al., "An Estimate of Differences Among Women Giving Birth to Deformed Babies and Among Those with Hydatidiform Mole Seen at the OB-GYN Hospital of Ho Chi Minh City in the South of Vietnam," 18 Chemosphere 801-803 (1989) (statistically significant connection between frequency of the occurrence of congenital abnormalities and of hydatidiform moles and a history of phenoxyherbicide exposure); Huong, et. al., "An Estimate of the Incidence of birth Defects, Hydatidiform Mole and Fetal Death in Utero Between 1952 and 1985 at the OB-GYN Hospital of Ho Chi Minh City, Republic of Vietnam," 18 Chemosphere 805-810 (1989) (sharp increase in the rate of fetal death in utero, hydatidiform mole (with or without choriocarcinoma) and congenital malformations from the pre 1965-1975 period, suggesting possible association to phenoxyherbicide exposure).

¹¹ Myers at 167

¹² Id.

homes and *crops* intended for human consumption.¹³ The Department of Defense simultaneously announced its suspension of all uses of Agent Orange.¹⁴

B. HEALTH STUDIES

As Agent Orange concerns grew, numerous independent studies were conducted between 1974 and 1983 to determine if a link exists between certain cancerous diseases, such as non-Hodgkin's lymphoma and soft-tissue sarcomas, and exposure to the chemical components found in Agent

Orange. These studies suggested just such a link.

In 1974, for example, Dr. Lennart Hardell began a study which eventually demonstrated a statistically significant correlation between exposure to pesticides containing dioxin and the development of soft tissue sarcomas.¹⁵

¹³ *Id.* Although Dow Chemical Company, the primary manufacturer of 2,4,5-T and 2,4-D, denied this teratogenicity, Dow's own tests confirmed that when dioxin was present in quantities exceeding production specifications, birth defects did occur. See J. McCullough, Herbicides: Environmental Health Effects: Vietnam and the Geneva Protocol: Developments During 1979, 13 (1970) (Congressional Research Report No. UG 447, 70—303SP). Pressure from industry subsequently led to some relaxation of the limits placed on the 2,4,5—T and 2,4—D. The only current uses for these chemicals in the United States are on rice, pastures, rangelands and rights of way.

¹⁴ *Id.* at 167. See also Dow Chemical v. Ruckelshaus, 477 F.2d 1317, 1319 (8th Cir. 1973) (secretaries announcement quoted in the opinion).

¹⁵ Hardell, L. and Sandstrom, A. "Case—control Study: Soft Tissue Sarcomas and Exposure to Phenoxyacetic Acids or Chlorophenols," 39 Brit. J. Cancer, 711—717 (1979). See also note 89 *infra* for the confirming results of follow-up studies by Hardell and others.

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In 1974, Axelson and Sundell reported a two—fold increase of cancer in a cohort study of Swedish railway workers exposed to a variety of herbicides containing dioxin contaminants.¹⁶

By 1976, the Occupational Safety and Health Administration, established rigorous exposure criteria for workers working with 2,4, 5-T.¹⁷

In 1977 the International Agency for Research on Cancer (IARC), while cautioning that the overall data was inconclusive, reported numerous anomalies and increased mortality rates in animals and humans exposed to 2,4-D or 2,4,5-T.¹⁸

¹⁶ Axelson and Sundell, "Herbicide Exposure, Mortality and Tumor Incidence: An Epidemiological Investigation on Swedish Railroad Workers," 11 Work Env't. Health 21-28 (1974).

¹⁷ U.S. Occupational Safety and Health Administration (1976), Air Contaminants; U.S. Code, Federal Register 29, Part 1910.93 at p. 27

¹⁸ With regard to 2,4-D, the IARC found the following anomalies: elevated levels of cancer in rats; acute and short—term oral toxicity in mice, rabbits, guinea pigs and rats—death, stiffness in the

extremities, incoordination, stupor, myotonia, and other physical abnormalities; in monkeys, injections caused nausea, vomiting, lethargy, muscular incoordination and head droop, fatty degeneration of the liver, spleen, kidneys and heart; foetal anomaly increases in some species; post-birth death rates increased in some species; higher mortality rates and morphological alterations in pheasant embryos and their chicks when spraying took place under simulated field conditions; higher mortality rates in rat pups in a 3 generation exposure; gene mutation after exposure to high concentrations; chromosomal aberrations when cultured human lymphocytes were exposed; increased frequency of aberrant metaphases (2 to 4 times) in mice exposed to toxic concentrations.

In humans the IARC found that: a 23 year old farming student, a suicide, had 6 grams of 2,4-D in his body, acute congestion of all organs, severe degeneration of ganglion cells in the central nervous system; 3 cases of peripheral neuropathy in humans sprayed with 2,4-D with initial symptoms of nausea, vomiting, diarrhea, swelling and aching of feet and legs with latency, in individual cases, paresthesia in the extremities, pain in the legs, numbness and aching of fingers and toes, swelling in hand joints, flaccid

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In 1978, the Environmental Protection Agency issued an emergency suspension of the spraying of 2,4,5-T in national forests after finding "a statistically significant increase in the frequency of miscarriages" among women living near forests sprayed with 2,4,5-T.¹⁹

In 1980, another provocative mortality study of workers

parapheresis; similar case reports in agriculture workers sprayed by 2,4-D; workers associated with 2,4-D developed symptoms of somnolence, anorexia, gastralgia, increased salivation, a sweet taste in the mouth, a sensation of drunkenness, heaviness of the legs and hyperacusea, rapid fatigue, headache, loss of appetite, pains in the region of liver and stomach, weakness, vertigo, hypotension, bradycardia, dyspeptic symptoms, gastritis, liver disfunction, changes in metabolic processes..

With regard to 2,4,5-Vs effect on animals the IARC found: it can increase the frequency of cleft palates in some strains of mice; fetal growth retardation may also be observed; cystic kidneys were observed in two strains of mice; in purest available form, it induced some fetal effects and skeletal anomalies in rats as well as behavioral abnormalities, changes in thyroid activity and brain serotonin levels in the progeny; increases in intrauterine deaths and in malformations in rats; fetal death and teratogenic effects in Syrian golden hamsters; chromosomal abnormalities.

The IARC reported in 1977 with respect to 2,4,5-T's effects on humans that: workers exposed at a factory in the USSR had skin lesions, acne, liver impairment, and neurasthenic syndrome; similar findings were reported by Jerasneh, et al (1973, 1974) in a factory in Czechoslovakia which in 1965-68 produced 76 cases of chloracne, 2 deaths from bronchogenic cancers. Some workers had porphyria cutanea tarda, urophryimuria, abnormal liver tests, severe neurasthenia, depression syndrome, peripheral neuropathy; in a 1975 accident in West Virginia, 228 people were affected. Symptoms included chloracne, melanosis, muscular aches and pains, fatigue, nervousness, intolerance to cold; 4 workers of 50 affected in a similar accident in the Netherlands in 1963 died

within 2 years and at least 10 still had skin complaints 13 years later.

¹⁹ June 1979 Congressional Hearings before House Commerce Committee, Subcommittee on Oversight and Investigations, quoted in "Human Disease Linked to Dioxin: Congress Calls for 2,4,5-T Ban After Dramatic Herbicide Hearings", 28 *Bioscience* 454 (August 1979). This study, otherwise known as the Alsea Study, has been cited as showing the first correlation between 2,4,5-T (and presumably its TCDD contaminant) and teratogenic effects in humans.

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involved in an accident at an industrial plant which manufactured dioxin compounds suggested that exposure to these compounds resulted in excessive deaths from neoplasms of the lymphatic and hematopoietic tissues. ²⁰

On September 22, 1980, the U.S. Interagency Work Group to Study the Long-term Health Effects of Phenoxy Herbicides and Contaminants concluded "that despite the studies' limitations, they do show a correlation between exposure to phenoxy acid herbicides and an increased risk of developing soft-tissue tumors or malignant lymphomas."²¹

To be sure, there remain skeptics who insist that the studies failed in one respect or another to establish a scientifically acceptable correlation.²² Yet, it can fairly be said that the general attitude both within and outside the scientific community was, and continues to be increasing concern over the mounting evidence of a connection between certain cancer

²⁰ Zack and Suskind, "The Mortality Experience of Workers Exposed to TCDD in a Trichlorophenol Process Accident," 22 *Journal of Medicine* 11—14 (1980).

²¹ See U.S. Interagency Workgroup to Study the Long-Term Health Effects of Phenoxy Herbicides and Contaminants (September 22, 1980) (executive summary).

²² See...e.g. "The Weight of the Evidence on the Human Carcinogenicity of 2,4-D" (January 1990) (This report, sponsored by the National Association of Wheat Growers Foundation and a grant from the Industry Task Force II on 2,4-D Research Data, an association of manufacturers and commercial formulators of 2,4-D, concluded that the toxicological data on 2,4-D does not provide a strong basis for predicting that 2,4-D is carcinogenic to humans. Nevertheless, the panel reviewing the evidence did conclude that "evidence indicates that it is possible that exposure to 2,4-D can cause cancer in humans.").

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illnesses and exposure to dioxins.

