IOM Identifies Herbicide Link with Chronic Lymphocytic Leukemia (CLL), Principi Extends Benefits

On January 23, 2003, the National Academy of Sciences’ Institute of Medicine (IOM), a highly respected, independent, non-governmental scientific review organization working at the request of the Department of Veterans Affairs (VA), officially released the fifth comprehensive scientific review in a series entitled Veterans and Agent Orange.

The latest report findings are similar to their earlier reviews, with one major change. The new report, subtitled Update 2002, concludes that there is “sufficient evidence of an association” between herbicides used in Vietnam and chronic lymphocytic leukemia (CLL). Department of Veterans Affairs Secretary Anthony J. Principi has accepted this assessment, and ordered the development of regulations to add CLL to the list of illnesses presumptively recognized for service connection among Vietnam veterans. (See list on pages 10-11). VA will be able to begin paying compensation benefits once the regulations are finalized later this year.

Principi Acts

With an advanced copy in hand, Secretary Principi asked key officials and scientists within and outside VA to evaluate the report’s findings and advise him on appropriate action. On January 23, based on the recommendations he received and his reading of the report, the Secretary announced that CLL would be added to the list of presumptively recognized conditions for service connection.

“Compelling evidence has emerged within the scientific community that exposure to herbicides such as Agent Orange is associated with CLL,” Principi declared. “I’m exercising my legal authority to ensure the full range of VA benefits is available to Vietnam veterans with CLL.” The Secretary added, “On the modern battlefield, not all injuries are caused by shrapnel and bullets. This latest IOM study and my decision to act upon it are the latest examples of VA’s continuing efforts to care for the needs of our combat veterans.” (Continued on page 2)

CLL and Other Leukemia

There are four basic forms of leukemia: acute and chronic forms of lymphocytic leukemia and the acute and chronic forms of myeloid leukemia. About 31,000 Americans will be diagnosed with some form of the disease this year and about 22,000 will die from it. Leukemias account for about 2.5 percent of new cancer diagnoses and about 4 percent of cancer deaths. The different forms have different patterns of rates and different risk factors.

Chronic Lymphocytic Leukemia (CLL)

CLL, the most common of the four types mentioned above, has many of the traits as lymphomas, including immunohistochemical characteristics, B cell origin, and progression to an acute aggressive form of non-Hodgkin’s lymphoma (NHL).

CLL is a disease that progresses slowly with increasing production of excessive numbers of white blood cells. The chance of recovery from CLL largely depends on the stage of the patient’s health and general health. Treatment plans depend on these factors.

(Continued on page 5)
What the Decision Means

The Secretary’s decision means that veterans with CLL who served in Vietnam during the Vietnam era do not have to prove that their illness is related to their military service to qualify for VA disability compensation. For more than 20 years, VA has also offered special access to medical care to Vietnam veterans for health problems that may have resulted from Agent Orange exposure, which will now include CLL. VA presumes that all Vietnam-era veterans who served in the Republic of Vietnam to have been exposed to Agent Orange or other herbicides. Secretary Principi’s decision will ensure greater access to care for those veterans with CLL.

A notice of proposed rulemaking was published in the Federal Register on March 26, 2003, 68 Federal Register 14567, proposing to create a presumption of service connection for CLL based on herbicide exposure. The comment period for the proposed regulation ended on May 27, 2003, shortly before this newsletter was completed. By law, VA is required to issue final regulations not later than 90 days after issuance of the proposed regulations.

Background

The initial IOM report, entitled Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam, dated 1994, was released in 1993. Updates were issued in 1996, 1999 (identified by IOM as Update 1998), and 2001 (dated 2000). In addition, the IOM has released two special reports on Agent Orange, one, published in 2000, regarding the possible association between herbicide exposure on diabetes, and another, published last year, on one type of childhood cancer.

In Update 2002, the IOM evaluated all available scientific and medical evidence from studies of veterans and other groups, to determine what health problems may be associated with exposure to Agent Orange and other herbicides used in Vietnam. VA requested that the IOM focus on CLL in Update 2002 because of concerns raised by some veterans that CLL shares some similarities with non-Hodgkin’s lymphoma, which has been presumptively recognized for service connection for several years.

Update 2002 was conducted by a 10-member committee of scientists, chaired by Irna Hertz-Picciotto, Ph.D., a professor in Department of Epidemiology, School of Public Health, University of North Carolina, Chapel Hill. Michelle C. Catlin, Ph.D., a program officer in the IOM’s Board on Health Promotion and Disease Prevention, was the Study Director.

IOM Identifies Herbicide Link (Continued from page 1)

The information that the committee reviewed was identified through a comprehensive search of relevant databases, including public and commercial databases covering biologic, medical, toxicologic, chemical, historical, and regulatory information. More than 9,000 potentially relevant studies were identified in their searches, and more than 1,000 of them were reviewed for their report. The IOM considered a wide range of worker, environmental, and veterans’ health studies. The committee reported that input received from veterans and others interested persons at public hearings and in written submissions also served as a valuable source of additional information.

IOM’s Four Categories of Findings

In their latest report, the IOM assigned each illness or disease considered in the report to one of four categories based on the amount and quality of scientific evidence of an association with Agent Orange or other herbicides used in Vietnam. This was the same procedure used for prior reports.

