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AGENT ORANGE: VETERANS' COMPLAINTS CONCERNING EXPOSURE TO HERBICIDES IN SOUTH VIETNAM

ISSUE BRIEF NUMBER IB80040

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MAJOR ISSUES SYSTEM

DATE ORIGINATED 09/06/79
DATE UPDATED 06/25/82

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ISSUE DEFINITION

From 1962 to 1971, the United States Air Force (USAF) sprayed various herbicide mixtures (chemicals that kill plants) in South Vietnam. The purpose of the spraying was to defoliate jungle growth to deprive the Communist forces of ground cover, and to destroy enemy crops to restrict food supplies. The most extensively used of these herbicide mixtures was known as Agent Orange, a 50:50 mix of two common herbicides called 2,4,5-T and 2,4-D (2,4,5-trichlorophenoxyacetic acid and 2,4-dichlorophenoxyacetic acid). A third chemical present in the mixture in small amounts was TCDD, an inevitable by-product of the manufacture of 2,4,5-T. This chemical, called tetrachlorodibenzo-para-dioxin or simply "dioxin," is highly toxic to laboratory animals when administered in its pure form. Acute (short-term) toxicity values in humans have not been established, although Gosselin et al., in the 1976 edition of Clinical Toxicology of Commercial Products, puts TCDD in a class of chemicals for which the "probable lethal dose" for humans would be less than 5 mg/kg, or about 7 drops for a 150 lb (70 kg) person.

CRS has been unable to locate any report of a human death from exposure to pure TCDD. The human health effect that has been most consistently documented following exposure to small amounts of TCDD as a contaminant in other compounds is a skin condition known as chloracne. There is other, less consistent, evidence of damage to the liver and the nervous system in humans. Extensive testing on laboratory animals has been done to determine possible long-term effects of exposure to TCDD. It can induce cancer in some strains of rats and mice (carcinogenicity), cause fetal death in several species (fetotoxicity) and birth defects in developing mouse fetuses (teratogenicity), but has been found not to cause genetic changes in mammalian cells (mutagenicity). The American Medical Association's Council on Scientific Affairs concluded that "there is no scientific evidence that 2,4-D, 2,4,5-T or TCDD has caused reproductive difficulties or hazards in the human."

Congressional interest was triggered by receipt of reports from Vietnam veterans who believed they had been harmed by exposure to herbicides, particularly Agent Orange. The 96th Congress held numerous hearings on the use of herbicides in South Vietnam, and various initiatives to deal with the problem were introduced. P.L. 96-151 was enacted to direct the Veterans Administration (VA) to conduct an epidemiological study on Vietnam veterans to determine whether there may be adverse human health effects associated with exposure to phenoxy herbicides and/or dioxin. This study and other studies planned will help elicit answers to the scientific questions posed by the Veterans Administration in determining whether or not the veterans' medical problems, allegedly due to exposure to Agent Orange and associated herbicides used in Vietnam, are compensable. Following recommendations made by the Interagency Work Group on Phenoxy Herbicides (now the Agent Orange Working Group), legislation was introduced in the 97th Congress to expand the scope of the VA's epidemiological study of the health effects of Agent Orange to include other factors related to military service in Vietnam. The legislation also allows veterans with medically certifiable conditions that might possibly have been caused by exposure to Agent Orange to receive medical care in VA facilities. The bill (H.R. 3499) was considered by the House and Senate in June 1981, put into final form in October, and signed by the President Nov. 3, 1981. Its title is the Veterans' Health Care, Training, and Small Business Loan Act of 1981 (P.L. 97-72).

BACKGROUND AND POLICY ANALYSIS

History

During the summer of 1969, the first reports of human birth defects allegedly attributed to Agent Orange appeared in Vietnamese newspapers. Based on these allegations and the results of a study sponsored by the National Cancer Institute that showed that 2,4,5-T contaminated with TCDD caused birth defects in laboratory animals, the USAF stopped spraying 2,4,5-T in South Vietnam by early 1971.

Although the Department of Defense maintains that only a limited number of U.S. military personnel can be positively identified as having been exposed to 2,4,5-T in South Vietnam (i.e., crews of aircraft that were used to spray herbicides), it is theoretically possible that large numbers of both military personnel (from the United States, South Vietnam, North Vietnam, Australia, and New Zealand) and civilians (especially South Vietnamese peasants) were exposed to 2,4,5-T through the USAF spraying program. A growing number of U.S. veterans who served in South Vietnam have begun to attribute the cause of various chronic ailments which they are now experiencing (especially nervous disorders, cancers, and birth defects in their offspring) to exposure to 2,4,5-T in South Vietnam, and many have filed claims with the VA for compensation. The VA has not yet awarded compensation to veterans for any claims related to 2,4,5-T exposure because of the lack of valid human data to prove a cause and effect relationship between exposure to 2,4,5-T and/or TCDD and specific health effects (except for chloracne).

TCDD Contamination

The industrial production of 2,4,5-T always results in some TCDD contamination although TCDD levels can be reduced to about 0.01 parts per million (ppm) with current technology. Because it was not widely recognized until the late 1960s that 2,4,5-T could contain hazardous amounts of TCDD, manufacturers did not start reducing the level of TCDD in 2,4,5-T until the USAF was already winding down its herbicide spraying program. The average TCDD levels in the 2,4,5-T - containing herbicide mixtures used in South Vietnam were approximately 2 ppm in Agent Orange (which accounted for approximately 96% of the 2,4,5-T used in South Vietnam), approximately 32.8 ppm in Agent Purple, and 65.6 ppm in Agents Pink and Green (Agents Purple, Pink, and Green contained the remaining 2,4,5-T used in South Vietnam). [The herbicides procured by the USAF were code named after the colored band that was placed around each 55 gallon drum in order to identify the contents.]