III. VETERANS' DIOXIN AND RADIATION EXPOSURE COMPENSATION STANDARDS ACT OF 1984

With the increasing volume of scientific literature giving credence to the belief of many Vietnam Veterans that exposure to Agent Orange during their military service was related to their contraction of several debilitating diseases -- particularly non-Hodgkin's lymphoma, soft tissue sarcoma ("STS") (malignant tumors that form in muscle fat, or fibrous connective tissue) and porphyria cutanea tarda ("PCT") (deficiencies in liver enzymes) -- Vietnam Veterans rightfully sought disability compensation from the Veterans Administration ("VA").

The VA determined, however, that the vast majority of claimants were not entitled to compensation since they did not have service connected illnesses.²³ As a consequence, Congress attempted to alter dramatically the process governing Agent Orange disability claims through passage of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984

²³ By October 1, 1983, 9170 veterans filed claims for disabilities that they alleged were caused by exposure to Agent Orange. The VA denied compensation to 7709 claimants on the grounds that the claimed diseases were not service connected. Only one disease was deemed associated with service related exposure to Agent Orange, a skin condition known as chloracne. See House Report No. 98-592, reprinted in U.S. Code Cong. & Adm. News, 98th Cong. 2d Sess., 1984, at 4452. See also Nehmer v. U.S. Veterans Administration, 712 F.Supp. 1404, 1407 (1989).

(hereinafter the "Dioxin Standards Act")²⁴ To ensure that the VA provided disability compensation to veterans exposed to herbicides containing dioxin while serving in Vietnam,²⁵ Congress authorized the VA to conduct rulemaking to determine those diseases that were entitled to compensation as a result of a service--related exposure to Agent Orange.²⁶

In promulgating such rules, the Dioxin Standards Act required the VA to appoint a Veterans' Advisory Committee on Environmental Hazards (the "Advisory Committee") -- composed of experts in dioxin, experts in epidemiology, and interested members of the public -- to review the scientific literature on dioxin and submit periodic recommendations and evaluations to the Administrator of the VA.²⁷ Such experts were directed to evaluate the scientific evidence pursuant to regulations promulgated by the VA, and thereafter to submit recommendations

²⁴ Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. 98--542, Oct. 24, 1984, 98 Stat. 2727 (hereinafter the Dioxin Standards Act). In passing the Act Congress found that

Vietnam Veterans were "deeply concerned about possible long term health effects of exposure to herbicides containing dioxin,"(Section 2 (1)), particularly since "(t)here is scientific and medical uncertainty regarding such long—term adverse health effects." (Section 2 (2)). In responding to this uncertainty, Congress mandated that "thorough epidemiological studies of the health effects experienced by veterans in connection with exposure . to herbicides containing dioxin" be conducted, (Section 2(4)), especially in light of the fact that "[t]here is some evidence that chloracne, porphyria cutanea tarda, and soft tissue sarcoma are associated with exposure to certain levels of dioxin as found in some herbicides." (Section 2 (5)).

²⁵ Id. at Section 3.

²⁶ Id. at Section 5.

²⁷ Id. at Section 6.

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and evaluations to the Administrator of the VA on whether "sound scientific or medical evidence" indicated a connection to exposure to Agent Orange and the manifestation of various diseases.²⁸

In recognition of the uncertain state of scientific evidence and the inability to make an absolute causal connection between exposure to herbicides containing dioxin and affliction with various rare cancer diseases,²⁹ Congress mandated that the VA Administrator resolve any doubt in favor of the veteran seeking compensation. As stated in the ~~Dioxin Standards Act~~:

~~It has always been the policy of the Veterans Administration and is the policy of the United States, with respect to individual claims for service connection of diseases and disabilities; that when, after consideration of all the evidence and material of record, there is an approximate balance of positive and negative evidence regarding the merits of an issue material to the determination of a claim, the benefit of the doubt in resolving each such issue shall be given to the claimant.~~³⁰

A. NEHMER V. U.S. VETERANS ADMINISTRATION

Despite Congressional intent to give the veteran the benefit of the doubt, and in direct opposition to the stated purpose of

²⁸ Id. at Section 5.

²⁹ See *Nehmer v. U.S. Veterans Admin.*, 712 F. Supp. 1404, 1408. (N.D. Cal. (1989)). wherein the court found after reviewing the legislative history of the Act "that Congress intended service connection to be granted on the basis of "increased risk of incidence" or a "significant correlation" between dioxin and various diseases," rather than on the basis of a casual relationship.

³⁰ See Dioxin Standards Act at Section 2 (23).

the Dioxin Standards Act to provide disability compensation to Vietnam Veterans suffering with cancer who were exposed to Agent Orange, the VA continued to deny compensation improperly to over 31,000 veterans with just such claims. In fact, in promulgating the rules specified by Dioxin Standards Act, the VA not only confounded the intent of the Congress, but directly contradicted its own established practice of granting compensable service-connection status for diseases on the lesser showing of a statistical association, promulgating instead the more stringent requirement that compensation depends on establishing a cause and effect relationship.³¹

Mounting a challenge to the regulations, Veterans groups prosecuted a successful legal action which found that the VA had "both imposed an impermissibly demanding test for grantingservice connection for various diseases and refused to give the

³¹ See e.g. 38 C.F.R. 3.310(b) (compensation granted for cardiovascular diseases incurred by veterans who suffered amputations of legs or feet); *Nehmer* at 1418.

The significance of the distinction between a statistical association and a cause and effect relationship is in the burden of proof that the veteran must satisfy in order to be granted benefits. A statistical association "means that the observed coincidence in variations between exposure to the toxic substance and the adverse health effects is unlikely to be a chance occurrence or happenstance," whereas the cause and effect relationship "describes a much stronger relationship between exposure to a particular toxic substance and the development of a particular disease than 'statistically significant association' does." *Nehmer*, 712 F.Supp. at 1416.

Thus, the regulation promulgated by the VA established an overly burdensome standard by incorporating the causal relationship test within the text of the regulation itself. 38 C.F.R. 1 3.311(d) ("[s] ound scientific and medical evidence does not establish a cause and effect relationship between dioxin exposure" and any diseases except some cases of chloracne) (emphasis added).

veterans the benefit of the doubt in meeting the demanding standard." *Nehmer v. U.S. Veterans Administration*, 712 F. Supp. 1404, 1423 (1989) (emphasis in original). As a result, the court invalidated the VA's Dioxin regulation which denied service connection for all diseases other than chloracne; ordered the VA to amend its rules; and further ordered that the Advisory Committee reassess its recommendations in light of the court's order.³²

Thus, on October 2, 1989, the VA amended 38 C.F.R. Part 1, which among other things set forth

various factors for the Secretary and the Advisory Committee to consider in determining whether it is "at least as likely as not" that a scientific study shows a "significant statistical association" between a particular exposure to herbicides containing dioxin and a specific adverse health effect.³³ Equally important, the

³² Nehmer, 712 F. Supp at 1423.

³³ 38 C.F.R. 1.17 (b) & (d). 38 C.F.R. 1.17 states:

- (a) From time to time, the Secretary shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to a herbicide containing 2,3,7,8 tetrachlorodibenzo-p-dioxin (dioxin) and/or exposure to ionizing radiation in the "Notices" section of the Federal Register.
- (b) Factors to be considered in evaluating scientific studies include:
- (1) Whether the study's findings are statistically significant and replicable.
 - (2) Whether the study and its findings have withstood peer review.
 - (3) Whether the study methodology has been sufficiently described to permit replication of the study.
 - (4) Whether the study's findings are applicable to the veteran population of interest.
 - (5) The views of the appropriate panel of the Scientific Council of the Veteran' Advisory Committee on Environmental Hazards.
- (c) When the Secretary determines, based on the evaluation of

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regulation permits the Secretary to disregard the findings of the Advisory Committee, as well as the standards set forth at 38

scientific or medical studies and after receiving the advice of the Veteran's Advisory Committee on Environmental Hazards and applying the reasonable doubt doctrine as set forth in paragraph (d) (1) of this section, that a significant statistical association exists between any disease and exposure to a herbicide containing dioxin or exposure to ionizing radiation, 3.311a or 3.311b of this title, as appropriate, shall be amended to provide guidelines for the establishment of service connection.

(d) (1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weights of valid positive and negative studies permit the conclusion that it is at least as likely as not that the purported relationship between a particular type of exposure and a specific adverse health effect exists.

(2) For purposes of this paragraph a valid study is one which:

- (i) Had adequately described the study design and methods of data collection, verification and analysis;
- (ii) Is reasonably free of biases, such as selection, observation and participation biases; however, if biases exist, the investigator has acknowledged them and so stated the study's conclusions that the biases do not intrude upon those conclusions; and
- (iii) Has satisfactorily accounted for known confounding factors.

(3) For purposes of this paragraph a valid positive study is one which satisfies the criteria in

paragraph (d) (2) of this section and whose findings are statistically significant at a probability level of .05 or less with proper accounting for multiple comparisons and subgroups analyses.

(4) For purposes of this paragraph a valid negative study is one which satisfies the criteria in paragraph (d) (2) of this section and has sufficient statistical power to detect an association between a particular type of exposure and a specific adverse health effect if such an association were to exist.

(e) For purposes of assessing the relative weights of valid positive and negative studies, other studies affecting epidemiological assessments including case series, correlational studies and studies with insufficient statistical power as well as key mechanistic and animal studies which are found to have particular relevance to an effect on human organ systems may also be considered.