The four categories are (1) sufficient evidence of an association, (2) limited/suggestive evidence of an association, (3) inadequate/insufficient evidence to determine whether an association exists, and (4) limited/suggestive evidence of no association.

Category 1 - Sufficient Evidence of an Association

IOM includes illnesses in the first category when a positive association has been observed between herbicides and the outcomes in studies in which chance, bias, and confounding could be ruled out with reasonable confidence.

In its initial report, the IOM included five illnesses in this category: soft-tissue sarcoma, non-Hodgkin’s lymphoma, Hodgkin’s disease, chloracne, and porphyria cutanea tarda (in genetically susceptible individuals). In the 1996 update, the IOM lowered porphyria cutanea tarda to the second category while the other conditions remained in the first. In the 1996, 1998, and 2000 updates, no additional health outcomes were included in this first category. The inclusion of CLL in this category marks the first time that a condition has been added to this category since the initial report was issued.

Category 2 - Limited/Suggestive Evidence of an Association

IOM lists conditions in the second category when the evidence reviewed is suggestive of an association between herbicides and the outcome, but is limited because chance, bias, and confounding could not be
ruled out with confidence. Health outcomes are included in this category when, for example, at least one high quality health study shows a positive association, but the results of other studies are different.

The IOM lists conditions in the second category when the evidence reviewed is suggestive of an association between herbicides and the outcome, but is limited because chance, bias, and confounding could not be ruled out with confidence. Health outcomes are included in this category when, for example, at least one high quality health study shows a positive association, but the results of other studies are different.

In the report released in 1993, the IOM included only three illnesses (respiratory cancers, prostate cancer, and multiple myeloma) in this category. Six illnesses were included in this category in 1996 and 1998. In addition to these three cancers and porphyria cutanea tarda (mentioned above), the IOM cited acute and subacute transient peripheral neuropathy in Vietnam veterans and spina bifida in their children. The initial report listed peripheral nervous system disorders as a group in the third category.

In the report released in 1996, 1998, 2000, and 2002 updates, the IOM distinguished between acute and subacute transient peripheral neuropathy and chronic peripheral nervous system disorders (which remained in the third category). Similarly, the IOM separated spina bifida from other birth defects (which remained in the third category).

In the special report on diabetes released in 2000, the IOM moved Type 2 diabetes from category three (inadequate/insufficient evidence to determine whether an association exists) to this one. In Update 2000, Type 2 diabetes remained in this category. In Update 2002, Type 2 diabetes is included in this category.

Another change in this category, made in Update 2000, was the addition of acute myelogenous leukemia (AML) in the children of Vietnam veterans. Under existing law, VA lacks authority to provide benefits or services to these children. AML was previously grouped with other childhood cancers among children of veterans. Careful analysis of U.S. and Australian studies led IOM to include this rare condition in Category 2. However, subsequent review by the IOM after Australian scientists discovered an error in their study, resulted in a downgrade to Category 3 last year. (For more information on this reversal, see the front page article in the May 2002 issue of the Agent Orange Review, online at www.va.gov/agentorange).

Category 3 - Inadequate/Insufficient Evidence to Determine Whether an Association Exists

Most conditions evaluated in IOM’s 2002 report (as well as in the earlier publications) were listed in this third category. The IOM places illnesses into this category when available studies are of insufficient quality, consistency, or size to permit a conclusion regarding the presence or absence of an association. Illnesses for which there are no available studies would also fall into this category.

The following illnesses were listed in IOM category three in Update 2002: hepatobiliary cancers, nasal or nasopharyngeal cancer, bone cancer, breast cancer, female reproductive cancer (cervical, uterine, and ovarian), urinary bladder cancer, renal cancer, testicular cancer, leukemia (other than CLL), skin cancer, spontaneous abortion, birth defects (other than spina bifida), neonatal or infant death and stillbirths, low birthweight, childhood cancers in offspring, including acute myelogenous leukemia, abnormal sperm characteristics and infertility, cognitive and neuropsychiatric disorders, motor or coordination dysfunction, chronic peripheral nervous system disorders, metabolic and digestive disorders (changes in liver enzymes, lipid abnormalities, and ulcers), immune systems disorders (immune suppression and autoimmunity), circulatory disorders, respiratory disorders, and AL-type primary amyloidosis, endometriosis, and the effects on thyroid homeostasis.

The 1996 changes are the two noted under Category 2 above (that is, the separation of acute and subacute transient peripheral neuropathy from chronic peripheral neuropathy; and spina bifida from other birth defects) plus an elevation of skin cancer from the fourth category. Urinary bladder cancer was added to this category in 1998.

In Update 2000, as a result of the change for acute myelogenous leukemia, the health outcome “childhood cancer in offspring” was modified to exclude this disease. However, as a result of subsequent revision, it was again included with other childhood cancers in this category where it remains in Update 2002.

For Update 2000, at VA’s request, the IOM evaluated the possible relationship between herbicides used in Vietnam and specifically AL-type primary amyloidosis, a condition similar in many ways to multiple myeloma (an illness already in Category 2). IOM concluded that there was inadequate/insufficient evidence to determine whether an association exists. VA had received several letters from interested individuals suggesting a link with herbicide exposure. In the 2002 report, the IOM added
IOM added endometriosis and the effects of thyroid homeostasis to Category 3.