Health Effects -- Animal Data

Although TCDD is well established as one of the most toxic chemicals known for acute (short-term) effects, there is no consensus in the scientific community over the chronic (long-term) effects on humans of exposure to low levels of TCDD (such as those levels found in the herbicides used in South Vietnam).

Statistically significant animal experiments have demonstrated that

2,4,5-T containing low levels of TCDD and/or TCDD alone have caused various tumors in mice and rats. A recently-released National Toxicology Program bioassay of TCDD confirms these earlier reports that TCDD is carcinogenic in some laboratory animals. Thymic atrophy (without a corresponding loss in immune function) and severe weight loss have been observed in many species after TCDD exposure. In some species, acute exposure to TCDD can cause liver damage. Birth defects such as cleft palate and kidney abnormalities have been reported in baby mice when the mothers were exposed during pregnancy. A National Toxicology Program animal study of male reproductive effects of exposure to TCDD, however, has failed to reveal a statistically significant increase in reproductive abnormalities in TCDD-exposed animals or birth defects in the TCDD-exposed male animals' offspring. Although there is some experimental evidence that TCDD may cause mutations (changes in the cell's genetic material that may produce birth defects in as-yet-unconceived offspring), these experiments have been few, they have been done mainly on non-mammalian species or in vitro (in test tubes), and they have basically been inconclusive.

Some investigators feel that humans are less sensitive than animals to the toxic effects of TCDD. There is wide variation of responses to TCDD among different species, and the mechanisms of its toxicity and metabolism are not understood. More work needs to be done to clarify whether human exposure to TCDD can produce the same health effects with the same potency as those observed in animal studies.

Health Effects -- Human Data

If a cause and effect relationship is to be scientifically established between human exposure to a chemical and chronic health effects, a study which meets the following minimum criteria must be conducted to prove that such a relationship exists: a group of people (the "study group") must be identified that has already been exposed to the chemical under study (it would help to know the level of exposure); this study group must be large enough to detect chronic effects with statistical significance (to find an effect that occurred in 1 out of 100 people, one would need to examine at least 100 people); a control group must be found that ideally would differ from the study group only by never having been exposed to the chemical under study (thus, any differences in chronic health effects between the study and control groups could be attributed only to exposure to the chemical under study); and, due to the long latency period for many chronic effects, the study and control groups must be followed for as many years after exposure as it takes for the chronic effects to show up (i.e., in carcinogenicity studies, subjects must be followed for a minimum of 10 to 20 years after exposure to the suspect carcinogen). These exacting criteria are not met by most of the studies that have explored the relationship between human exposure to TCDD and/or 2,4,5,-T and subsequent health effects. Only for chloracne has such a cause and effect relationship been well established.

Workers who have been exposed to TCDD and/or 2,4,5-T in industrial explosions or who have had other occupational exposure are frequently found to have a skin condition known as chloracne -- which resembles normal acne except that it is caused by chemical exposure. Chloracne can appear from weeks to months after initial exposure and while mild cases (blackheads) may clear in a matter of months, severe cases (inflammatory lesions and scars) may last up to 30 years after exposure has ceased. While the severity of chloracne is not thought to correlate precisely with the intensity or duration of exposure to TCDD and/or 2,4,5-T, chloracne is associated so

closely with exposure that some scientists argue that patients who have not exhibited chloracne are unlikely to have suffered other toxic effects of TCDD and/or 2,4,5-T exposure.

Studies of these exposed workers have also indicated a variety of other health problems. For example, the United States Air Force Technical Report on the Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and its Associated Dioxin (1978) listed a number of symptoms, signs, or disorders that had been reported after occupational exposure to TCP (trichlorophenol, 2,4,5-T's precursor), 2,4,5-T, or TCDD (see Appendix). As noted, these studies, which reported symptoms associated with human exposure to dioxin, were not conducted in such a way as to prove a cause-and-effect relationship between exposure to TCDD and/or 2,4,5-T and any of these effects, but they may be indicative of such a relationship.

Several of the above studies have focused on investigating cancer rates among exposed workers. These studies do not show a clear cause/effect relationship between carcinogenicity associated with exposure to TCDD and/or 2,4,5-T because very few exposed workers (with the exception of those in Nitro, West Virginia) have been followed for more than ten years (the latency period for most cancers being 15 to 40 years after exposure) and the results have been equivocal. However, they support a continuing suspicion and indicate a need for further study. When the scientific panel of the Interagency Work Group on Phenoxy Herbicides reviewed five research papers by European scientists, it concluded that despite the studies' limitations, they do "show a correlation between exposure to phenoxy acid herbicides and an increased risk of some forms of cancer." A soft-tissue sarcoma study has been proposed that will be conducted jointly by the Armed Forces Institute of Pathology and the National Cancer Institute.

Studies that have been conducted in non-industrial settings have not been able to prove a cause and effect relationship between exposure to TCDD and/or 2,4,5-T and specific health effects. The National Academy of Sciences (NAS) was directed by Congress [P.L. 91-441, sec. 506(c)] to conduct a study on the effects of herbicides in South Vietnam, including health effects. This NAS study, as well as at least three other similar studies that were conducted in South Vietnam during the early 1970s, were unable to find adequate data upon which to reach any conclusions concerning a causal effect between exposure to herbicides and any health effects, including birth defects.