(f) Notwithstanding the provisions of paragraph (d) of this section, a "significant statistical association" may be deemed to exist between a particular exposure and a specific disease if, in the Secretary's judgment, scientific and medical evidence on the whole supports such a decision.

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C.F.R. § 1.17 (d) and determine in his own judgment that the scientific and medical evidence supports the existence of a "significant statistical association" between a particular exposure and a specific disease. 38 C.F.R. § 1.17 (f).

The Secretary recently exercised his discretionary authority under this rule when he found a significant statistical association between exposure to Agent Orange and non—Hodgkin's lymphoma, notwithstanding the failure of his own Advisory Committee to recommend such action in the face of overwhelming scientific data.³⁴

B. THE WORK OF THE VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

To assess the validity and competency of the work of the Advisory Committee, I asked several impartial scientists to

³⁴ After reviewing numerous scientific studies, at least four of which were deemed to be valid positive in demonstrating the link between exposure to herbicides containing dioxin and non--Hodgkin's lymphoma, the Advisory Committee still concluded that:

The Committee does not find the evidence sufficient at the present time to conclude that there is a significant statistical association between exposure to phenoxy acid herbicides and non—Hodgkin's lymphoma. However, the Committee cannot rule out such an association.

The Secretary should be interested to note that a new mortality study positively confirms that farmers exposed to herbicides containing 2,4-D have an increased risk of developing non-Hodgkin's lymphoma. See Blair, "Herbicides and Non-Hodgkin's Lymphoma: New Evidence From a Study of Saskatchewan Farmers," 82 Journal of the National Cancer Institute 575--582 (1990).

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review the Advisory Committee transcripts. Without exception, the experts who reviewed the work of the Advisory Committee disagreed with its findings and further questioned the validity of the Advisory Committee's review of studies on non—Hodgkin's lymphomas .

For instance, a distinguished group at the Fred Hutchinson Cancer Research Institute in Seattle, Washington, upon reviewing the Advisory Committee transcripts, concluded "that it is at east., as likely as not that there is a significant association (*as defined by the Secretary of Veterans Affairs*) between (exposure to phenoxy acid herbicides and non-Hodgkin's lymphoma.)" ³⁵ This same group further asserts that the Committee's work was "not sensible" and "rather unsatisfactory" in its review and classification of the various studies it reviewed. Additionally, these scientists regarded Dr. Lathrop's views as "less than objective" and felt that the possibility exists that "his extreme views (e.g., in respect to the role of dose--response testing) may have unduly affected the Committee's work." Finally, the Hutchinson scientists argue that the issue of chemical-specific effects, in which animal studies have been sufficient to demonstrate the carcinogenicity of dioxin, is an important factor "not well considered by the Committee." (emphasis in original)

A second reviewer of the Committee's work, Dr. Robert

³⁵ Letter to Admiral Zumwalt from Dr. Robert W. Day, Director of the Fred Hutchinson Cancer Research Center of Seattle, Washington (Feb. 20, 1990).

Hartzman (considered one of the U.S. Navy's top medical researchers), effectively confirms the views of the Hutchinson group. Dr. Hartzman states that "the preponderance of evidence from the papers reviewed [by the Advisory Committee) weighs heavily in favor of an effect of Agent Orange on increased risk for non—Hodgkin's lymphoma."³⁶ Dr. Hartzman also attests that:

an inadequate process is being used to evaluate scientific publications for use in public policy. The process uses scientific words like 'significant at the 5% level' and a committee of scientists to produce a decision about a series of publications. But in reality, the Committee was so tied by the process, that a decision which should have been based on scientific data was reduced to vague impressions... Actually, if the reading of the rules of valid negative found in the transcript is correct ('a valid negative must be significant at the $p=.05$ level' that is statistically significant on the negative side) none of the papers reviewed are valid negatives. ³⁷

A third reviewing team, Dr. Jeanne Hager Stellman, PhD (Physical Chemistry) and Steven D. Stellman, PhD (Physical Chemistry), also echo the sentiments expressed by the Hutchinson Group and Dr. Hartzman on the validity of the Committee's proceedings and conclusions. In fact, the Stellmans' detailed annotated bibliography and assessment of numerous cancer studies relevant to herbicide exposure presents a stunning indictment of the Advisory Committee's scientific

interpretation and policy judgments regarding the link between Agent Orange and Vietnam

³⁶ Letter to Admiral Zumwalt from Dr. R.J. Hartzman Capt. MC USN (March 7, 1990).

³⁷ Id. at p.3

Veterans . ³⁸

A fourth reviewer, a distinguished scientist intimately associated with government sponsored studies on the effects of exposure to Agent Orange, states the same conclusions reached by the other reviewers:

The work of the Veterans' Advisory Committee on Environmental Hazards, as documented in their November 2, 1989 transcript, has little or no scientific merit, and should not serve as a basis for compensation or regulatory decisions of any sort...

My analysis of the NHL articles reviewed by the committee reveals striking patterns which indicate to me that it is much more likely than not that a statistical association exists between NHL and herbicide exposure.

As these various reviewers suggest, the Advisory Committee's conclusions on the relationship between exposure to Agent Orange and non--Hodgkin's lymphoma were woefully understated in light of the clear evidence demonstrating a significant statistical association between NHL and exposure to phenoxy acid herbicides such as Agent Orange.

Perhaps more significant than the Committee's failure to make such obvious findings is the distressing conclusion of the independent reviewers that the Committee's process is so flawed

³⁸ See Stellman & Stellman, "A Selection of Papers with Commentaries Relevant to the Science Interpretation and Policy: Agent Orange and Vietnam Veterans," (March 1, 1990) . See also note 51 and accompanying text infra for additional discussion of the Stellmans' work.

³⁹ A copy of the anonymous reviewer's analysis can be made available for the Secretary's personal inspection and review. In another paper, this same source stated: "I estimate that the Vietnam Veterans are experiencing a 40% to 50% increase in sarcomas and non--Hodgkin's lymphoma rates."

as to be useless to the Secretary in making any determination on the effects of Agent Orange. From a mere reading of Committee transcripts, these reviewers detected overt bias in the Committee's evaluation of certain studies. In fact, some members of the Advisory Committee and other VA officials have, even before reviewing the evidence, publicly denied the existence of a correlation between exposure to dioxins and adverse health effects.⁴⁰ This blatant lack of impartiality lends credence to the suspicion that certain individuals may have been unduly influenced in their evaluation of various studies. Furthermore, such bias among Advisory committee members suggests that the Secretary should, in accordance with the Dioxin Standards Act, appoint new personnel to the Advisory Committee.

III. THE CDC STUDIES

Were the faulty conclusions, flawed methodology and noticeable bias of the Advisory Committee an isolated problem, correcting the misdirection would be more manageable. But, experience with other governmental agencies responsible for specifically analyzing and studying the effects of exposure to

⁴⁰ For instance, Dr. Lawrence B. Hobson (Director, Office of Environmental Medicine, Veterans Health Services and Research Administration), claims that TCDD 'presents no threat from the exposures experienced by the veterans and the public at large,' and virtually accuses scientists who find that such health effects do exist to be nothing more than witch doctors. See Hobson, 'Dioxin and Witchcraft' presented at the 5th International Symposium on Chlorinated Dioxins and Related Compounds (September 1985).

Agent Orange strongly hints at a discernible pattern, if not outright governmental collaboration, to deny compensation to Vietnam Veterans for disabilities associated with exposure to dioxin.

A case in point is the Centers for Disease control ("CDC"). As concerns grew following the first studies of human exposure to Agent Orange, Congress commissioned a large scale epidemiological study to determine the potential health effects for Vietnam Veterans exposed to Agent Orange. Initially, this study was to be conducted by the VA itself. When evidence surfaced, however, of the VA's footdragging in commencing the study (and initial disavowal of any potential harm from exposure to Agent Orange), Congress transferred the responsibility for the study to the CDC in 1983.

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Unfortunately, as hearings before the Human Resources and Intergovernmental Relations Subcommittee on July 11, 1989 revealed, the design, implementation and conclusions of the CDC study were so ill conceived as to suggest that political pressures once again interfered with the kind of professional, unbiased review Congress had sought to obtain.⁴²

The Agent Orange validation study, for example, a study of

⁴¹ See 135 Congressional Record, Statement of Senator Tom Daschle (November 21, 1989); See also Agent Orange Hearings at p.37.

⁴² Oversight Review of CDC's Agent Orange Study: Hearing Before the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations House of Representatives, 101st Cong., 1st Sess. at p. 71 and 330 (1989) [hereinafter cited as Agent Orange Hearing].

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the long—term health effects of exposures to herbicides in Vietnam, was supposedly conducted to determine if exposure could, in fact, be estimated.⁴³ After four years and approximately \$63 million in federal funds, the CDC concluded that an Agent Orange exposure study could not be done based on military records.⁴⁴ This conclusion was based on the results of blood tests of 646 Vietnam Veterans which ostensibly demonstrated that no association existed between serum dioxin levels and military— based estimates of the likelihood of exposure to Agent Orange.⁴⁵ Inexplicably, the CDC then used these "negative" findings to conclude that not only could an exposure study not even be done, but that the "study" which was never even conducted proves that Vietnam Veterans were never exposed to harmful doses of Agent Orange.