**Category 4 - Limited/Suggestive Evidence of No Association**

Health outcomes are included in IOM’s the fourth category when several adequate studies, covering the full range of levels of exposure that humans are known to encounter, are mutually consistent in not showing a positive association between exposure to herbicides and the outcome at any level of exposure.

The 2002 report, like the 1996, 1998, and 2000 documents, puts the following conditions in Category 4: gastrointestinal tumors (stomach, pancreatic, colon, and rectal cancers) and brain tumors. The only change in 1996 from the first report in this category was the elevation of skin cancer to the third category. The only change in 1998 was the elevation of urinary bladder cancer to the third category. In the 2000 and current updates, there is no change in this category compared with the 1998 IOM update.

**Research Recommendations**

In *Update 2002*, the IOM also offers several research recommendations. The committee suggests (1) continuing of the Air Force Health Study of Operation Ranch Hand personnel (the unit involved in the aerial spraying of Agent Orange), (2) expanding the studies of Army Chemical Corps veterans, and (3) following the experience of Vietnam veterans as they age, with emphasis on diseases associated with aging.

The committee also concludes that certain rare tumors are worthy of further investigation despite previous evidence of no association. The committee supports steps that would continue development of collaborative research programs between U.S. and Vietnamese scientists.

**Required by Law**

Under Public Law 102-4, the Agent Orange Act of 1991, within 60 days after the Secretary of Veterans Affairs receives a report on the possible long-term health effects of Agent Orange and other herbicides used in Vietnam from the National Academy of Sciences’ IOM, the Secretary must determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary concludes that a presumption of service connection is warranted, he or she must issue regulations within 60 days of this determination.

If the Secretary determines that a presumption of service connection is not warranted, he or she, within 60 days of making the determination, must publish it in the *Federal Register* a notice of that finding. The notice must include an explanation of the scientific basis for the determination.

VA’s authority to establish regulatory presumptions of service connection under Public Law 102-4 expired on September 30, 2002. However, section 201(d) of the Veterans Education and Benefits Expansion Act of 2001, Public Law 107-103, reestablished that authority and extended it through September 30, 2015.

**Earlier VA Responses**

IOM reviews on Agent Orange health effects have had a significant impact on VA compensation policy.

The 1993 and 1996 IOM reports resulted in big changes in VA policy. On July 27, 1993, the day IOM released its first report, then-VA Secretary Jesse Brown announced that Hodgkin’s disease and porphyria cutanea tarda would be added to the list of conditions presumed to be service-connected for veterans exposed to herbicides in Vietnam.

Two months later, after further review of the IOM document, Secretary Brown announced that multiple myeloma and respiratory cancers would be added to the list of conditions presumed to be service-connected for veterans exposed to herbicides in Vietnam.

After reviewing the 1996 IOM update, Secretary Brown concluded that acute and subacute transient peripheral neuropathy (if manifested within 1 year of exposure to an herbicide in Vietnam and resolved within 2 years of onset) and prostate cancer would be added to the list of conditions presumed to be service-connected for veterans exposed to herbicides in Vietnam.

In 1996, when the IOM found an association between herbicides used in Vietnam and the birth defect spina bifida in the children of Vietnam veterans, VA sent draft proposal to Congress to provide for certain benefits and various services for these children. This legislation was enacted, with minor modification, as part of Public Law 104-204 in September 1996.

*Update 1998* and *Update 2000* did not result in changes in compensation policy. The IOM’s special 2000 report on Type 2 diabetes resulted in that condition being added to the list of presumptively recognized conditions for service connection.
As a condition in Category 1, CLL was a relatively easy and noncontroversial call under the guidelines established by Congress. Historically, all illnesses in that category have promptly been recognized for service connection. All illnesses in the second category have ultimately been recognized as well.

**IOM Report on the Internet, Also Available for Purchase**

Copies of the IOM reports are available for purchase from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055. The cost varies. The telephone numbers are (toll-free) 1-800-624-6242 and (in the Washington, DC, metropolitan area) 202-334-3313. The reports are also available for free at [www.nap.edu](http://www.nap.edu).

**IOM Report Will Continue**

The IOM will be evaluating new scientific and medical evidence on the possible long-term health consequences of herbicide exposures. Based upon the results of the most recent report, VA has requested that the IOM take a careful look at other forms of leukemia in their next update, due in 2004.

The IOM was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under responsibility given to the Academy by its congressional charter to be an adviser to the Federal Government and, upon its own initiative, to identify issues of medical care, research, and education. For information about the IOM, see [www.iom.edu](http://www.iom.edu).

The January 23, 2003, VA news release on the Secretary’s action related to CLL can be found at [www.va.gov/opa](http://www.va.gov/opa).

**CLL and Other Leukemia (Continued from page 1)**

The IOM report described above concluded that farming, especially where there is exposure to the herbicides found in Agent Orange, is associated with significant risk of CLL. Many more studies support the idea that herbicide exposure can contribute to the risk of developing NHL. IOM concluded that there is sufficient evidence of an association between exposure to herbicides used in Vietnam and CLL.

**Acute Lymphocytic Leukemia (ALL)**

ALL is a disease of the young and of people over 70 years old. Neither group contains many Vietnam veterans. The incidence of ALL is slightly higher in Caucasians than African-Americans and in males compared with females. Exposure to high doses of ionizing radiation is a known risk factor for ALL. The evidence on other risk factors is mixed. IOM has not found ALL to be associated with herbicides used in Vietnam.

