West Seeks Benefits for Women Vietnam Veterans' Children with Birth Defects, Asks for Special IOM Review of Diabetes

On July 23, 1999, Secretary of Veterans Affairs Togo D. West Jr., announced that the Department of Veterans Affairs would seek the legal authority to provide benefits for children with birth defects who were born to women Vietnam veterans. Secretary West also indicated that he has asked the National Academy of Sciences (NAS) Institute of Medicine (IOM) for a special review of the evidence regarding diabetes mellitus. This was in response to a recent study by the National Institute for Occupational Safety and Health (NIOSH) that suggested a possible link. The Secretary asked that the IOM complete this special review "as soon as possible."

Secretary West said, "To have a child with birth defects can be devastating for any family. I am pleased that VA can reach out to women veterans of the Vietnam War and help them and their children."

Secretary West's actions were based, in large measure, on the findings and recommendations of the 1999 Agent Orange Task Force that he established to advise him regarding appropriate action on the IOM report, entitled Veterans and Agent Orange: Update 1998, and other available information. (A lengthy article regarding the IOM report was included in the March 1999 issue of the "Agent Orange Review".)

Other Information Drove the Decisions, IOM Report Secondary

The Secretary's actions to seek benefits for certain children with birth defects and a special IOM review of diabetes did not come only from the IOM report. Task Force members had available to them important recent information not available to IOM. The IOM cut-off date for the literature reviewed was December 1997, before the NIOSH report was available.

Birth Defects in Offspring of Women Vietnam Veterans

Most epidemiologic studies regarding Vietnam veterans provide information on the health consequences of Vietnam service on male veterans. Women veterans were routinely excluded from many studies due to their small numbers. The studies of birth defects among male Vietnam veterans have been mostly negative. These studies have shown that Vietnam service was not associated with an increase in the risk of birth defects, spontaneous abortions, stillbirths, or neonatal deaths.

The VA Environmental Epidemiology Service (EES) recently completed an investigation of reproductive outcomes among women Vietnam veterans. This study was not finalized before the completion of the 1998 IOM report, and consequently it was not reviewed by IOM. (There is a lengthy article about this study and its findings in the March 1999 issue of the "Agent Orange Review.")

The EES study identified a statistically significant increase in the risk of birth defects in women Vietnam veterans. EES investigators also found an increase in the risk of severe birth defects. The risk of having a child with birth defects was significantly elevated even after adjustment for age, demographic variable, military characteristics, smoking and alcohol consumption of the mothers. Similarly, the risk of having a child with a severe birth defect was significantly elevated among women Vietnam veterans.

Based on these findings, the Task Force recommended that the Secretary seek statutory authority (from Congress) to provide benefits for children with birth defects born to women Vietnam veterans.

Following release of the 1996 IOM report, which indicated that there is "limited/suggestive" evidence of an association between herbicide exposure and the birth defect spina bifida in the children of Vietnam veterans, VA successful sought authority to provide certain benefits and services for Vietnam veterans' children with this birth defect.

Diabetes

A recently published NIOSH morbidity study of two U.S. plants with TCDD-exposed production workers suggested a possible association between high levels of TCDD exposure and diabetes. (TCDD is the dioxin contaminant produced during the manufacture of one of the ingredients of Agent Orange.)
In addition to associations described in occupational studies, research investigations examining the association between TCDD exposure and the risk of diabetes in veterans have been positive. A recent report of Ranch Hand personnel revealed a modest but statistically significant increase in prevalence of diabetes in the highest-exposure category compared to a well-matched comparison group.

A recent study of Australian Vietnam veterans also found an increased risk for diabetes among these veterans, and the Australian government recently recognized diabetes for service connection in Australian troops who served in Vietnam.

Prior to the publication of the NIOSH study, the 1998 IOM update concluded that there is "inadequate/insufficient evidence to determine whether an association exists" between herbicide/dioxin exposure and an increased risk of diabetes. Under the standards set forth in Public Law 102-4, the Secretary is to presumptively recognize as service connected only those conditions where the evidence is indicative of a "positive association" between herbicide exposure and the condition.

In light of the NIOSH study, Secretary West asked for an expedited opinion from the IOM based on the NIOSH data in conjunction with earlier findings. The IOM is expected to complete the diabetes review by late January 2000.

"I requested quick turnaround to determine the significance of a recent study of the incidence of diabetes among certain dioxin-exposed employees" said Secretary West. "We amended our contractual agreement with NAS so veterans do not have to wait two years until the next scheduled NAS report for a decision on whether or not a presumption for diabetes should be established based on this new evidence."