Even more disturbing, when the protocol for this "study" and the blood test procedures were examined further, there appeared to be a purposeful effort to sabotage any chance of a meaningful Agent Orange exposure analysis. For , the original protocol for the Agent Orange exposure study understandably called for subject veterans to be tracked by company level

⁴³ Id. at 37; See also, Protocol for Epidemiologic Studies of the Health of Vietnam Veterans, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services (November, 1983).

⁴⁴ Agent Orange Hearings at 13 (Statement of Dr. Vernon Houk).

⁴⁵ Id. at 12—13.

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location.⁴⁶ By tracking company level units of 200 men, rather than battalions of 1,000 men, the location of men in relation to herbicide applications would be known with greater precision, thereby decreasing the probability that study-subjects would be misclassified as having been or not been

exposed to Agent Orange.

However, in 1985 the CDC abruptly changed the protocol to have battalions, rather than companies, serve as the basis for cohort selection and unit location.⁴⁷ By the CDC's own admission, changing the protocol to track veterans on the broader battalion basis effectively diluted the study for the simple reason that many of the 1,000 men in a battalion were probably not exposed to Agent Orange. Why then did the CDC change the protocol in 1985?

According to Dr. Vernon Houk, Director of the Center for Environmental Health and Injury control, the department within the CDC responsible for conducting the Agent Orange study, the protocol was changed because the CDC concluded that company—specific records were unreliable and contained too many gaps of information. As a result, military records could simply not be used to assess exposure.⁴⁸

⁴⁶ Id. at 41.

⁴⁷ Id. at 38.

⁴⁸ Agent Orange Hearing: Testimony of Dr. Vernon Houk at 38-40 and 69. Dr. Houk sports an unbounded skepticism for the health hazards of dioxin. He recently endorsed the lessening of the dioxin dumping standard in the State of Georgia at a rate 500 times more lenient than EPA recommended guidelines. See Letter from Dr. Vernon N. Houk to Leonard Ledbetteber, Commissioner Georgia Department of Natural Resources (November 27, 1989).

Richard Christian, the former director of the Environmental Study Group of the Department of Defense ("ESG") testified that not only was this conclusion false, but that he had personally informed the CDC that adequate military records existed to identify company—specific movements as well as spray locations.⁴⁹ Furthermore, in a February 1985 report to the Congressional Office of Technology Assessment, the CDC reported that in analyzing 21 of 50 detailed computer HERBs tapes developed by the ESG on company movements that it was possible to correlate the exposure data to areas sprayed with Agent Orange with consistent results.⁵⁰ Indeed, a peer reviewed study sponsored by the American Legion conclusively demonstrated that such computerized data could be used to establish a reliable exposure classification system essential to any valid epidemiologic study of Vietnam Veterans.⁵¹

In addition to altering the protocol from company units to battalions, the CDC further diluted the study by changing the protocol on the length of time study subjects were to have served in Vietnam. Whereas the original protocol required subjects to have served a minimum of 9 months in combat companies, the CDC reduced the minimum to 6 months. Furthermore, the CDC eliminated

⁴⁹ Agent Orange Hearing, Testimony of Richard Christian at 41.

⁵⁰ Interim Report, Agent Orange Study: Exposure Assessment: Procedures and Statistical Issues. See Also American Legion Magazine Special Issue, "Agent Orange" (1990) at p. 12.

⁵¹ Agent Orange Hearing 155-220 (Testimony of Steven and Jeanne Stellman); American Legion and Columbia University Vietnam Experience Study, Environmental Research (December, 1988).

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from consideration all veterans who served more than one tour in Vietnam. Finally, while the original protocol called only for subjects who served in Vietnam from 1967 to 1968, the years that Agent Orange spraying was at its height, the CDC added an additional 6 months to this time period. The net effect of these various changes was seriously to dilute the possibility that study subjects would have been exposed to Agent Orange, which in turn would impair any epidemiological study's ability to detect increases in disease rate.⁵²

Although the above referenced problems cast serious suspicion on the work of the CDC, perhaps its most controversial

⁵² Agent Orange Hearing at 46-49. This "dilution effect" is considered the classic flaw in epidemiological study design. Most epidemiologists would try to optimize the chances of observing an effect by including, rather than excluding, the subjects who are most likely to have been exposed to the suspected disease causing agent. This statistical ability to observe an effect if one is present is generally referred to as the "statistical power" of a given study.

When the CDC chose to generalize exposure to Agent Orange to groups of veterans who were less likely, rather than more likely, to be exposed, the power of the study was diluted. For example, if we assume that 1 out of every 5 men who served in Vietnam was exposed to Agent Orange, any possible effects of the exposure will be diluted when the 4 non—exposed men are averaged in. If we assume further that exposure to Agent Orange caused a doubling of the incidence of cancers among the 20% of men exposed, the effect would largely be obscured since 80% of the group being studied would not have been sprayed with Agent Orange and would thus have a normal background rate of cancer. Consequently, only exceptionally large increases in the cancer rate would be discovered and or reach statistical significance in a study group so diluted from the outset. See Agent Orange Hearing at 149 (Testimony of John F. Sommer, Jr., Director National Veterans Affairs and Rehabilitation commission the American Legion).

See also Agent Orange Legislation and Oversight: Hearing Before the Committee on Veterans' Affairs, United States Senate, 100th Cong.,(May 12, 1988) (Testimony of Dr. Joel Nichalek) at pp. 65, 66 and 668.

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action was to determine unilaterally that blood tests taken more than 20 years after a veteran's service in Vietnam were the only valid means of determining a veteran's exposure to Agent Orange. In addition, Dr. Houk further "assumed" that the half-life for dioxin in the blood was seven years.⁵³ When the underlying data for Houk's assumptions were recently reviewed, however, 11 percent of the blood tests were invalid (i.e. study subjects had higher values of dioxin in their blood in 1987 than in 1982 even though the subjects had no known subsequent exposure to dioxin) and the half lives of dioxin in the remaining study subjects ranged from a low of 2 to a high of 740 years!⁵⁴ Yet despite this tremendous variance in the data and the high incidence of false results, Houk and the CDC concluded, rather remarkably, that a large scale exposure study was simply not possible since "negative" blood tests appeared to "confirm" that study subjects were not even exposed to Agent Orange.

Such conclusions are especially suspect given the fact that scientists have consistently cautioned against the use of blood tests as the sole basis for exposure classification. Although blood and adipose tissue tests can be used to confirm that

⁵³ Agent Orange Hearing at 59. Dr. Houk's assumption was based on a study of only 36 former Ranch Handlers (members of "Operation Ranch Hand," the Air Force herbicide defoliation program) who had volunteered blood samples in 1982 and 1987.

⁵⁴ American Legion Magazine Reprint "Agent Orange" at 12 See also Agent Orange Hearing at p. 67 (testimony of Dr. Houk revealed that the senior-statistician on the Agent Orange project believed that the dioxin blood analysis was so flawed there is a substantial likelihood that there is no correlation between the exposure scores and the blood levels).

Vietnam veterans were heavily exposed to Agent Orange and the contaminant dioxin⁵⁵, even the CDC's own researchers have unequivocally stated that "much more has to be learned about the kinetics of dioxin metabolism and half-life before current levels can be used to fully explain historic levels of exposure."⁵⁶

While the CDC's changes in protocol have been "justified", however unreasonably, on the basis of "scientific" explanations⁵⁷, what cannot be justified is the evidence of political interference in the design, implementation and drafting of results of the CDC study by Administration officials rather than CDC scientists. As early as 1986, the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce documented how untutored officials of the Office of Management and Budget (OMB) interfered with and second-guessed the professional judgments of agency scientists and multidisciplinary panels of outside peer review experts

⁵⁵ See Kahn, "Dioxins and Dibenzofurans in Blood and Adipose Tissue of Agent Orange Exposed Vietnam Veterans and Matched Controls," 259 Journal of the American Medical Association 1661 (1988). This report found that "Vietnam veterans who were heavily exposed to Agent Orange. exceeded matched control subjects in both blood, and adipose tissue levels of 2,3,7, 8—tetrachlorodibenzo-p—dioxin (TCDD) but not in the levels of the 12 other 2,3,7,8-substituted dioxins and dibenzofurans that were detected. Since only TCDD among these compounds was present in Agent Orange but all are present in the population of the industrialized world, it is likely that the elevated TCDD levels arose from wartime exposure."

⁵⁶ Patterson, "Levels of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans in Workers Exposed to 2,3,7,8 --tetrachlorodibenzo-p—dioxin., 16 American Journal of Industrial Medicine 135, 144 (1989).

⁵⁷ See generally, Agent Orange Hearing (Testimony of Dr. Vernon Houk) at 44--50.