An explosion in a Hoffman-LaRoche chemical plant in Seveso, Italy in July 1976 caused thousands of people to be exposed to varying doses of TCDD as a toxic cloud drifted across the Italian countryside in a cone-shaped pattern about a mile long and half a mile wide. Some 5400 people lived in the two zones most directly affected, with an additional 40,000 people potentially exposed. Animals began to die 2 to 3 days after the incident with over 1,100 animals killed by direct exposure to TCDD. Over 700 people were evacuated from their homes. Chloracne was reported in 187 people, mostly children, and it tended to heal rapidly. Long-term human health effects of exposure to TCDD at Seveso are still being studied. Preliminary findings reported in 1979 by Hoffman-LaRoche revealed that Seveso residents had suffered liver damage but that there was no permanent breakdown in liver function. They also reported that rates of spontaneous abortions, fetal malformations, congenital defects, chromosome aberrations, reactions to infectious disease, and morbidity and mortality were not affected by TCDD exposure. As reported by the American Medical Association's Council on Scientific Affairs, "The most recent progress report on the long-term epidemiologic survey of the residents of the Seveso area emphasizes the preliminary nature of their

findings and reiterates the conclusions of prior investigators. Except for the skin, no organs or body functions were impaired. No derangement of gestation, no fetal lethality and loss, no gross malformations, no growth retardation at term and no cytogenetic abnormalities have yet occurred."

Health effects of domestic use of 2,4,5-T have been kept under surveillance by various Government agencies for some years. In April 1970, the Departments of Agriculture, Interior, and Health, Education and Welfare jointly announced the suspension of certain uses of 2,4,5-T following studies indicating that it was a teratogen. On Apr. 21, 1978, the Environmental Protection Agency (EPA) issued a Rebuttable Presumption Against Registration (RPAR) on 2,4,5-T, finding that the herbicide had exceeded certain risk criteria and inviting comments from interested parties. The RPAR was based on toxicological data from animal studies showing a correlation between 2,4,5-T exposure and cancer and birth defects. One of the comments received was from Alsea, Oregon, claiming that there was a high incidence of miscarriage among area women following spraying of the local forests with 2,4,5-T. EPA investigated this claim and reported its conclusion that the incidence of spontaneous abortion over a 6-year period in Alsea was higher than the rates in two other regions of Oregon that had lower rates of 2,4,5-T usage. Based on the combination of evidence from the animal studies and the Alsea study, EPA announced the emergency suspension of the domestic use of 2,4,5-T on forests, pastures, and rights-of-way on Feb. 28, 1979. The Alsea study has been criticized on methodological grounds by various groups, and its results are rejected by a number of writers. EPA hearings on cancellation of 2,4,5-T began in June 1979. On Mar. 24, 1981, EPA and Dow Chemical requested a recess in the hearing to discuss the possiblity of negotiating a settlement. The recess has been extended while the negotiations continue.

Herbicide Spraying in Vietnam

Approximately 107 million pounds of herbicides were aerially disseminated on 6 million acres of South Vietnam (an area about the size of Connecticut) from January 1962 to February 1971. Approximately 276,000 gallons of Agents Green, Pink, and Purple were sprayed in South Vietnam prior to 1965 when they were replaced by Agent Orange. Approximately 11 million gallons of Agent Orange were then sprayed in South Vietnam -- making it the most widely used herbicide of the war. Ninety percent of Agent Orange was sprayed on 2.9 million acres of inland forests and mangrove forests for defoliation, 8% was sprayed on enemy crops for crop destruction, and the remaining 2% was sprayed around base perimeters, cache sites, waterways, and communications lines.

The Air Force continued to operate its herbicide spraying program in South Vietnam until the late 1960s when the National Cancer Institute released results of an animal bioassay that showed 2,4,5-T to be teratogenic and/or fetotoxic in rodents, and newspapers in South Vietnam started reporting health problems among the rural populations who had been exposed to such herbicides. The Air Force first restricted the use of Agent Orange to areas remote from populations in October of 1969, then stopped all airplane spraying of Agent Orange in early 1970 and all helicopter spraying of Agent Orange by 1971. All remaining herbicide stocks were gathered and stored at either Gulfport, Mississippi or Johnston Island in the Pacific until they were incinerated at sea in 1977.

The following table outlines major military projects involving the handling of Agents Orange, Purple, Pink, or Green in South Vietnam.

MILITARY PROJECTS INVOLVING AGENTS ORANGE, PURPLE, PINK, OR GREEN

PROJECT	DATES	DESCRIPTION
AGILE	1960-68	Selection of herbicides, and development and evaluation of defoliation techniques.
RANCH HAND	1962-71	Aerial spraying of herbicides in South Vietnam.
Various USAF Projects	1962-70	Development and testing of aerial spray equipment.
PACER IVY	1971	Redrumming and movement of surplus herbicide from South Vietnam to Johnston Island.
Air Force Logistics Command Project	1972-77	Maintenance of herbicide inventory and research on options for disposal.
PACER HO	1977	Dedrumming of herbicide inventory and at-sea incineration of Agent Orange.

Each of these projects involved some human exposure to the herbicide 2,4,5-T and its contaminant, TCDD. The difficulty lies in determining who may have been exposed and at what level.

Personnel Exposed

The early trials that were conducted in South Vietnam to improve aircraft spray systems (1960 to early 1962) were conducted by USAF personnel assigned to the Special Aerial Spray Flight Division, Langley AFB, Va. (USAF personnel engaged in the herbicide program did not receive permanent change of station assignments to South Vietnam until 1964 -- thus making it more difficult to track personnel who may have been exposed to herbicides). During late 1962 and early 1963, the Crops Division at Fort Detrick and the USAF Armament Laboratory at Eglin Air Force Base, Florida were involved in efforts to provide improvements in spray system components in support of Operation RANCH HAND.

Most of the personnel involved in the actual handling of herbicide drums were Vietnamese. However, a USAF flight mechanic or crew chief was responsible for ensuring that the aircraft were properly loaded and that the spray systems were functional. Each herbicide aircrew consisted of a pilot and a copilot (both usually officers) and a flight mechanic/spray unit operator (usually enlisted). The aircrews were frequently joined by South Vietnamese and U.S. observers. As noted in a USAF report, "within the aircraft, it was not uncommon to have herbicide leakage from around the numerous hose connections joining the spray tank and pumps with the wing and aft spray booms. In hot weather, the odor of herbicide within the aircraft was decidedly noticeable."