**Acute Myeloid Leukemia (AML)**

AML is the most common acute leukemia among adults. It becomes more common in people over 40 years old. AML is slightly more common in males than in females. Factors associated with an increased risk of AML include high doses of ionizing radiation, occupational exposure to benzene, and some medications used in chemotherapy. Fanconi’s anemia and Down’s syndrome are associated with an increased risk of AML, and tobacco smoking may also be a risk factor.

In its *Veterans and Agent Orange: Update 2000*, IOM concluded that there is “limited/suggestive evidence” of an association between Vietnam veterans’ exposure to herbicides in Vietnam and AML in their children. As described previously, this conclusion was later reversed when a serious flaw was found in an Australian study upon which the finding was largely based. IOM has not found AML to be associated with herbicides used in Vietnam.

**Chronic Myeloid Leukemia (CML)**

The rate of CML increases steadily with age in people over 30 years old. It is associated with a genetic abnormality known as the Philadelphia chromosome. Exposure to high doses of ionizing radiation is a risk factor. IOM has not found CML to be associated with herbicides used in Vietnam.

**Request for Agent Orange Examination Increases**

Agent Orange Registry analysts report a substantial increase in Registry participants in past two years. Annually 5,000-8,000 veterans had been requesting and receiving the Agent Orange Registry examination in recent years. Then, in Calendar Years 2001 and 2002, the number of examination participants swelled to more than 23,000 a year. In contrast, fewer than 20,000 were added during the 3 previous years combined. The Agent Orange Registry Health Examination Program began in 1978. (Continued on page 6)
Ms. Helen Malaskiewicz, Senior Registry Coordinator in VA Central Office, said that, as of the end of 2002, more than 314,000 veterans have participated in this program.

She feels that a number of factors have contributed to this large increase in examination requests, including the recognition for service-connection of type 2 diabetes, the aging of Vietnam veterans, better publicity, the decision to open the registry first to Vietnam-era veterans who served in Korea in 1968-69 and then to all veterans who while on active duty military service were exposed to Agent Orange or other herbicides during testing, transporting, or spraying of these herbicides for military purposes.

Ms. Malaskiewicz, who oversees similar health registries for veterans who served in the Gulf War and veterans who were exposed to ionizing radiation during their military service, reports that the recent activity...
levels in these programs are miniscule in comparison to the Agent Orange program. She noted that the number of Gulf War Health Examination Registry participants had only increased during the 2-year period (2001-2002) by about 4,000 (in contrast with the approximate 46,000 new participants in the Agent Orange Registry during the same time period). It is interesting that the number of new participants in the Gulf War Registry actually decreased by about 50 percent in 2001-2002 compared to the prior 2 years (1999-2000) when more than 8,000 Gulf War veterans were added.

Ms. Malaskiewicz has served as Senior Registry Coordinator for over 12 years. She predicts that increased numbers for Agent Orange Registry participants will continue.

Estimates of Herbicide Use Revised Upward; Dioxin Amounts Sprayed Doubled; IOM: AO Study Feasible

On April 17, 2003, the prestigious scientific journal *Nature* published an article prepared by Dr. Jeanne Mager Stellman of Columbia University and several of her colleagues which indicates that more herbicides were used in Vietnam than was previously reported and the amount of dioxin sprayed almost doubled. In 1970, Congress directed the Department of Defense to contract with the National Academy of Sciences (NAS) for a comprehensive study of the ecological and physiological effects of defoliation of Vietnam. In 1974, NAS published estimates of the extent and distribution of herbicides sprayed.

The *Nature* article presents revised estimates, developed using more complete data. The spray inventory is expanded by more than seven million liters. Furthermore, the estimates for the amount of dioxin sprayed are almost doubled. The authors conclude that relatively small amounts of highly dioxin-contaminated Agents Purple and Pink, sprayed in Vietnam between 1961-65 may have deposited a relatively large percentage of the total dioxin.

The article indicates that census data shows that millions of Vietnamese people were likely to have been directly sprayed.

*Nature* is copyrighted by the Nature Publishing Group. More information is available at [www.nature.com/nature](http://www.nature.com/nature). The article is in Volume 422, pages 681-687.

IOM: Agent Orange Study Feasible

In a closely related development, also in April 2003, the National Academy of Sciences (NAS) Institute of Medicine (IOM) released a report that concluded that a good exposure reconstruction model for wartime herbicides of U.S. veterans of Vietnam is feasible.

For decades scientists have had problems studying the health effects of Agent Orange and other herbicides used in Vietnam because they could not be sure how much Agent Orange and other herbicides used in Vietnam individuals veterans were exposed to. Congress mandated a study in 1979 (Public Law 96-151). In the late 1980’s, the government all but abandoned hope of a major study of the health effects of herbicide exposure on ground troops who served in Vietnam.

The seven-member IOM Committee recommended that the Department of Veterans Affairs (VA) and other government agencies “facilitate additional epidemiologic studies of veterans by nongovernmental organizations and independent researchers.” IOM is a nongovernmental organization.