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effectively to alter or forestall CDC research on the effects of Agent Orange, primarily on the grounds that "enough" dioxin research had already been done.⁵⁸ These Agent Orange Hearings revealed additional examples of political interference in the CDC's Agent Orange projects by members of the White House Agent Orange Working Group.⁵⁹

Dr. Philip 3. Landrigan, the former Director of the Environmental Hazards branch at the CDC, upon discovering the various irregularities in CDC procedures concluded that the errors were so egregious as to warrant an independent investigation not only of the methodology employed by the CDC in its validation study, but also a specific inquiry into what actually transpired at the Center for Environmental Health of the CDC.⁶⁰

With these suspicions in mind, it should come as no surprise that those familiar with the CDC's work found little credence in the conclusions reached by the CDC in its recently released Selected Cancers Study. Even though the CDC has previously stated that it believes exposure to Agent Orange is impossible to assess, it found no difficulty in reporting to the *press* upon the release of the Selected Cancers Study that exposure to Agent

⁵⁸ OMB Review of CDC Research: Impact of the Paperwork Reduction Act; A Report Prepared for the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, 99th Cong. 2nd Sess. (October 1986).

⁵⁹ See Agent Orange Hearing at 49-54 (Testimony of Dr. Vernon Houk).

⁶⁰ Agent Orange Hearing at 229 and 330

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Orange does not cause cancer. This conclusion was reached despite the fact that the CDC made no effort to determine, through military records or blood/adipose tissue tests, if study subjects were, indeed, exposed to dioxins; nor did the CDC attempt to verify exposure to Agent Orange of those study subjects who actually contracted cancerous diseases. In fact, according to scientists who have made preliminary reviews of the CDC's findings, the statistical power of any one cancer grouping, with the exception of non—Hodgkin's lymphoma, was so low as to make any conclusion virtually impossible.

IV. RANCH HAND STUDY

Unfortunately, political interference in government sponsored studies associated with Agent orange has been the norm, not the exception. In fact, there appears to have been a systematic effort to suppress critical data or alter results to meet preconceived notions of what alleged scientific studies were meant to find.⁶¹ As recently as March 9, 1990 Senator Daschle disclosed compelling evidence of additional political interference in the Air Force Ranch Hand study, a separate government sponsored study meant to examine the correlation between exposure to Agent Orange and harmful health effects among Air Force veterans who participated in Agent Orange spraying

⁶¹ See generally Agent Orange Nearing; Congressional Record, S 2550 (March 9, 1990); Congressional Record, (November 21, 1989) (Statements of Senator Thomas Daschle).

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missions under Operation Ranch Hand. As Senator Daschle explained:

In January 1984, the scientists in charge of the Ranch Hand Study issued a draft baseline morbidity report that described some very serious health problems in the Ranch Hand veterans and stated that the Ranch Handers, by a ratio of five to one, were generally less well than the veterans in the control group. The opening sentence of the draft report's conclusion was clearly stated: "It is incorrect to interpret this baseline study as 'negative.'

After the Ranch Hand Advisory Committee, which operates under the White House Agent Orange Working Group of the Domestic Policy Council, got its hands on the document, the final report was changed in some very important ways. Most notably, the table and exposition explaining that the Ranch Handers were generally less well than the controls was omitted, and the final conclusion was altered substantially. The statement that the baseline study was not negative was completely omitted and the study was described as "reassuring." ⁶²

By altering the study's conclusion, opponents of Agent Orange compensation were able to point to "irrefutable proof" that Agent Orange is not a health problem: if those veterans most heavily exposed to Agent Orange did not manifest any serious health problems, they argued, then it could safely be deduced that no veteran allegedly exposed to Agent Orange in smaller doses could have health problems. Yet, when Senator Daschle questioned Air Force scientists on why discrepancies existed between an Air Force draft of the Ranch Hand Study and the final report actually released to the press, the answers suggested not merely disagreements in data evaluation, but the perpetration of fraudulent conclusions. In a word, the major premise was badly

⁶² See Congressional Record S 2550 (March 9, 1990)

flawed.

For example, in 1987 Ranch Hand scientists confirmed to Senator Daschle that an unpublished birth defects report shows that birth defects among Ranch Hand children are double those of children in the control group and not "minor" as originally reported in 1984.⁶³

This increase in birth defects takes on added significance when one considers that the original CDC birth defects study, which found no increase in birth defects, merely examined birth defects as reported on birth certificates, rather than as reported by the child's parent or physician. The CDC never recorded hidden birth defects, such as internal organ malformations and other disabilities that only became apparent as the child developed. Consequently, it is very likely that the CDC's negative findings on birth defects were also vastly understated.⁶⁴

In addition to elevated birth defects, Ranch Handers also showed a significant increase in skin cancers unrelated to overexposure to the sun as originally suggested in the 1984 report. Air Force scientists also admitted that Air Force and White House Kanagement representatives were involved in

⁶³ Congressional Record, (November 21, 1989) (Statement of Senator Thomas Daschle).

⁶⁴ The CDC birth defects study was confined to Vietnam Veterans located in the Atlanta, Georgia region. The study was not an Agent Orange birth defects study since no effort was made to determine whether the veterans had even been exposed to Agent orange. See notes 10 and 18 supra for additional information on birth defects.

scientific decisions in spite of the study's protocol which prohibited such involvement.⁶⁵

On February 23, 1990, the Air Force released a follow-up morbidity report on the Ranch Handers. That report, "1987 Followup Examination Results," described statistically significant increases in health problems among Ranch Handers including: all cancers — skin and systemic combined, both verified and suspected; skin cancers alone; hereditary and degenerative neurological diseases and other problems. The Air Force-concluded, however, that these and other problems cannot necessarily be related to Agent Orange/dioxin exposure, as they do not always show a "dose-response" relationship — particularly since the exposure index used in the data analysis "is not a good measure of actual dioxin exposure."⁶⁶

With this conclusion, the Air Force for the first time officially acknowledged that the conclusions reached in its original 1984 Ranch Hand study are not simply moot, but that the Ranch Hand study is not, at this date, an Agent Orange study at all since dioxin exposure could not be determined reliably in the first place. In other words, the Air Force could just as easily have concluded that the health problems associated with the Ranch Handers were not necessarily related to eating beer nuts.

⁶⁵ Congressional Record, S 2551 (March 9, 1990) (Statement of Senator Daschle).

⁶⁶ Wolfe, St. al., Air Farce Health Study and Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides (Feb. 1990) at p. vi.

For the Air Force to have made the statement in 1990 of no evidence of a link between exposure to Agent Orange and the cancer problems experienced by Ranch Handers is, as Senator Daschle notes, "patently false."⁶⁷ Although not yet conclusive, what the Ranch Hand and CDC studies demonstrate is that there is evidence of a link between health problems and dioxin exposures which may become definitive when a new and reliable exposure index is used to evaluate the data.

As stated by Dr. James Clary, one of the scientists who prepared the final Ranch Hand report:

The current literature on dioxin and non--Hodgkin's lymphoma and soft tissue sarcoma can be characterized by the following:

1. It underestimates (reduced risk estimates) the effect of dioxins on human tissue systems. As additional studies are completed we can expect to see even stronger correlations of dioxin exposure and NHL/STS.
2. Previous studies were not sensitive enough to detect small, but statistically significant increases in NHL/STS. As time progresses, and additional evidence is forthcoming, it will be increasingly difficult for anyone to deny the relationship between dioxin exposure and NHL/STS

V. INDEPENDENT STUDIES

Shamefully, the deception, fraud and political interference that has characterized government sponsored studies on the health

⁶⁷ Congressional Record 5. 2551 (March 9, 1990). See also Letter from Maj. Gen. James G. Sanders, U.S.A.F. Deputy Surgeon General to Senator Thomas Daschle (February 23, 1990).

⁶⁸ Letter from Dr. James Clary to Senator Tom Daschle (September 9, 1988).

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effects of exposure to Agent Orange and/or dioxin has not escaped studies ostensibly conducted by independent reviewers, a factor that has only further compounded the erroneous conclusions reached by the government.

For instance, recent litigation against the Monsanto corporation revealed conclusive evidence that studies conducted by Monsanto employees to examine the health effects of exposure to dioxin were fraudulent. These same fraudulent studies have been repeatedly cited by government officials to deny the existence of a relationship between health problems and exposure to Agent Orange. According to court papers:

Zack and Gaffey, two Monsanto employees, published a mortality study purporting to compare the cancer death rate amongst the Nitro workers who were exposed to Dioxin in the 1949 explosion with the cancer death rate of unexposed workers. The published study concluded that the death rate of the exposed worker was exactly the same as the death rate as the unexposed worker. However, Zack and Gaffey deliberately and knowingly omitted 5 deaths from the exposed group and took 4 workers who had been exposed and put these workers in the unexposed group, serving, of course, to decrease the death rate in the exposed group and increase the death rate in the unexposed group. The exposed group, in fact, had 18 cancer deaths instead of the reported 9 deaths (P1. Ex. 1464), with the result that the death rate in the exposed group was 65% higher than expected (emphasis in original)⁶⁹.

⁶⁹ Brief of Plaintiffs-appellees in Kemner. et. al. v. Monsanto Company, No. 5--88--0420 (5th Dist., Illinois Appellate Court) (Oct. 3, 1989) (as the facts were proven at trial, the appeal only considered appealable matters of law). Plaintiff's brief refers to Zack and Gaf fey, "A Mortality Study of Workers Employed at the Monsanto Company Plant in Nitro, WV., man Environmental Risks of Chlorinated Dioxins and Related Compounds (1983) pp. 575--591. It should be noted that the Advisory Committee classified this report as "negative" in evaluating compensation for NHL

The brief also states that another study of the workers exposed in the 1949 accident was also fraudulent (e.g. R.R. Suskind

Similarly, recent evidence also suggests that another study heavily relied upon by those opposed to Agent Orange compensation to deny the existence of a link between dioxin and health effects was falsified. Three epidemiologic studies and several case report studies about an 1953 industrial accident in which workers at a BASF plant were exposed to dioxins concluded that exposure to TCDD did not cause human malignancies.⁷⁰ A reanalysis of the data that comprised the studies, all of which was supplied by the BASF company itself, revealed that some workers suffering from chloracne (an acknowledged evidence of exposure to dioxin) had actually been placed in the low--exposed or non--exposed cohort groups. Additionally, 20 plant supervisory personnel, not believed to have been exposed, were placed in the exposed group.