The USAF has data on 6,542 herbicide spraying missions that took place between August 1965 and February 1971 on its "HERBS" computer tape. These data were compiled on a mission-by-mission basis from reports and files in various commands and offices in South Vietnam and the United States. The HERBS tape contains the following data for each mission: date; mission number; location; province and UTM coordinates; type of herbicide (basically, Agents Orange, White, or Blue); quantity of herbicide; area covered; purpose of mission (defoliation, crop destruction, etc.); and type of aircraft (plane or helicopter). The NAS used the HERBS tape in its evaluation of the effects of herbicides on South Vietnam. After evaluating the HERBS data, the NAS concluded that the HERBS tape accounted for approximately 86% of all herbicide operations in South Vietnam and that "despite certain recognized deficiencies," the HERBS tape is "a reliable source for an assessment of the major part of the herbicide operation in South Vietnam" and "is the best and in fact the only available comprehensive computation of the major part of the herbicide operations conducted in the Vietnam war."

When the DOD suspended all use of 2,4,5-T in South Vietnam, the USAF was left with an inventory of 2.22 million gallons of unused Agent Orange (1.37 million gallons which had been shipped to South Vietnam and 0.85 million gallons which were waiting to be shipped at the Naval Construction Battalion Center at Gulfport, Mississippi). In April 1972, the 1.37 million gallons of Agent Orange were moved from South Vietnam to Johnston Island in the Pacific Ocean for storage. The total amount of TCDD in the remaining Agent Orange stock was approximately 44.1 pounds. Problems began to arise in both locations as drums reportedly began to leak and the USAF expressed concern over further leakage problems that could occur if a tornado hit the Mississippi site or if a typhoon hit the Pacific site. After exploring a number of options, the USAF decided to dispose of the Agent Orange by burning it at high temperatures at sea on the Dutch incinerator ship named the "Vulcanus." The Agent Orange was drained from the drums at each site and

transferred to the Vulcanus. The empty drums were then rinsed with diesel fuel and crushed. The rinse fluid was combined with the Agent Orange for incineration at sea. A total of 15,480 drums of Agent Orange were processed at the Mississippi site between May 24, 1977, and June 10, 1977, by approximately 110 USAF officers/technicians from the five Air Logistics Centers of the Air Force Logistics Command (located at Kelly AFB Texas; Hill AFB, Utah; Warner Robbins AFB, Georgia; Tinker AFB, Oklahoma; and McClellan AFB, California). A total of 24,795 drums of Agent Orange were processed at the Johnston Island site between July 27, 1977, and Aug. 23, 1977. Approximately 100 civilian employees hired by a contractor performed the dedrumming process. At both the Johnston Island and Mississippi sites, workers were provided with daily changes of work clothes and some with protective clothing. The Agent Orange was incinerated at sea in the period from July to September 1977. Results of industrial hygiene studies conducted at the time of the disposal operation by the U.S. Air Force (Gulfport) and the Battelle Memorial Institute (Johnston Island) revealed no immediate adverse health effects among the personnel involved in the operation.

Department of Defense Efforts

The USAF has stated that it can now identify 1,264 servicemen who were directly exposed to Agent Orange as they handled herbicide containers and flew spraying missions in South Vietnam. The Air Force has initiated a health effects study of Air Force personnel involved in operation "Ranch Hand," who sprayed Agent Orange in Vietnam. The Department of Defense (DOD) believes that these individuals had at least 1000 times more exposure to Agent Orange than the average ground troops. The epidemiological study will try to determine whether a causal relationship can be established between exposure to the 2,4-D/2,4,5-T mixture and long-term health effects. Although the study was originally scheduled to begin in October 1979, peer review of its protocols forced delays. The University of Texas School of Public Health, the U.S. Air Force Scientific Advisory Board and the Armed Forces Epidemiological Board reviewed the study protocols and recommended modifications. Then the Air Force asked the National Academy of Sciences (NAS) to review the protocols. On May 6, 1980, the NAS announced recommendations that the scope and duration of the study be expanded to increase the likelihood of obtaining definitive data. NAS also expressed concern about the public perception of credibility and impartiality of a study conducted internally by the Air Force. The Interagency Work Group's Scientific Panel, however, has recommended that the study, as designed by the Air Force, be conducted because, despite its limitations, it provides "a focus as to the type of health effects that may possibly occur in other (ground troop) personnel."

The Ranch Hand study is proceeding in several phases and will continue for 20 years. The first phase consists of a detailed medical history questionnaire, which has been administered to the Ranch Handers in their homes by trained interviewers from Louis Harris and Associates. A carefully matched control group, selected from military records held by the Air Force, has also been interviewed. The first data from the questionnaire should be available by mid-summer 1982. Also underway is the second phase of the study, a 3-day series of physical examinations, including a battery of psychological tests, which will be given to both the study group and the controls. The contractor for this phase is Kelsey-Seabold of Houston. The exams are scheduled to be completed by September 1982, with preliminary findings available 2 to 3 months later. Follow-up exams will be conducted at 1, 3, 5, 10, and 20 years. A mortality analysis on the Ranch Hand group is

in progress at the Air Force School of Aerospace Medicine, with data anticipated around August 1982, and a mortality tracking program will be continued throughout the study. Information on the health status of the veterans, as shown by the questionnaires and the physical examinations, will provide data for a morbidity analysis.

Many of the veterans who have filed claims with the VA for compensation for health effects caused by exposure to TCDD in South Vietnam did not hold jobs that caused direct exposure to 2,4,5-T. They claim that their exposure occurred indirectly either by being sprayed with overhead planes (although substances other than herbicides were also sprayed from planes) or by being exposed to 2,4,5-T in the environment. According to the DOD, military personnel did not usually enter areas sprayed with Agent Orange until 4 to 6 weeks after treatment. However, a recent General Accounting Office investigation concluded that a large number of Marines in the I Corps section of Vietnam from 1966-1969 were in, or close to, areas sprayed with Agent Orange on both the day of spraying and within 4 weeks afterward. Some Army units were also close to Agent Orange spraying.