**Task Force Personnel**

Kenneth W. Kizer, M.D., M.P.H., then Under Secretary for Health, chaired the 1999 Task Force, appointed by Secretary West. The other Task Force members were the VA's Under Secretary for Benefits, General Counsel, and Chief Consultant, Occupational and Environmental Health Strategic Healthcare Group. A Working Group of VA headquarters staff and subject matter experts assisted the Task Force.

Secretary West asked the Task Force to review the IOM report and make recommendations to him regarding possible VA actions on the findings. The IOM report, released February 11, 1999, contains no major change in category of association for any disease compared with the previous report, issued in 1996. Urinary bladder cancer was changed from the category "limited/suggestive evidence of no association" to "inadequate/insufficient evidence to determine whether an association exists" because studies (including but not limited to new studies) showed non-significant risks, weakening previous evidence of no association.

The IOM, a non-governmental organization under contract with VA, evaluated the body of scientific evidence to determine what health outcomes may be associated with exposure to Agent Orange and other herbicides used in Vietnam.

In the 1998 report, the IOM reviewers indicated that they found additional support for some previously-identified associations, specifically lung cancer, prostate cancer, and spina bifida. The IOM report made several recommendations on research regarding herbicide exposure and diabetes risk. It recommends that a then unpublished NIOSH study of diabetes in dioxin-exposed workers in chemical plants be documented more completely and published in a peer-reviewed journal.

The IOM also recommends further analyses of the Ranch Hand data and suggests that consideration be given to a combined analysis of the Ranch Hand and NIOSH studies to further examine the possibility that herbicide exposure leads to an increased risk of diabetes. The Ranch Hand Study is an Air Force research effort designed to assess the long-term health consequences of herbicide exposure on individuals who served in the unit responsible for most of the aerial spraying of herbicides in Vietnam.

Although finding that available evidence is insufficient to determine whether an association exists between herbicide exposure and any forms of skin cancer, the IOM encourages further study of basal and squamous forms of skin cancer incidence among exposed workers and Vietnam veterans' populations. The IOM suggested that in any future studies, careful attention should be paid to exposure assessment, as well as to controlling for ultraviolet (UV) exposures. The Task Force and the Secretary agreed.

Researchers categorize chondrosarcomas of the skull, a type of malignant tumor, with bone cancers even though they resemble soft tissue sarcomas in some respects. Soft tissue sarcomas are recognized by VA for service connection while bone cancers are not. The IOM advises VA that the epidemiologic classification of skull chondrosarcomas should not be used as a substitute for...
the expert judgment of pathologists in individual cases.

**Action Required by Public Law 102-4**

Under Public Law 102-4, the Agent Orange Act of 1991, the Secretary of Veterans Affairs 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. If the Secretary determines that a presumption of service connection is not warranted, he or she must publish in the Federal Register a notice of that finding. The notice must include an explanation of the scientific basis for the determination. After the Secretary issues any proposed regulations regarding these diseases, the Secretary must issue final regulations. Such regulations are effective the day of issuance.

In addition to the special report on diabetes, the IOM will continue to re-evaluate existing scientific evidence while assessing new information regarding the possible long-term health consequences of herbicide exposures, as required by Public Law 102-4, the Agent Orange Act of 1991. The next comprehensive report should be released in about two years.

**IOM Reports Available for Purchase**

**Veterans and Agent Orange: Update 1998,** ISBN 0-309-06326-4; 1999, 704 pages (estimated), 6 x 9, $79.00 (estimated), can be purchased from the National Academy Press. The Executive Summary of the report is available on-line at: [http://www.nap.edu/readingroom/books/update98/](http://www.nap.edu/readingroom/books/update98/).

The book may be ordered by mail, phone, or over the internet. Mail orders should be sent to the National Academy Press, 2101 Constitution Avenue, NW, Lockbox 285, Washington, DC 20055. All orders must be prepaid. To order by telephone using VISA/MasterCard/American Express, call toll-free 1-1-800-624-6242 or call 202-334-3313 in the Washington, DC metropolitan area. The fax number is 202-334-2451. The National Academy Press web bookstore gives a 20% discount off all titles ordered from their internet site: [http://www.nap.edu](http://www.nap.edu).

Quantity discounts are also available -- to be eligible for the discount, all copies must be shipped and billed to one address. Standard shipping and handling cost for the first copy is an additional $4.00 and $0.50 for each additional copy. Purchasers from California, Washington, DC, Florida, Maryland, Missouri, Texas, or Canada must add the applicable sales tax or GST Prices apply only in the United States, Canada, and Mexico, and are subject to change without notice.

**Veterans and Agent Orange: Update 1996,** ISBN 0-309-05487-7; 1996, 384 pages, 6 x 9, $49.00, can also be purchased from the National Academy Press, at the above address. The Executive Summary of this report is available on-line at [http://www.nap.edu/readingroom/books/veterans/](http://www.nap.edu/readingroom/books/veterans/).