When the 20 supervisory personnel were removed from the exposed group, thereby negating any dilution effect, the reanalysis revealed statistically significant increases in cancers of the respiratory organs (lungs, trachea, etc.) and

and V.S. Hertzberg, "Human Health Effects of 2,4,5-T and Its Toxic Contaminants," Journal of the American Medical Association, Vol. 251, No. 18 (1984) pgs. 2372-2380.) The study reported only 14 cancers in the exposed group and 6 cancers in the unexposed group. Trial records conclusively demonstrated, however, that there were 28 cancers in the group that had been exposed to dioxins, as opposed to only 2 cancers in the unexposed group.

⁷⁰ See e.g. Thiess, Frentzel-Beyme, Link, "Mortality Study of Persons Exposed to Dioxin in a Trichlorophenol Process Accident that occurred in the BASF AG on November 17, 1953", 3 American Journal of Industrial Medicine 179—189 (1982)

cancers of the digestive tract.⁷¹ According to the scientist who conducted this study, "t)his analysis adds further evidence to an association between dioxin exposure and human malignancy."⁷²

Recent evidence also reveals that Dow Chemical, a manufacturer of Agent Orange was aware as early as 1964 that TCDD was a byproduct of the manufacturing process. According to Dow's then medical director, Dr. Benjamin Holder, extreme exposure to dioxins could result in "general organ toxicity" as well as "psychopathological" and "other systemic" problems.⁷³ In fact, a

⁷¹ Friedemann Rohleder, "Dioxins and Cancer Mortality Reanalysis of the BASF Cohort," presented at the 9th International Symposium on Chlorinated Dioxins and Related Compounds, Toronto, Ontario (Sept. 17-22, 1989). BASF recently published a study in an attempt to refute the <http://www.gulfwarvets.com/ao.html>

allegations that the original studies related to the accident were fraudulent. See Zobier, Messerer & Huber, "Thirty Four Year Mortality Follow Up of BASF Employees, 62 Occupational Environmental Health 139-157, (Oct. 19, 1989). While the company states that "there was no significant increase in deaths from malignant neoplasms," the study does conclude that:

There was, however, a significant excess for all cancers combined among the chloracne victims 20 or more years after initial exposure when an excess would be most likely to occur. In addition, there is the notable finding on one case of liver cancer without cirrhosis in a worker with an exceptionally high level of TCDD in the blood.

Id. at 155. See also id. at 139 ("In general, our results do not appear to support a strong association between cancer mortality and TCDD, but they do suggest that some hazard may have been produced.) (emphasis added) and 149 ("Although TCDD blood levels were available for only 5 of the 10 subjects, the three highest levels were found in subjects with liver cancer, leucosis and Merckel—cell carcinoma of the skin.").

⁷² Wanchinski, "New Analysis Links Dioxin to Cancer," New Scientist, (Oct. 28, 1989) p. 24.

⁷³ See L. Casten, Patterns of Secrecy: Dioxin and Agent Orange (1990) (unpublished manuscript detailing the efforts of government and industry to obscure the serious health consequences of exposure to dioxin).

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recent expert witness who reviewed Dow Chemical corporate documents on behalf of a plaintiff injured by exposure to dioxin who successfully sued Dow⁷⁴ states unequivocally that "the manufacturers of the chlorphenoxy herbicides have known for many years about the adverse effects of these materials on humans who were exposed to them."⁷⁵

VI. CURRENT SCIENCE ON HEALTH EFFECTS OF HERBICIDES AND DIOXIN

Despite its poor record in carrying out its responsibility to ascertain the health effects of exposure to Agent Orange, the CDC has been candid in some of its findings. As early as 1983, for instance, the CDC stated in the protocol of its proposed Agent Orange Studies "(t)hat the herbicide contaminant TCDD is considered to be one of the most toxic components known. Thus any interpretation of abnormal findings related to 2,4,5—T must take into consideration the presence of varying or undetermined

⁷⁴ Peteet v. Dow Chemical Co., 868 F.2d 1428 (5th Cir. 1989) cert...denied 110 S.Ct. 328 (1989).

⁷⁵ Letter from Daniel Teitelbaum, M.D., P.C. to Admiral E.R. Zumwalt, Jr. (April 18, 1990). Dr Teitelbaum additionally states:

What I do think...may bear on the Agent Orange issue, is the fact that in review of Dow's 2,4-D documentation I found that there are significant concentrations of potentially carcinogenic materials present in 2,4-D which have never been made known to the EPA, FDA, or to any other agency. Thus, in addition to the problem of the TCDD which, more likely than not, was present in the 2,4,5--T component of Agent Orange, the finding of other dioxins and closely related furans and xanthenes in the 2,4--D formulation was of compelling interest to me.

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amounts of TCDD." ⁷⁶

In 1987, after first being leaked by the New York Times, a VA mortality study was released indicating a 110 percent higher rate of non-Hodgkin's lymphoma in Marines who served in heavily sprayed areas as compared with those who served in areas that were not sprayed. ⁷⁷ The study also found a 58 percent higher rate of lung cancer among the same comparative groups. ⁷⁸

Also in 1987, a second VA study found a suggestive eight-fold increase in soft tissue sarcoma among veterans most likely to

⁷⁶ CDC Protocol, see note 1 supra The CDC went on to state that a wide variety of health effects have been observed following the administration of TCDD to experimental animals including soft tissue sarcomas and lymphoma, nasal and nasopharyngeal cancers, birth defects, changes in thymus and lymphoid tissues, and other numerous cancers. Additionally, the CDC acknowledged the toxic effects of occupational exposure to dioxin, including evidence that exposure "may be associated with an increased risk of soft tissue sarcoma and lymphoma" and perhaps nasal and nasopharyngeal cancers.

⁷⁷ Breslin, et. al. "Proportionate Mortality Study of U.S. Army and U.S. Marine Corps Veterans of the Vietnam War," Veterans Administration (1987).

⁷⁸ Id. Some scientists, including the Advisory Committee have attempted to denigrate these significant findings on the basis that Army personnel did not show similar results. The explanation for this lack of comparative Army findings is directly attributable to the dilution effect caused by including logistics personnel as part of the Army study. Marines were studied as a separate group. The Marine's logistical support personnel (i.e. the Navy), were not included. Thus, the increased cancers among Marines were clearly associated with field exposure to Agent Orange.

The Army study, on the other hand, combined field personnel with personnel on logistics assignments who were unlikely to have been exposed to Agent Orange. As a result, the Army findings were drastically diluted. Additionally, Army personnel generally engaged the enemy and returned to base, whereas Marines consistently remained in areas presumably sprayed by Agent Orange to provide medical, health and engineering assistance to the local population. Such

"pacification" efforts gave Marines additional opportunities to be exposed to dioxins.

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have been exposed to Agent Orange.⁷⁹

A proportionate mortality study of deaths in pulp and paper mill workers in New Hampshire from 1975 to 1985 showed that one or more of the exposures experienced by such workers (dioxin is a byproduct of pulp and paper production) posed a "significant risk" for cancers of the digestive tract and lymphopoietic tissues.⁸⁰

Another case control study of farmers in Hancock County, Ohio, showed a "statistically significant" rise in Hodgkin's disease and non-Hodgkin's lymphoma. Although the study speculates that exposure to phenoxy herbicides may be the cause of such elevated cancers, the study recognizes that, given the size of its cohort, the only credible conclusion that can be drawn is that it "adds to the growing body of reports linking farming and malignant lymphoma, particularly NHL."⁸¹

A study of disease and non—battle injuries among U.S. Marines in Vietnam from 1965 to 1972 showed a significantly higher rate of first hospitalizations for Marines stationed in Vietnam as opposed to Marines stationed elsewhere, particularly

⁷⁹ Kang, et. al., "Soft-Tissue Sarcoma and Military Service in Vietnam: A Case Control Study," 79 Journal of the National Cancer Institute 693 (October, 1987). The increases were not statistically significant as reported. Nonetheless, the results are remarkable.

⁸⁰ E · Schwartz, "A Proportional Mortality Ratio of Pulp and Paper Mill Workers in New Hampshire," 45 British Journal of Industrial Medicine, 234—238 (1988).

⁸¹ Dubrow, Paulson & Indian, "Farming and Malignant Lymphoma in Hancock county, Ohio," 45 British Journal of Industrial Medicine 25—28 (1988).

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for neoplasms, diseases of the blood and blood forming organs and diseases of the circulatory and respiratory systems.⁸² Of particular significance is the fact that the rate of first hospitalization for disease and non—battle injuries among Vietnam personnel rose steadily, reaching a peak in 1969, while the rate of non—Vietnam personnel remained relatively constant.⁸³ This rise in hospitalization for non—combat injuries coincides exactly with the increased use of Agent Orange, reaching a peak in 1969, and declining thereafter until its elimination in 1971.