The Department of Defense has recently made progress in identifying ground troops that may have been exposed to Agent Orange. Two Army and one Marine battalion - 31st Engineer Battalion, 2050 troops; 1st Squadron, 9th Calvary (Air Mobil), 2300 troops and 3rd Battalion, 1st Marines, have been identified as being in areas of Agent Orange operations. Exact numbers, locations, and identities of individuals who may have been sprayed are impossible to determine.

Veterans' Problems and Veterans Administration Efforts

The first reports of veterans' concerns over health effects of exposure to 2,4,5-T began to appear in late 1977 and early 1978, following media coverage of several veterans' claims. Veterans have associated a number of illnesses with exposure to 2,4,5-T, including skin conditions, fatague, nervousness, numbness in extremities, vision and/or hearing impairments, birth defects in offspring, reduced libido, miscarriages, impotency, respiratory problems, gastro-intestinal tract disturbances, and various cancers, as well as a variety of other illnesses.

As of Apr. 1, 1982, the VA had received 13064 claims for damage reportedly related to in-service exposure to herbicides; 2986 claims have been made due only to exposure to the herbicides and not for any specific condition; 10078 claims have been filed for specific conditions related to herbicide exposure, but 3469 of these have not had the diagnosis confirmed by medical authority. Of the 6609 claims with a confirmed diagnosis, 923 (13.7%) have been allowed for reasons other than Agent Orange exposures and 5686 (86.3%) have been denied. Approximately 93% or 858 of the total 923 claims allowed were for service-connected skin conditions, and the remaining 7% or 65 claims were allowed for cancer, psychiatric and neurological conditions, and various other miscellaneous disabilities. The 5686 claims denied fall into the following categories (many claims have more than one claimed diagnosis): 3055 for various skin conditions; 2335 for nervousness, headache, or fatigue; 886 for paralysis or numbness; 751 for gastro-intestinal or genito-urinary conditions; 399 for various malignancies; 356 for impaired sexual activity; 394 for eye, ear, nose, and throat conditions; 274 for lung conditions; 227 for cardiovascular conditions; and 137 for miscellaneous conditions. The VA has not awarded compensation for the claims of chronic illnesses related to Agent Orange exposure because of the lack of valid human data to prove a

cause and effect relationship between exposure to a 2,4,5-T/2,4-D mixture and/or TCDD and specific chronic health effects. Previously, the difficulty of determining which veterans were or were not exposed to Agent Orange was also a factor in denying compensation, but more recently the VA has conceded exposure for all veterans who were in Vietnam.

The VA is maintaining a registry of all Vietnam veterans who have come to VA hospitals and health care facilities expressing concern about possible herbicide-related health problems. Each such veteran, whether experiencing any health problems or not, is given a physical examination; currently, some 2700-2800 exams are being conducted each month. Data from all the exams is being computerized into a central Agent Orange Registry in addition to the individual records being maintained at the local VA facilities. As of Mar. 25, 1982, 81,670 veterans had received the initial exam, and about 61,000 of the records had been coded into the computer. Information from the registry is being analyzed to determine if the veterans have an increased rate of any particular diseases. Thus far, nothing unusual or unexpected has turned up. Treatment of any health problems uncovered by the exams is handled under normal VA procedures regarding service-connection, ability to pay for medical care, etc., with the exception that special guidelines have been issued for the handling of conditions possibly related to Agent Orange. In the Federal Register of Dec. 2, 1981, pursuant to Public Law 97-72, the VA issued guidelines for use by its physicians to "assist them in making determinations in individual cases as to whether a disability may have been caused" by exposure to Agent Orange. Even though treatment may be given for some conditions, the VA specified that "In accordance with congressional intent, a determination to furnish care under this authority does not establish that the condition for which medical care is provided is service-connected" for purposes of compensation or vocational rehabilitation eligibility.

Three additional VA activities on Agent Orange include participation in the tissue registry, the Chloracne Task Force, and investigations into TCDD residues in body fat tissue of veterans. When VA facilities perform surgery or autopsies on Vietnam veterans, tissue samples are taken and sent to the Armed Forces Institute of Pathology where a special tissue registry is being maintained. Examination of approximately 800 specimens has so far shown no significant clustering of tumors or other particular disease features. The Chloracne Task Force was established in response to a congressional request to sift out those cases of skin conditions that either resemble or are truly chloracne. Those veterans whose medical records show a definite possibility of chloracne will be invited to come to non-VA clinics for re-examination by dermatologists who have an expert knowledge of the disease. The VA has conducted a study to determine if TCDD can be detected in the body fat tissues of Vietnam veterans at any higher levels than in veterans who were not in Vietnam. Dioxin in body fat is measured in parts per trillion, levels which are at the technological limits of available detection methods. The test requires surgical removal of tissue from the abdomen and chemical analysis of the sample on gas chromatography/high resolution mass spectrometry instruments. The results of the study were inconclusive, and the VA has decided that the reliability of the procedure is not sufficient to warrant its use in attempting to verify dioxin exposure. An additional problem is that dioxin contamination is so ubiquitous (from domestic herbicide use and from its formation in municipal incinerators) that it may likely be found in everyone's fat tissue.