The IOM Committee, formally known as the Committee on the Assessment of Wartime Exposure to Herbicides in Vietnam, was chaired by David G. Hoel, a member of the Institute of Medicine, and Distinguished University Professor, Department of Biometry and Epidemiology, Medical University of South Carolina, Charleston, SC. The other members were S. Katherine Hammond, Loren D. Koller, Dana P. Loomis, Thomas J. Smith, David J. Tollerud, and Lauren Zeise.

In 1991, Congress passed and the President signed the Agent Orange Act of 1991 (Public Law 102-4), that directed VA to contract with NAS for a review of the scientific evidence on the possible health effects of exposure to Agent Orange and other herbicides. As a result in July 1993, NAS released a comprehensive initial report (over 800 pages), four comprehensive updates, two reports on single illnesses, and this most recent herbicide exposure reconstruction model feasibility report.

As part of the initial report (released in July 1993), recommendations were offered concerning the need for additional scientific studies. Three of these recommendations focused on exposure assessment studies of Vietnam veterans:
• A nongovernmental organization with appropriate experience in historical exposure reconstruction be commissioned to develop and test models of herbicide exposure or for use in studies of Vietnam veterans.

• The exposure reconstruction models developed be evaluated by an independent, nongovernmental scientific panel established for this purpose.

• If the proposed scientific panel determines that a valid exposure construction model is feasible, VA and other government agencies facilitate additional epidemiologic studies.

In response to the recommendations, VA requested that IOM establish a committee to oversee the development/evaluation of models of herbicide exposure for use in studies of Vietnam veterans. That committee developed and disseminated a Request for Proposals (RFP), evaluated the proposals received, selected a contractor to develop the exposure model, and provided scientific and administrative oversight of the contractor’s work. Dr. Jeanne Mager Stellman and several colleagues were selected as the contractor.

Based on the Committee’s review of the Dr. Stellman’s output to date, the Committee reached the following findings:

• The contractor has developed databases of wartime spraying and accidental dispersion of herbicides, of troop locations and movements, and of land features and soil typology.

• The contractor has developed an effective exposure assessment tool to assign a metric for herbicide exposure based on proximity in space and time to spraying and amount/agent sprayed.

• The range of calculated Exposure Opportunity Index and information gather so far on troop locations is sufficient to demonstrate the feasibility of future epidemiologic studies.

Additional location data for troops not now included in the exposure assessment model appear to be available at the National Archives for abstraction and use by researchers and other interested parties in future studies.

• Given the current knowledge and available data, the contractor has adequately demonstrated that the draft model represents a valid means for assessing wartime herbicide exposure in Vietnam veterans.

(The Exposure Opportunity Index indicates the likelihood of exposure to herbicides in Vietnam and the extent of such exposures.)

The Committee will produce a second (final) report that will review the contractor’s completed research effort; transmit their report and support material to VA; and offer any additional findings, conclusions, recommendations deemed appropriate.

Circuit Court Ruling Allowing Veterans to Sue Stands as a Result of High Court Deadlock on Challenge; Suits to Continue

On February 26, 2003, the United States Supreme Court heard arguments attacking the settlement in the Class action lawsuit known as “In re Agent Orange Product Liability” litigation. On June 9, 2003, a deadlocked 4-4 vote was announced in the case, identified as Dow Chemical et al. v. Stephenson et al., Docket No. 02-271. This article was written by Agent Orange Review editor Donald J. Rosenblum, a non-lawyer, based on information he received from the Supreme Court and other sources. It provides basic information regarding this matter. The various appeals and legal details are not included due to space limitation.

On May 7, 1984, representatives of Vietnam veterans and the manufacturers of Agent Orange reached a settlement that called for the chemical companies to pay a lump sum of $180 million into a fund for the benefit of the “class,” Vietnam veterans and their families. The settlement prohibited members of the class from bringing further action against the manufacturers for damages relating to the use of herbicides in Vietnam.
Later that year, Judge Weinstein conducted 11 days of hearings throughout the U.S. to receive comments on the proposed settlement. Following these “fairness hearings,” Weinstein preliminarily approved the settlement. He issued a final order approving the settlement on January 7, 1985. He supervised, with special master Kenneth Feinberg, the distribution of the settlement funds.

The distribution plan provided most of the funds be distributed directly to the survivors of deceased veterans and to veterans who became totally disabled due to illness before January 1, 1995. Much of the remaining monies were set aside to support a class assistance foundation to help class members with medical and related problems. By 1997, all of the Agent Orange settlement funds had been disbursed. In 1998, Daniel Stephenson, a helicopter pilot in Vietnam was diagnosed with multiple myeloma. Two years earlier Joe Isaacson, an Air Force crewman at an airfield that supported the Agent Orange mission, had been diagnosed with non-Hodgkin’s lymphoma. (Both multiple myeloma and non-Hodgkin’s lymphoma have long been presumptively recognized by VA for service connection based on evidence of an association with Agent Orange or other herbicides used in Vietnam.)

The attorney for these two veterans argued that they should not be barred from bringing their own claims for injuries that appeared after 1994, when they were no longer eligible to receive money from the settlement. The lawyer representing the manufacturers argued that they negotiated and agreed to a fair arrangement and that it should stand.

Initially, a Federal judge dismissed the lawsuits by Stephenson and Isaacson on the grounds that they were bound by the 1984 settlement. However, the appeals court rejected this position. That court concluded that the two plaintiffs could not be constitutionally bound by the 1984 settlement.