In a recently published article entitled "2,4--D, 2,4,5 --T, and 2,3,7,8 --TCDD: An Overview", the

authors acknowledge that at least three weaknesses in research related to dioxins are sufficient to cast doubt on the validity of any study.⁸⁴ The

⁸² Palinkas & Coben, "Disease and Non—Battle Injuries Among U.S. Marines in Vietnam, 153 *Military Medicine* 150 (March, 1988).

⁸³ *Id.* at 151. It should be noted that the year of greatest combat activity, as measured by the number of personnel wounded in action, 1968, had the smallest disease and non-battle injury vs. wounded in action ratio. *Id.* at 152.

⁸⁴ Lilienfeld and Gallo "2,4-D, 2,4,5—T and 2,3,7,8-TCDD An Overview," *Epidemiologic Review*, Vol. II (1989). Three major criteria must be considered in evaluating the numerous epidemiologic studies of phenoxy herbicides and 2,3,7,8-TCDD: 1) the accuracy of exposure assessment; 2) the studies' statistical power; and 3) the adequacy of follow-up. Problems in any one of the three areas leaves the study open to criticism and subject to manipulation.

For instance, in retrospective studies, various proxies of exposure to herbicides and 2,3,7,8,—TCDD have been used such as military service in Vietnam or residence in an area in which the herbicides were sprayed. The weakness in such an approach is that unless the proxy corresponds to exposure, the "exposed group" is diluted with the individuals who have NOT been exposed, thereby reducing the magnitude of the strength of the association. In fact, such reduction may be of such a degree as to preclude detection of any

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authors report that while the data on soft tissue sarcoma and phenoxy acids are too inconsistent to allow for any comment at this time, there is evidence of a strong association between STS and the suspect chemicals in 2 of the 8 studies analyzed in their article. Furthermore, the birth defect studies analyzed "suggest that adverse reproductive effects can be caused by (dioxin).⁸⁵

Recent studies in Vietnam continue to show statistically significant reproductive anomalies and birth defects among women, and children of women presumably exposed to Agent Orange spraying.⁸⁶

of a serum marker for 2,3,7,8-TCDD by Kahn may provide the means of identifying persons who have been exposed.

Furthermore, studies concerning Agent Orange have nearly all been conducted in the past decade. This 10 year latency period is generally thought to be insufficient for many cancers to be clinically detected.

⁸⁵ Id.

⁸⁶ See note 10 supra. It should be noted that as early as 1977 information about Agent Orange's potential for genetic damage was known to the VA. For example, a "NOT FOR RELEASE" VA document expressly noted Agent Orange's "high toxicity" and "its effect on newborn, deformed children — similar to the thalidomide situation." See L. Casten, Patterns of Secrecy note 73 supra at Department of Veteran Affairs p.4. Similarly, in March of 1980, Senator Tom Daschle and Rep. David Bonior received an anonymous memorandum written on VA stationery which stated:

chemical agents 2,4,5-T and 2,4-D commonly known as Agent Orange and Agent Blue, are mutagenic and teratogenic. This means they intercept the genetic DNA message processed to an unborn fetus, thereby resulting in deformed children being born. Therefore, the veteran would appear to have no ill effects from the exposure but he would produce deformed children due to this breakage in his genetic chain.... Agent Orange is 150,000 times more toxic than organic arsenic.

Id. See also Wolfe & Lathrop, "A Medical Surveillance Program for Scientists Exposed to Dioxins and Furans," Human and Environmental Risks of Chlorinated Dioxins and Related Compounds, 707—716 (1983)

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In the December 1, 1989, issue of *Cancer*, a study of the cancer risks among Missouri farmers found elevated levels of lip and bone cancer as well as nasal cavity and sinuses, prostrate, non-Hodgkin's lymphoma and multiple myeloma. Smaller elevations, but elevations nonetheless, were found for cancers of the rectum, liver, malignant melanoma, kidney and leukemia. According to the authors, evidence of the cause for the elevated risks for these illnesses "may be strongest for a role of agricultural chemicals, including herbicides, insecticides and fertilizers." ⁸⁷

Both the U.S. Environmental Protection Agency (EPA) and the International Agency for Research on Cancer (IARC) have concluded that dioxin is a "probable human carcinogen." ⁸⁸

In a work entitled "Carcinogenic Effects of Pesticides" to be issued by the National Cancer Institute Division of Cancer Etiology, researchers conclude that while confirmatory data is lacking there is ample evidence to suggest that NHL, STS, colon, nasal and nasopharyngeal cancer can result from exposure to phenoxy herbicides .

A just released case control study of the health risks of exposure to dioxins confirmed previous findings that exposure to

(Proceedings of International Symposium on Chlorinated Dioxins and Related Compounds, Arlington, VA, October 25—29, (1981)). The article explains the possible mechanism for paternally transmitted birth defects.

⁸⁷ Brownson, et. al. "Cancer Risks Among Missouri Farmers," 64 Cancer 2381, 2383 (December 1, 1989).

⁸⁸ Agency for Toxic Substances and Disease Registry, pp. 7., 61—68, 94 reprinted in Rachel's Hazardous Waste News # 173 (March 21, 1990)

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phenoxyacetic acids or chlorophenols entails a statistically significant increased risk (i.e. 1.80) for soft tissue sarcoma.⁸⁹

As recently as February 28, 1990 an additional study found that farmers exposed to various herbicides containing 2,4—D may experience elevated risks for certain cancers, particularly cancers of the stomach, connective tissue, skin, brain, prostate, and lymphatic and hematopoietic systems."⁹⁰

This week a scientific task force, after reviewing the scientific literature related to the potential human health effects associated with exposure to phenoxyacetic acid herbicides and/or their associated contaminants (chlorinated dioxins) concluded that it is at least as likely as not that exposure to Agent Orange is linked to the following diseases: non—Hodgkin's lymphoma, soft tissue sarcoma, skin disorders/chloracne, subclinical hepatotoxic effects (including secondary coproporphyrinuria and chronic hepatic porphyria), porphyria cutanea tarda, reproductive and developmental effects, neurologic

⁸⁹ Eriksson, Hardell & Adami, "Exposure to Dioxins as a Risk Factor for Soft Tissue Sarcoma: A Population--Based Case--Control study," 82 Journal of the National Cancer Institute 486—490 (March 21 1990) . It should be noted that in this study the median latency for phenoxyacetic acid and chlorophenols exposure was 29 and 31 years respectively, thereby suggesting that many of the veterans who are at risk have not yet manifested symptoms of STS.

⁹⁰ Blair, "Herbicides and Non-Hodgkin's Lymphoma: New Evidence From a Study of Saskatchewan Farmers," 82 Journal of the National cancer

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effects and Hodgkin's disease.⁹¹

On the same day that this scientific task force reported a statistically significant linkage between exposure to the dioxins in Agent Orange and various cancers and other illnesses, the Environmental Protection Agency reported that the cancer risk posed by the release of such a "potent carcinogen" as dioxin in the production of white paper products is "high enough to require tighter controls on paper

mills."⁹²

CONCLUSIONS

As many of the studies associated with Agent Orange and dioxins attest, science is only at the threshold of understanding the full dimension of harmful toxic effects from environmental agents on various components of the human immune system.⁹³ In

⁹¹ Report of the Agent Orange Scientific Task Force of the American Legion, Vietnam Veterans of America, and the National Veterans Legal Services Project, reported by McAllister, "Viet Defoliant Linked to More Diseases, Washington Post, May 1, 1990 at AS, col. 4. The report also found that there are other disorders for which there is evidence suggesting an association with exposure to Agent Orange, but for which statistically significant evidence is not currently available. Those diseases include: leukemias, cancers of the kidney, testis, pancreas, stomach, prostate, colon hepatobiliary tract, and brain, psychosocial effects, immunological abnormalities, and gastrointestinal disorders.

⁹² Weisskopf, "EPA Seeking to Reduce Dioxin in White Paper: Cancer Risk Said to Justify Mill Restrictions," Washington Post, May 1, 1990 at AS, col. 1.

⁹³ A recent report in the Washington Post suggests that there is an inherent uncertainty in trying to measure the dangers posed by the chemicals humans eat, drink and breathe. Since human experimentation is impossible to assess the effect of varied doses of a chemical on human health, scientists are ultimately required

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fact, a whole new discipline — immunotoxicology — has developed to explore further the effects of environmental chemicals on human health and to relate animal test results to humans.⁹⁴

Immunotoxicology has established, however, at a minimum that at least three classes of undesirable effects are likely occur when the immune system is disturbed by environmental exposure to chemicals such as dioxin, including: 1) immunodeficiency or suppression; 2) alteration of the host defense mechanism against mutagens and carcinogens (one theory is that the immune system detects cells altered by mutagens or other carcinogenic trigger and destroys these cells. Thus, an impaired immune system may not detect and destroy a newly forming cancer); and 3) hypersensitivity or allergy to the chemical antagonist. Because of dioxin's ability to be both an immunosuppressant and a carcinogen, as early as 1978 immunologists were suggesting that "(a) gents such as TCDD.. .may be far more dangerous than those possessing only one of these properties."⁹⁵

While scientists are not in agreement, some immunotoxicologists argue that one molecule of a carcinogenic agent, like dioxin in the right place and at the right time can

to speculate or guess as to the health effects of a given chemical to the human body. See *Measuring Chemicals' Dangers: Too Much Guesswork?* Washington Post, March 23, 1990.