As mandated in P.L. 96-151, the Veterans' Affairs Amendments, the VA is currently preparing to perform an epidemiological study of Vietnam veterans exposed to Agent Orange. Although the study's protocol has been developed

and validated by an independent group, the VA will perform the testing and collect the data, with oversight by a non-VA scientific committee. Procurement of an independent contractor for the study's protocol was delayed for 14 months by a protest filed by the National Veterans Law Center (NVLC). The NVLC alleged that not only was the VA violating procurement law, but also the study as currently contemplated did not comply with the requirements of P.L. 96-151. On Feb. 2, 1981, the General Accounting Office concluded its investigation and denied the NVLC protest. On May 5, 1981, the VA announced the awarding of a contract to the University of California at Los Angeles (UCLA) School of Public Health for the design of the epidemiological study. UCLA submitted its first draft of the protocol to the VA in August 1981; it was peer-reviewed by the VA Advisory Committee on Health-Related Effects of Herbicides, by the Office of Technology Assessment, and by the Science Panel of the Agent Orange Working Group. All the review groups judged the draft protocol to be inadequate and not in compliance with the contract. UCLA has since modified the protocol, expanding on problem areas and incorporating the suggestions of the review groups; its final submission to the VA is due April 29, 1982. As with the Ranch Hand study, this epidemiological study will have two main parts: a questionnaire on health status and medical and occupational history, and a physical exam with laboratory workup. The study group will be 18,000 veterans, divided into 3 cohorts of 6000 each. Two of the cohorts will have had Vietnam service, and will be distinguished as having a high or a low likelihood of herbicide exposure. The third cohort will be veterans with non-Vietnam military service. Inclusion of the third group will generate data about the health effects of Vietnam service in addition to the information expected about herbicide-related health effects. The study will commence with a pilot project to field test its procedures and the questionnaire.

P.L. 96-151 also mandated the VA to conduct a comprehensive review and scientific analysis of the worldwide literature on Agent Orange and other phenoxy herbicides. JRB Associates prepared the review under contract, and the VA published the 2-volume study in October 1981. The VA is now preparing to contract for an update to the literature review, to reflect new reports and data that have appeared.

The Interagency Work Group on Phenoxy Herbicides and Contaminants, established in December 1979, recommended that the Centers for Disease Control (CDC) perform a case-control study to see if there is an increased incidence of specific malformations in children of Vietnam veterans. The population to be studied is a group of 7500 children who have birth defects and who are registered in CDC's Birth Defects Program (in operation since the late 1960s). Information on the families of these children, gained by extensive interviews and questionnaires, will be compared with that for 300 normal controls. The data will be analyzed to see what risk factors in the parents' lives, including military service in Vietnam, may be related to increased incidence of malformations in their children. CDC has completed a pilot study on a representative sample of the two groups to test the questionnaire and the procedures for finding the families. The main study will be started in late April 1982, and a preliminary report on the issue of Vietnam service is expected in the fall of 1983. Detailed analysis of the data on all risk factors will take several years to complete.

On Sept. 22, 1980, the Work Group held its first public meeting to discuss problems and proposals related to exposure to herbicides. On Jan. 19, 1981, the Secretary of Health and Human Services established the "Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants" to advise the Secretary and

the Chair of the Interagency Work Group on Herbicides concerning the Advisory Committee's oversight of the conduct of the Ranch Hand Study being conducted by the Air Force. In its seventh report to the White House, the Work Group's Scientific Panel concluded that:

> While it is difficult to accept logically that a single causative factor -- Herbicide Orange -- could be responsible for such a diverse set of health effects [as alleged by Vietnam veteran claims to the VA], there is no definitive evidence that permits selective exclusion of some of these illnesses. Further, it is possible that some of these health effects are occurring as a consequence of Vietnam service but not due to exposure to Herbicide Orange. The Science Panel is not aware of any data that suggest a modification of its previous recommendation that the focus of a study of Vietnam veterans should be broadened to consider Vietnam service as the exposure factor rather than focus solely on Herbicide Orange exposure.... The Science Panel is in receipt of data which indicate that there is at best a remote chance of accurate identification of specific ground troops who were exposed to Herbicide Orange.... The Panel is therefore of the opinion that design of a scientifically valid Herbicide Orange study of ground troops may not be possible. If the focus of a study of Vietnam veterans is broadened to consider Vietnam service as the exposure factor, a study of ground troops is necessary and a scientifically valid study can be designed.

On July 17, 1981, the Interagency Work Group was renamed and its membership expanded. Now called the Agent Orange Working Group, it is part of the Cabinet Council on Human Resources. The Department of Health and Human Services is the lead agency.

Because the VA currently recognizes only chloracne as a human health effect that can be proven to be caused by exposure to 2,4,5-T, veterans may have difficulty being compensated for even those effects for which there is strong animal evidence (i.e., cancer and birth defects caused in utero which are those birth defects that cannot be caused by the father and require the mother and fetus to be exposed during the actual pregnancy). Veterans who claim compensation for health effects which are not supported by strong animal data (i.e., mutations -- which could cause genetic defects in the father's sperm that would affect children conceived after exposure) may have an even tougher case to argue.

The veteran's question then becomes: How much evidence is required to prove the right to compensation? On whom does the burden of proof lie (the veteran or the VA)? If more evidence is needed, who will generate it? And finally, what constitutes fair treatment of veterans while the necessary data are being gathered?

Congressional Action of the 96th Congress

The 96th Congress responded to the problems of establishing a cause and effect relationship between veterans' exposure to herbicides in South Vietnam and the various health problems they are now experiencing by holding hearings and enacting legislation.

The Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce held hearings on June 24 and 25, 1979, to hear testimony from veterans who allegedly have been affected by herbicide exposure and from the Veterans Administration regarding its efforts to unequivocally determine the relationship between herbicide exposure and health effects. The Subcommittee on Medical Benefits and Facilities of the House Committee on Veterans' Affairs held two sets of hearings on the hazards associated with TCDD, veterans' complaints of health effects associated with Agent Orange exposure, and Veterans Administration's efforts to resolve the Agent Orange problem.

The Senate Veterans' Affairs Committee also held hearings to examine the Agent Orange problem.