The initial report, **Veterans and Agent Orange: Health Effects of Herbicides Used In Vietnam,** ISBN 0-309-04887-7: 1994, 832 pages, 6 x 9, $79.95, is also available.

**Diabetes Information**

Diabetes mellitus is characterized by high blood sugar levels that result from defects in the body's ability to produce and/or resistance to the actions of the hormone insulin. There are two major types of diabetes: type I and type II. Type I occurs most commonly among juveniles but occasionally among adults. Type II occurs primarily in adults and only occasionally in juveniles.

More than 90 percent of the approximately 7 million diabetics in the United States are type II diabetics. Many of these patients initially exhibit few or no symptoms, although increased urination and excessive thirst may be present. Diabetes is associated with high levels of serum glucose. The presence of obesity or a strongly positive family history for mild diabetes suggests a high risk for the development of type II diabetes.

Diabetes is the Nation's sixth-leading cause of death and the leading cause of blindness in the United States. It can also lead to heart disease, stroke, kidney failure, and amputation. Approximately 15 percent of veterans receiving care in Department of Veterans Affairs (VA) medical facilities have been diagnosed with diabetes. VA diabetes patients require an estimated $2.5 billion dollars annually for their treatment and healthcare, including more than 200,000 bed-days per year.

Nationally, more than 16 million people are estimated to be diabetic. More than $100 billion are spent for their treatment and care annually. More than 650,000 additional diabetics are newly diagnosed each year.

Many animal studies provide potential biological mechanisms for an association between herbicide exposure and diabetes risk. Although many earlier reports on humans suggest little association, the 1997 report from the Ranch Hand Study (the Air Force Health Study of the unit responsible for most of the herbicide aerial spraying in Vietnam) raises the possibility that veterans in the highest herbicide exposure category may be at increased risk.
IOM Herbicide Reviews

The National Academy of Sciences Institute of Medicine (IOM) has reviewed the scientific evidence of an association between exposure to herbicides used in Vietnam and the development of diabetes in its reports released in 1993, 1996, and 1999. In each of these reports, the IOM found that there is "inadequate or insufficient" evidence to determine whether an association exists between exposure to herbicides and diabetes mellitus.

In the 1993 report, the IOM reviewers noted that there was "limited" information suggesting the possibility of diabetes in chemical production workers and Ranch Hand veterans exposed to TCDD or dioxin (the contaminant produced during the manufacture of one of the ingredients of Agent Orange), but that the data were "inconclusive." After careful review, then Secretary Jesse Brown concluded, in 1993, that the credible evidence for an association does not equal or outweigh the credible evidence against an association between exposure to herbicides used in Vietnam and the development of metabolic and digestive disorders, including diabetes mellitus.

On January 4, 1994, VA published a notice in the Federal Register that Secretary Brown has determined that a presumption of service connection based on exposure to herbicides in Vietnam is not warranted for a long list of conditions identified in the IOM report. Metabolic and digestive disorders, including diabetes mellitus were included in this list.

As noted above, the 1996 IOM report concluded that there is "inadequate or insufficient" evidence to determine whether an association exists between exposure to herbicides and diabetes mellitus. After careful review, Secretary Brown again determined that the credible evidence for an association does not equal or outweigh the credible evidence against an association between exposure to herbicides used in Vietnam and the development of metabolic and digestive disorders, including diabetes mellitus.

On August 8, 1996, VA again published a notice in the Federal Register that Secretary Brown has determined that a presumption of service connection based on exposure to herbicides in Vietnam is not warranted for a long list of conditions identified in the NAS report. Metabolic and digestive disorders, including diabetes mellitus again were included in this list.

Like the two earlier IOM reports, the 1998 update concluded that there is "inadequate or insufficient" evidence to determine whether an association exists between exposure to herbicides and diabetes mellitus. The 1998 update "strongly" urged that the NIOSH study be documented more completely and published in the peer-review literature, so that its potentially important findings can be fully evaluated. The IOM report "strongly" recommended that the Ranch Hand study develop a better statistical model that fully controls (Continued on Page 5)

About the Review...

The "Agent Orange Review" is prepared by VA's Environmental Agents Service (EAS). The "Review" is published to provide information on Agent Orange and related matters to Vietnam veterans, their families, and others with concerns about herbicides used in Vietnam. The first issue was released in November 1982. The most recent edition (prior to 1999 release is the thirtieth issue. It was written in late July 1999 and does not include developments that occurred since that time.

Comments or questions about the content of the "Review" are encouraged. Suggestions and ideas for future issues should be sent to Donald J. Rosenblum, Agent Orange Review, Deputy Director, Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.