Vietnam veterans and their families who are seeking additional information about the lawsuit can contact the attorney for the two veterans. He is Gerson Smoger of Smoger & Associates in Oakland, CA 94602. Dr. Smoger requests that inquiries be sent to his email address at gerson@texasinjurylaw.com. Veterans who are unable to access him by email can call him at 510-531-4529.

Note: VA was not a party to the settlement, and was not involved in the distribution of the settlement funds.

Additional Regulations Published for Women Vietnam Veterans’ Children With Certain Birth Defects

On January 3, 2003, the third of three final rules was published in the Federal Register amending VA regulations implementing provisions of Public Law 106-419 that provide for certain benefits and services for women Vietnam veterans’ children with “covered birth defects.”

The January 3 publication pertains to health care for eligible children. Other related final rules were published on July 31, 2002 (monetary allowance) and on December 6, 2002 (vocational training benefits). The three regulations were published for public comment Federal Register as proposed rules on January 2, 2002. The rules are applicable retroactively to December 1, 2001.

The law is based on the results of a comprehensive health study by VA scientists of 8,280 women Vietnam-era veterans (half of whom served in Vietnam and half of whom served elsewhere). Public Law 99-272 mandated the study. This research, completed in October 1998, and entitled “Women Vietnam Veterans Reproductive Outcomes Health Study,” was conducted by VA’s Environmental Epidemiology Service. A report of part of the study, “Pregnancy Outcomes Among U.S. Women Vietnam Veterans,” was published in the American Journal of Industrial Medicine 38: 447-454 (2000). For additional information about this study see the Agent Orange Review issues of December 2000 or July 2001.

Under the regulations “covered birth defects” means any birth defect identified by VA as a birth defect associated with the service of women Vietnam veterans in Vietnam from February 28, 1961, to May 7, 1975, and that has resulted, or may result, in permanent physical or mental disability. However, the term does not include a condition due to a familial (this is, inherited) disorder; birth-related injury; or fetal or neonatal infirmity with other well-established causes. Not covered are conditions that are congenital malignant neoplasms, chromosomal disorders, or developmental disorders. In addition, conditions that do not result in permanent physical or mental disability are not covered birth defects. All birth defects that are not excluded under the language above are covered birth defects.
A referral for services at a WRIISC can be made after a veteran has had a comprehensive medical evaluation at their local VA Medical Center. The veteran’s primary care provider must make all referrals to the WRIISC. Information on the referral process can be found at www.va.gov/environagents.

The WRIISCs also have programs engaged in scientific research on deployment health questions, such as war related illnesses and injuries, risk communication regarding deployment-related hazards, and outreach and education for VA patients and their families and health care providers. For more information on these special programs, check out the VA Web site mentioned above.

Health Conditions Presumptively Recognized to Date

The following health conditions are presumptively recognized for service connection. Vietnam veterans with one or more of these conditions do not have to show that their illness(es) is (are) related to their military service to get disability compensation. VA presumes that their condition is service-connected.

Conditions Recognized in Veterans

1. Chloracne (must occur within 1 year of exposure to Agent Orange)
2. Non-Hodgkin’s lymphoma
3. Soft tissue sarcoma (other than osteosarcoma, chondrosarcoma, Kaposi’s sarcoma, or mesothelioma)
4. Hodgkin’s disease
5. Porphyria cutanea tarda (must occur within 1 year of exposure)
6. Multiple myeloma
7. Respiratory cancers, including cancers of the lung, larynx, trachea, and bronchus
8. Prostate cancer
9. Acute and subacute transient peripheral neuropathy (Must appear within 1 year of exposure and resolve within 2 years of date of onset)
10. Type 2 diabetes
11. Chronic lymphocytic leukemia (Final rule pending – see article on page 1)
Conditions Recognized in Children of Vietnam Veterans

1. Spina bifida (except spina bifida occulta)
2. Certain other birth defects in the children of women Vietnam veterans (See article on pages 9-10)

Conditions Briefly Described

Chloracne: A skin condition that looks like common forms of acne seen in teenagers. The first sign may be excessive oiliness of the skin. This is accompanied or followed by numerous blackheads. In mild cases, the blackheads may be limited to the areas around the eyes extending to the temples. In more severe cases, blackheads may appear in many places, especially over the cheekbone and other facial areas, behind the ears, and along the arms.

Non-Hodgkin’s lymphoma: A group of malignant tumors (cancers) that affect the lymph glands and other lymphatic tissue. These tumors are relatively rare compared to other types of cancer, and although survival rates have improved during the past two decades, these diseases tend to be fatal.

Soft tissue sarcoma: A group of different types of malignant tumors (cancers) that arise from body tissues such as muscle, fat, blood and lymph vessels, and connective tissues (not in hard tissue such as bone or cartilage). These cancers are in the soft tissue that occurs within and between organs.

Hodgkin’s disease: A malignant lymphoma characterized by progressive enlargement of the lymph nodes, liver, and spleen, and by progressive anemia.

Porphyria cutanea tarda: A disorder characterized by liver dysfunction and by thinning and blistering of the skin in sun-exposed areas.

Multiple myeloma: A cancer of specific bone marrow cells that is characterized by bone marrow tumors in various bones of the body.

Respiratory cancers: Cancers of the lung, larynx, trachea, and bronchus.