As a step to gain access to records to locate veterans who may have been exposed to herbicides in-service, Title V of H.R. 2282, the Veterans' Disability Compensation and Survivors' Benefits Amendments of 1979, requires the Director of the National Institute for Occupational Safety and Health, upon request by the VA (or other appropriate agency) to request the current mailing address from the Internal Revenue Service of persons whom the VA certifies may have been exposed to occupational hazards. H.R. 2282 was passed in lieu of its companion bill, S. 689, and became Public Law 96-128 on Nov. 28, 1979.

Title III of H.R. 3892, the Veterans' Affairs amendments, directs the Veterans Administration to conduct an epidemiological study of the long-term health effects on individuals from exposure to dioxins in Vietnam, upon the Office of Technology Assessment's (OTA) approval of its protocol. Its companion bill, S. 1039, was incorporated in H.R. 3892 as an amendment, and the measure was enacted by Congress and signed by the President on Dec. 20, 1979 (P.L. 96-151).

If enacted, S. 2096 would have directed the Secretary of Health, Education, and Welfare (now, Health and Human Services) to undertake an epidemiological study to determine the long-term adverse human health effects associated with exposure to dioxins produced during the manufacture of phenoxy herbicides. This bill proposed to investigate the long-term health effects of exposure to dioxins, in general, not just to Agent Orange. As similarly incorporated in H.R. 3892, S. 2096 would have required that the study's protocol be approved by the Congressional Office of Technology Assessment. This bill was presented to the President on Dec. 21, 1979, and vetoed by him on Jan. 2, 1980. President Carter vetoed the bill because the White House counsel believed that such a procedure violated the separation of power between the legislative branch and the executive branch. He did not feel that the Department of Health and Human Services' study protocol should be subject to approval by a congressional agency.

Title X of H.R. 5288, the Veterans' Rehabilitation Program and Veterans' Educational Assistance Program would have directed the Secretary of Health and Human Services to conduct a study of veterans and other groups exposed to the herbicide known as "Agent Orange" to determine if there may be adverse health effects associated with such exposure. Like H.R. 3892 (P.L. 96-151) and S. 2096, the bill called for OTA approval of the study's protocol. The bill also would have required the Secretary of Health and Human Services to coordinate its efforts with other studies in the Federal Government. During the debate on S. 1188, its companion bill, the Disabled Veterans' Rehabilitation Act, the Senate adopted an amendment offered by Senator

Cranston to expand the study on health effects of exposure to Agent Orange to include other factors related to service in Vietnam. The Senate also adopted an amendment offered by Senator Heinz requiring the VA to promulgate regulations regarding guidelines to resolve veterans' disability claims based on exposure to Agent Orange. The amendments were striken by the House because they were considered to be "non-germane" to the primary focus of the bill.

S. 1872 (the Vietnam Veterans' Act); H.R. 6050 (the Vietnam Veterans' Act); H.R. 6377 (the Vietnam Era Veterans Agent Orange Act); each would have established a presumption of service-connected disability for health effects in Vietnam veterans (and birth defects in their children) exposed to Agent Orange. H.R. 8238 (Independent Agent Orange Study) would have directed the Veterans Administrator to request the National Academy of Sciences to conduct a study on veterans exposed to Agent Orange. H.R. 8300 would have expanded the scope of the Agent Orange study currently being coordinated by the VA and would have established deadlines for promulgating regulations related to Agent Orange exposure claims. These bills received no action.

LEGISLATION

P.L. 97-72, H.R. 3499

Veterans' Health Care, Training and Small Business Loan Act of 1981. Amends title 38, U.S. Code, to extend the Vietnam-era veterans' readjustment counseling program, to provide medical care for Vietnam veterans exposed to herbicide defoliants (including Agent Orange), to recover the cost of certain health care provided by the VA, and authorizes the VA to expand the scope of its epidemiological study on the health effects of Agent Orange, and other purposes. Introduced May 7, 1981; referred to Committee on Veterans' Affairs. Committee consideration and mark-up session held May 12. Reported to House (amended) by Committee on Veterans' Affairs (H.Rept. 97-79) May 19. Passed House (amended) June 2, 1981. Received in the Senate June 3. Senate struck all after the Enacting Clause and substituted the language of S. 921, June 16. Passed Senate in lieu of S. 921 with amendments, June 16, 1981. House concurred in Senate amendments with amendments Oct. 2, 1981. Senate agreed to House amendments Oct. 16, 1981. Signed into law Nov. 3, 1981.

H.R. 523 (Roe)

Amends Title 38, U.S. Code, to waive the 1-year limitation on claims for compensation from the Veterans Administration for disabilities and diseases incurred in or aggravated by military service in the case of claims by veterans who served in Southeast Asia during the Vietnam era for compensation for disabilities resulting from exposure to the phenoxy herbicides known as Agent Orange or other phenoxy herbicides. Introduced Jan. 5, 1981; referred to Committee on Veterans' Affairs.

H.R. 1173 (Montgomery, by request)

Amends section 307 of P.L. 96-151, by assigning the responsibility of designating a protocol for, and conducting an epidemiological study of, veterans who were exposed to Agent Orange, to an independent scientific agency. Introduced Jan. 22, 1981; referred to Committee on Veterans' Affairs.

H.R. 1962 (Gilman)

Amends the Veterans Health Programs Extension and Improvement Act of 1979 to require the Veterans Administration and the National Academy of Sciences to enter into an agreement under which the Academy will conduct an epidemiological study of veterans exposed to Agent Orange. Introduced Feb. 19, 1981; referred to Committee on Veterans' Affairs.