⁹⁴ Silbergeld & Gaisewicz, "Dioxins and the Ah Receptor," 16 American Journal of Industrial Medicine 455, 468—69 (1989).

⁹⁵ Inadvertent Modification of the Immune Response — The Effect of Foods, Drugs, and Environmental Contaminants; Proceedings at the Fourth FDA symposium; U.S. Naval Academy (August 28-30, 1978), p. 78.

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cause the human immune system to turn on itself, manifesting such breakdowns in the form of cancer. Indeed, even some courts have accepted this theory of causation in matters specifically related to exposure to dioxin.⁹⁶

With additional evidence from Vietnam suggesting that Agent Orange contaminants have the ability to migrate away from actual spray locations via river channels and the food chain, the opportunity for a Vietnam Veteran to have been exposed to dioxin contaminant molecules increases significantly.⁹⁷

It cannot be seriously disputed that any large population exposed to chemical agents, such as Vietnam Veterans exposed to Agent Orange, is likely to find among its members a number who will develop malignancies and other mutagenic effects as a result of being exposed to harmful agents.

To be sure, decisions today with regard to the seriousness of Agent Orange health effects must be made while the science of

⁹⁶ See Peteet V. Dow Chemical Co., 868 F.2d 1428, 1433 (5th Cir. 1989) cert denied 110 S.Ct. 328 (1989).

⁹⁷ See e.g. Schecter, et. al., "Levels of 2,3,7,8—TCDD in Silt Samples Collected Between 1985—86 From Rivers in the North and South of Vietnam," 19 Chemosphere 547—550 (1989) (suggestive findings that the predominant dioxin isomer in Agent Orange has moved into downstream rivers in the South of Vietnam); Olie, et. al., "Chlorinated Dioxin and Dibenzofuran Levels in Food and Wildlife Samples in the North and South of Vietnam," 19 Chemosphere 493-496 (1989) (food and wildlife specimens in South Vietnam had a higher relative abundance of 2,3,7,8-TCDD suggesting contamination from Agent Orange); Schecter, et · al. "Chlorinated Dioxin and Dibenzofuran Levels in Food Samples Collected Between 1985—87 in the North and South of Vietnam," 18 Chemosphere 627—634 (1989) (Agent Orange contaminants, specifically 2,3,7,8-TCDD found at relatively elevated levels in food and wildlife samples 15-25 years after environmental contamination with

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compound in South of Vietnam

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immunotoxicology is in its infancy. After having evaluated and considered all of the known evidence on Agent Orange and dioxin contaminants, it is evident to me that enough is known about the current trends in the study of dioxins, and their linkage with certain cancers upon exposure, to give the exposed Vietnam Veteran the benefit of the doubt.

This benefit of the doubt takes on added credence given two separate means for determining exposure to Agent Orange — 1) HERBs and Service HERBs tapes establishing troop location for comparison with recorded Ranch Hand spraying missions; and 2) blood testing from living Veterans, to ascertain elevated dioxin levels. The inexplicable unwillingness of the CDC to utilize this data has had the effect of masking the real increase in the rate of cancers among the truly exposed. There is, in my opinion, no doubt that had either of these methods been used, statistically significant increased rates of cancer would have been detected among the Veterans for whom exposure can still be verified.

Since science is now able to conclude with as great a likelihood as not that dioxins are carcinogenic directly and indirectly through immunosuppression, and since a large proportion of those exposed to dioxin can be so ascertained, I am of the view that the compensation issue for service—related illnesses associated with exposure to Agent Orange should be resolved in favor of Vietnam Veterans in one of the two following ways:

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COMPENSATION FOR SERVICE RELATED ILLNESSES

Alternative 1:

Any Vietnam Veteran, or Vietnam Veteran's child who has a birth defect, should be presumed to have a service—connected health effect if that person suffers from the type of health effects consistent with dioxin exposure and the Veteran's health or service record establishes 1) abnormally high TCDD in blood tests; or 2) the veteran's presence within 20 kilometers and 30 days of a known sprayed area (as shown by HERBs tapes and corresponding company records); or 3) the Veteran's presence at fire base perimeters or brown water operations where there is reason believe Agent Orange have- occurred.

Under this alternative compensation would not be provided for those veterans whose exposure came from TCDD by way of the food chain; silt runoff from sprayed areas into unsprayed waterways; some unrecorded U.S. or allied Agent Orange sprayings; inaccurately recorded sprayings; or sprayings whose wind drift was greater than 20 kilometers. Predictably, problems generated by the foregoing oversights, the mass of data to be analyzed as claims were filed, and the known loss of many service records would invalidate many veterans' legitimate claims

Alternative 2:

Any Vietnam Veteran or child of a Vietnam Veteran who experiences a TCDD—like health effect shall be presumed to have a service—connected disability. This alternative is admittedly

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broader than the first, and would provide benefits for some veterans who were not exposed to Agent Orange and whose disabilities are not presumably truly service—connected. Nevertheless, it is the only alternative that will not unfairly preclude receipt of benefits by a TCDD exposed Vietnam Veteran.

Furthermore, this alternative is consistent with the Secretary's decision regarding the Service—connection of non—Hodgkin's lymphoma, as well as legal precedent with respect to other diseases presumed by the Department of Veterans Affairs to be connected to one or more factors related to military service (i.e. veterans exposed to atomic radiation and POW's with spastic colon).

PRESUMPTIONS OF AGENT ORANGE RELATED HEALTH EFFECTS

I have also given considerable thought to which health effects are to be presumed likelier than not to be related to TCDD exposure and therefore service—connected. Any such determination must be made in light of: 1) the review of the scientific literature, including animal studies where human data does not exist or has been manipulated; 2) the inappropriate processes of the Veterans Advisory Committee on Environmental Hazards; 3) the past political manipulations of Ranch Hand and CDC studies; and 4) the recent discoveries of manipulation by scientists hired by chemical manufacturers of dioxin contaminants to evaluate the potentially best epidemiological data concerning TCDD's effects on humans.

My evaluation of the evidence has been made with just such

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considerations in mind. Additionally, I have conferred with several experts in the field. After evaluating all the evidence and material of record, I am convinced that there is better than "an approximate balance of positive and negative evidence" on a series of Agent Orange related health effects.

It can, in my judgment, be concluded, with a very high degree of confidence, that it is at least as likely as not that the following are caused in humans by exposure to TCDD: non—Hodgkin's lymphoma, chloracne and other skin disorders, lip cancer, bone cancer, soft tissue sarcoma, birth defects, skin cancer, lung cancer, porphyria cutanea tarda and other liver disorders, Hodgkin's disease, hematopoietic diseases, multiple myeloma, neurological defects and auto—immune diseases and disorders.

In addition, I am most comfortable in concluding that it is at least as likely as not that liver cancer, nasal/pharyngeal/esophageal cancers, leukemia, malignant melanoma, kidney cancer, testicular cancer, pancreatic cancer, stomach cancer, prostate cancer, colon cancer, ~~brain cancer~~, psychosocial effects, and gastrointestinal disease are service-- connected.

I have separated the two foregoing subsets subjectively only because there is somewhat more data to support the former than the latter. Nonetheless, immunological and toxicological theory supports both subsets and fully justifies, in my view, the inclusion of both subsets of the foregoing health effects in determining a service--connected injury.

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Such a resolution of the embarrassingly prolonged Agent Orange controversy would be on the order of decisions to compensate U.S. soldiers who contracted cancer after exposure to radiation from atomic tests and U.S. soldiers involved, without their knowledge, in LSD experiments. With the scientific basis now available for it to be stated with confidence that it is at least as likely as not that various health effects are related to wartime exposure to Agent Orange, there is the opportunity finally to right a significant national wrong committed against our Vietnam Veterans.

RECOMENDATIONS

1. That the Secretary undertake a prompt reevaluation of the compensation decision impacting on Vietnam Veterans exposed to Agent Orange in light of accumulating scientific evidence that discredits earlier "findings" of an insufficient linkage between dioxin contaminants in Agent Orange and rare disease, such as cancer illnesses.

2. To the extent that the Secretary deems it necessary to use the Veterans' Advisory Committee on Environmental Hazards to assist in his reevaluation, the current members should be dismissed — having demonstrated a disturbing bias in their review to date of the scientific literature related to Agent Orange and dioxin -- and new members should be appointed in accordance with Section G of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, including persons with recognized scientific and medical expertise in fields pertinent

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to understanding the health effects of exposure to dioxin. The Committee meeting currently scheduled for May 16th and May 17th should be cancelled.

3. That the Secretary in making his decision regarding Agent Orange compensation for Vietnam Veterans do so on the basis of his independent evaluation of the existing scientific and medical evidence on the health effects of exposure to dioxins, as cataloged and discussed in this Report, and in full recognition that the standard to be applied -- as mandated by both Congress and the courts -- requires the resolution of doubts as to a number of cancers linked to dioxins in favor of the Vietnam Veterans.

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