Prostate cancer: Cancer of the prostate; one of the most common cancers among men.

Peripheral neuropathy (transient acute or subacute): A nervous system condition that causes numbness, tingling, and muscle weakness. This condition affects only the peripheral nervous system, that is, only the nervous system outside the brain and spinal cord. Only the transient acute (short-term) and subacute forms of this condition (not the chronic persistent form) have been associated with herbicide exposure.

Chronic lymphocytic leukemia (regulations pending): A disease that progresses slowly with increasing production of excessive numbers of white blood cells.

Spina bifida (in the children of Vietnam veterans): A neural tube birth defect that results from the failure of the bony portion of the spine to close properly in the developing fetus during early pregnancy.

Diabetes mellitus: Often referred to as Type 2 diabetes; a condition characterized by high blood sugar levels resulting from the body’s inability to respond properly to the hormone insulin.

Other (than spinal bifida) disabilities in the children of women Vietnam veterans: Covered birth defects include a wide range conditions. Eighteen defects are specifically included and others not specifically excluded are covered. For more information, see article on pages 9 - 10, entitled “Additional Regulations Published…”

Q’s and A’s

The “Review” occasionally includes a questions-and-answer section in which VA responses to inquiries from readers regarding Agent Orange, problems experienced by Vietnam veterans, their families, and others concerned about the long-term health consequences of exposure to Agent Orange and its dioxin component, and programs initiated by VA and other Federal departments and agencies to help veterans exposed to Agent Orange and their families.

Questions should be sent to Mr. Donald J. Rosenblum, Deputy Director, Environmental Agents Service (131), ATTN: AO REV – Q’s & A’s, VA Central Office, 810 Vermont Avenue, N.W., Washington 20420.

R.B. of Minot, ND, asked about the relationship between Agent Orange and sleep disorder. The multiple volumes of the comprehensive scientific reviews of available literature regarding the association between exposure to Agent Orange and its dioxin component, and programs initiated by VA and other Federal departments and agencies to help veterans exposed to Agent Orange and their families.

D.K. of Cleveland, OH, praised the article on prostate cancer in the October 2001 issue. He suggested that we do similar article on other conditions that have been presumptively recognized. An article on type 2 diabetes has been prepared for the next issue. Also see description of conditions, in additional to the list of the illnesses.
O.R. of Asheville, NC, asked if there is a fund set up for Agent Orange research. She added that she has a family member who would like to make a donation. We know of no specific fund set up for Agent Orange research. Funds could be donated to the Washington DC VA Medical Center Institute for Clinical Research 50 Irving Street, NW, Washington, DC 20422, with a designation that it be used for Agent Orange Vietnam veterans health study by the Environmental Epidemiology Service. (Note: This is not a solicitation – just an answer to a veteran’s question. Please do not send cash.)

C.F. of Durham, NC, asked whether a veteran who worked as a housekeeper in Japan and claims exposure to Agent Orange is eligible for an Agent Orange Registry examination. The criteria for examinations do not extend to all veterans who claim exposure to Agent Orange/dioxin. The policy limits the examinations to Vietnam veterans who served in Vietnam, 1962-1975; veterans who served in Korea, 1968-1969; and any other U.S. military veterans who may have been exposed to dioxin, or other toxic substance in a herbicide or defoliant, during the conduct of, or as a result of, the testing, transporting, or spraying of herbicides for military purpose. Service as a civilian housekeeper in Japan would not qualify the veteran even if he/she were exposed to dioxin.

Similarly, a veteran who was exposed to dioxin on the farm where he/she lived as a civilian would not qualify solely on the basis of that exposure. The veteran would be eligible if he/she served in Vietnam (during the Vietnam era), in Korea (during the specified dates), or was exposed during the specified...
How does this help veterans?

It provides needed medical care for 2 years to veterans who served in a combat theater without requiring them to make a copayment for the care they receive, even without proof that their injury or illness was caused or aggravated by their military service.

What type of injuries and illnesses does this cover?

This benefit covers all illnesses and injuries, including those that are unexplained or difficult to diagnose. However, it does not cover those clearly unrelated to military service, such as a common cold, injuries from accidents after discharge, or disorders that existed before joining the military.
How is this different from previous policy?

The key distinction is that these veterans will be provided free medical care immediately upon discharge and for a period of 2 years. They need not prove their injury or illness was connected to their service or show that they have a relatively low income or other grounds for eligibility. Previously, many of these veterans would have been liable for a copayment until their illness or injury had been evaluated by VA and ruled to be a service-connected disability.

Under what authority can VA offer this care?

VA’s policy is in accordance with the authority granted in section 102 of Public Law 105-368 as codified in Section 1710(e)(1)(D) of Title 38 of the United States Code.

Is this limited to hospital care?

No. The policy includes other appropriate medical care and nursing home care as well.

What is the effective date for establishing the 2-year time period?

The 2-year period begins when the military member is discharged or retired from active duty.

Does receipt of care establish proof of a service-connected disability rating?

No. The care is designed to meet the medical needs of combat veterans for 2 years after they leave active duty. It is expected that during this time veterans’ claims for disability compensation for these injuries, illnesses, or medical conditions will have been adjudicated. If veterans’ claims are approved as service connected, they will be placed in the appropriate priority group and continue to receive their care without a copayment. If their claim is disapproved, they will still be able to receive care, but will be required to make a copayment for the services.