H.R. 2157 (Mottl)

Expands the scope of a study required to be conducted by the Administrator of Veterans' Affairs concerning the effect on humans of exposure to the chemical known as Agent Orange. Introduced Feb. 25, 1981: referred to Committee on Veterans' Affairs. VA requested Executive comment Mar. 2, 1981. Referred to Subcommittee on Hospitals and Health Care Apr. 28. Hearings held Apr. 30. Subcommittee consideration and mark-up session held. Clean bill forwarded to full committee.

H.R. 2297 (Downey)

Amends Title 38, United States Code, to waive the 1-year limitation on claims for compensation from the Veterans Administration for disabilities and disease incurred in or aggravated by military service in the case of claims by veterans who served in Southeast Asia during the Vietnam era for compensation for disabilities resulting from exposure to the phenoxy herbicides known as "Agent Orange" or other phenoxy herbicides. Introduced Mar. 4, 1981; referred to Committee on Veterans' Affairs.

H.R. 2493 (Daschle)

Amends Title 38, United States Code, to provide a presumption of service connection for the occurrence of certain diseases in veterans who were exposed to herbicides in Southeast Asia during the Vietnam era. Introduced Mar. 12, 1981; referred to Committee on Veterans' Affairs.

H.R. 2953 (Daschle)

Entitles veterans exposed to Agent Orange during the Vietnam era to specified medical benefits. Extends the period during which veterans of such era may initially request psychological readjustment counseling. Extends specified educational assistance without delimiting periods for vocational training for specified veterans determined to be in need of such assistance. Introduced Apr. 1, 1981; referred to Committee on Veterans' Affairs. Referred to Subcommittee on Hospitals and Health Care Apr. 28. Hearings held Apr. 28. Subcommittee consideration and mark-up session held Apr. 30, 1981.

H.R. 3163 (Railsback)

Requires the Secretary of Health and Human Services to arrange for an independent epidemiological study of persons exposed to Agent Orange. Introduced Apr. 8, 1981; referred to Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment Apr. 9, 1981.

S. 636 (Cranston et al.)

Entitles the United States to recover the costs of certain medical care and services furnished to a veteran for a non-service-connected disability when disability is covered by another form of insurance or compensation. Permits the expansion of the scope of the epidemiological and literature

study of the long term adverse health effects of exposure to Agent Orange during the Vietnamese conflict to include the effects of other factors. Introduced Mar. 5, 1981; referred to Committee on Veterans' Affairs.

S. 689 (Heinz)

Amends section 307 of the Veterans Health Programs Extension and Improvement Act of 1979 to require the promulgation of regulations containing guidelines for resolving claims for veterans benefits based on exposure to Agent Orange, and for other purposes. Introduced Mar. 12, 1981; referred to Committee on Veterans' Affairs. Hearings held Apr. 30, 1981.

S. 921 (Simpson)

Extends the authority of the Administrator of Veterans' Affairs to contract for hospital care or medical services in Puerto Rico and the Virgin Islands without reference to patient loads or incidence of provision of medical services for veterans treated by the Veterans' Administration in the contiguous 48 States. Introduced Apr. 8, 1981; referred to Committee on Veterans' Affairs. Reported with amendment May 15, 1981 (S.Rept. 97-89); H.R. 3499 passed in lieu (see P.L. 97-72 above) June 16, 1981.

S. 1345 (Heinz)

Authorizes the Administrator of the Veterans' Administration to provide hospital or nursing home care to a veteran for treatment of a condition associated with exposure to Agent Orange during service in Vietnam. Extends the Vietnam-era veterans' readjustment counseling program. Directs the Administrator to expand the scope of the epidemiological study of long term adverse health effects of other factors involved in such service. Introduced June 8, 1981; referred to Committee on Veterans' Affairs.

S. 1953 (Specter)

Amends title 38, United States Code to provide a presumption of service connection for the occurrence of certain diseases in veterans who were exposed to phenoxy herbicides while serving in Southeast Asia during the Vietnam era. Introduced Dec. 15, 1981; referred to Committee on Veterans Affairs.

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----- Scientific community report on Agent Orange. Hearing, 96th Congress, 2d session. Sept. 16, 1980. 145 p.

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Signs, Symptoms, and Disorders Reported After Occupational Exposure to TCP, 2,4,5-T or TCDD

Source	Headaches	Sensory Nerves and Tracts	Neuralgia or Myalgia	Paresis	Hemorrhage	Porphyria	Hyperpigmentation or Hirsutism	Acne	Fetal Disorders	Cancer	Asthenia	Other Psychiatric	Abdominal Pain or Pressure	Anorexia, Nausea Vomiting, Diarrhea	Death
Baader and Bauer (6)			8	2				17			4				
Bauer, et al. (9)	4[a]	3	6	9			5	8			9	6	5		
Bleiberg et al. (14)						11	18	20							
Poland et al. (62)	8	2		7		1	30	48					+	22	
Dugois et al. (24)	+[b]							17			+		+	+	
Hardell (33)										87					
Kimmig and Schulz (44)				+				31			+				
Kramer (49)	3										4	2			
Jirasek et al. (37)	+		+	+		12	19	78		2	+	+		+	3
Jirasek et al. (38)		+				+						+			
Pazderova et al. (61)			+	+		23	+	53		2	27	8	+	+	3
Miura et al. (54)								+							
Oliver (57)	2	1	1				3	2			3	1	1	1	
Ter Beek et al. (79)	+					+		+			+	+		+	
Zelikov and Danilov (88)								1							
Total number of cases reported[c]	17	6	15	18	0	47	75	275	0	91	47	17	6	23	6

[a]Number entries in table reflect the number of cases in which sign, symptom or disorder was reported. [b]+ = Sign, symptom or disorder reported but number of cases not given.
[c]Numbers do not include cases represented by "+" and totals may represent some double counting due to the overlap to studies by Jirasek et al. and Pazderova et al.

SOURCE: Young, Alvin et al. The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and Its Associated Dioxin, p. VI-14. (Numbers in parentheses identify sources in Young's bibliography.)