Does this include members of the National Guard and Reserve forces?

Yes. The policy also applies to National Guard and Reserve personnel who were activated and served in a theater of combat or in combat against a hostile force. Members of the Guard and Reserve forces must be ordered to active duty by a Federal declaration, serve the full period for which they were called or ordered to active duty, and be released, discharged, or retired under conditions other than dishonorable.

How does VA define “hostilities?”

“Hostilities” is defined as conflict in which the members of the Armed Forces are subjected to danger comparable to the danger they would face in a period of war. To determine whether a period of hostilities is within the scope of this special authority, VA relies upon the same citation and criteria used to determine eligibility for VA Readjustment Counseling Service.

Why has it taken almost 4 years for VA to act on this authority?

On March 23, 1999, 4 months after enactment of the law authorizing VA to provide this care, VA issued a directive to its medical centers, detailing the policy. As troops began to provide this care, VA issued a directive to its medical centers, detailing the policy. As troops began to deploy to Afghanistan and other places around the world in the war against terrorism, VA officials believed it would be helpful to provide further information about post-discharge benefits for veterans who served in a combat theater.

What happens to these veterans after the 2 years are up?

After 2 years, their copayment status will depend on whether their illness, injury or medical condition was officially found by VA to be service-connected or whether they are otherwise qualified for care. They will be enrolled in the appropriate priority group for VA health care.

TRICARE Allows Expectant Mothers to Participate in Spina Bifida Study

TRICARE, the Department of Defense’s health care management agency, recently signed an agreement with the National Institute of Child Health and Human Development, which will permit female TRICARE beneficiaries whose pregnancies are complicated by myelomeningocele, the severest form of spina bifida, to participate in a clinical trial designed to study a new approach to treatment of this condition: intrauterine surgery.
Where to Get Help

Vietnam veterans with questions or concerns about Agent Orange – contact VA’s Gulf War/Agent Orange Helpline. The national toll-free telephone number is 800-749-8387. A great deal of information is also available on our Web page at [http://www.va.gov/agentorange](http://www.va.gov/agentorange).

Vietnam veterans (plus veterans who served in Korea in 1968 or 1969), and other veterans who may have been exposed while on military service to Agent Orange or other herbicides elsewhere during the testing, transporting or spraying of herbicides for military purposes and who are concerned about possible long-term health effects of Agent Orange exposure – contact the nearest VA medical center and request an Agent Orange Registry health examination. More than 300,000 Vietnam veterans have already participated in this program.

Vietnam veterans who need medical treatment for conditions that may be related to their exposure to Agent Orange or other herbicides used in Vietnam – contact the nearest VA medical center for eligibility information and possible medical treatment or call the following toll-free telephone number for information about eligibility and enrollment: 1-877-222-8387.

Vietnam veterans with illnesses that they believe were incurred or aggravated by exposure to Agent Orange or other aspects of military service – contact a VA veterans services representative at the nearest VA regional office or health care facility and apply for disability compensation. The counselors have information about the wide range of benefit programs administered by VA. The national toll-free number is 1-800-827-1000.

Vietnam veterans who encounter difficulties at a VA medical center – contact the “patient advocate” or “patient representative” at that facility for assistance in resolving the problem. Ask the medical center telephone operator for the patient advocate or representative.

Vietnam veterans with children who have spina bifida – contact the VA national toll-free hotline at 1-888-820-1756, or the nearest VA regional office by calling toll-free: 1-800-827-1000. Additional information on spina bifida is available from the Spina Bifida Association of America at 4590 MacArthur Blvd., N.W., Suite 250, Washington, DC 20007-4226; toll free telephone: 800-621-3141; e-mail address: sbaa@sbaa.org; and web site: [www.sbaa.org](http://www.sbaa.org).

Women Vietnam veterans with “covered” birth defects – see pages 9 - 10 of this newsletter for information regarding what birth defects are covered – contact the nearest VA regional office at 1-800-827-1000.

Representatives of veterans service organizations, including The American Legion (1-800-433-3318, www.legion.org), Paralyzed Veterans of America (1-800-424-8200, www.pva.org), Veterans of Foreign Wars of the United States (1-800-VFW-1899, www.vfw.org), Disabled American Veterans (1-877-426-2838, www.dav.org), AMVETS (1-877-726-8387, www.amvets.org), Vietnam Veterans of America (1-800-882-1316, www.vva.org), and others, have also been very helpful to Vietnam veterans seeking disability compensation. (These organizations are cited as examples. There are many other excellent veterans service organizations. VA does not endorse or recommend any specific group over another.)

County and State Veteran Service Officers also have been of great help to many military veterans, including Vietnam veterans, seeking benefits they earned through their service to the Nation. Some States have established Veterans Affairs offices, State Departments of Health, Agent Orange Commissions, or other entities that have been very helpful to Vietnam veterans.

TRICARE (Continued from page 14) Questions have been raised whether the VA can support/fund participation of Vietnam veterans’ wives in such research. VA guidelines are very explicit on this subject: Research in which the subject is a fetus, in utero or ex-utero (including human fetal tissue), must not be conducted by VA investigators while on official duty or at VA facilities or approved off-site facilities.

For additional information, interested individuals can contact TRICARE at [www.tricare.osd.mil/](http://www.tricare.osd.mil/).