VA updates the "Review" mailing address listing annually based on IRS records. "Review" recipients who have not been filing Federal income tax returns annually and have moved to another residence are encouraged to send their old and new addresses and Social Security number to the Agent Orange Review, Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

Questions about the Agent Orange Registry examination program should be directed to the Registry Physician or Agent Orange Registry Coordinator at the nearest VA medical center. Questions regarding eligibility for health care should be directed to the hospital administration service at the nearest VA medical center. Questions regarding VA benefit programs, including disability compensation, should be referred to a veterans benefits counselor at the nearest VA facility. The telephone numbers can be found in the telephone directory under the "U.S. Government" listings. The national toll-free telephone number for information regarding VA benefits is 1-800-827-1000.
for baseline age and obesity and, if possible, for family history of diabetes, central fat distribution, diabetogenic drug exposure, and a measure of obesity at the time of Vietnam service.

The NAS reviewers also recommended that consideration be given to a combined analysis of Ranch Hand and NIOSH studies to further examine the possibility that herbicide or dioxin exposure leads to an increased risk of diabetes. The IOM added that using the "new" ADA definition of diabetes, outcome data from both studies could be made comparable.

Shortly after the IOM report was released, one additional important study was published (Calvert GM, Sweeney MH, Deddens J, Wall DK. 1999. An Evaluation of Diabetes Mellitus, Serum Glucose, and Thyroid Function Among U.S. Workers Exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. Occupational and Environmental Medicine 56:270-276). This led Secretary West to request that the IOM review its previous finding in light of the recent paper. The review is in progress.

**Joint Efforts with JDF and ADA**

In November 1995, VA Medical Research Service sent a Request for Applications to field stations to establish diabetes research centers at selected VA Medical Centers. In 1996, VA and the Juvenile Diabetes Foundation (JDF) announced three new diabetes research centers to be co-sponsored in a partnership between the two organizations. The VA/JDF Diabetes Research Centers are located in VA medical centers in Iowa City, Iowa; Nashville, Tennessee; and San Diego, California.

The Iowa City Center is focusing on the effects of diabetes of the vascular system. This center is using a multidisciplinary approach aimed at defining the underlying mechanisms of early vascular defects and designing therapies that will either prevent their occurrence or lessen their impact.

The Nashville Center is focusing its research efforts on the study of the cellular and molecular processes by which intensive therapy reduces insulin resistance, the role of exercise in modulating the effectiveness of therapy, and the mechanisms responsible for defective low blood sugar counterregulation in diabetic patients.

The San Diego Center is conducting research to learn more about the basic mechanisms of insulin action so that the causes of insulin resistance can be better understood. The San Diego Center is also conducting research aimed at better understanding the basic causes of complications of the vascular system and kidney.

On March 3, 1998, VA and the American Diabetes Association (ADA) signed a Memorandum of Understanding and announced that they would collaborate in determining the most effective ways to treat diabetes. This includes assessing blood monitoring devices and other technology; sharing information to guide research and further collaboration; and exploring the exchange of benchmarking information on quality cost, and productivity.

The ADA is the largest voluntary health organization dedicated to diabetes research. It operates programs in all 50 States and in more than 800 communities.

**Nehmer Case Revisited**

In a May 1989 decision in the case of Nehmer v. U.S. Veterans' Administration, Judge Henderson, of the U.S. District Court for the Northern District of California, struck down a VA regulation, former 38 C.F.R. § 3.311a(d) which had stated that scientific evidence had failed to demonstrate a causal relationship between herbicide exposure and any condition other than chloracne. Judge Henderson also voided all VA denials made "under" that regulation. In 1991, Congress enacted the Agent Orange Act of 1991, which required VA to determine whether to establish presumptions that certain diseases are associated with herbicide exposure. In 1993 and 1994, VA established regulatory presumptions of service connection for several diseases, located in 38 C.F.R. §§ 3.307(a)(6) and 3.309(e).

Pursuant to an agreement approved by Judge Henderson in the Nehmer case, VA was required to apply its new regulations and to readjudicate all claims which had been denied "under" former section 3.311a(d) (section 3.311 a(d) was in effect from September 1985 to May 1989). If VA awarded benefits on readjudication, the effective date of the award would relate back to the date of the claim which led to the voided decision.

A controversy arose in two cases where VA had awarded benefits under its 1994 regulations, but refused to make the award retroactive to the date of a prior claim that was denied between 1985 and 1989. VA's position was that the prior claim had not been denied "under" former section 3.311a(d) because the claimant had not asserted that the disability or death was due to herbicide exposure and VA had not relied on former section 3.311a(d) in its prior decision.

In a February 1999 decision, Judge Henderson ruled that VA's position was incorrect. Judge Henderson stated that, if the prior claim sought service connection for a disease which is now presumptively service connected
under VA’s herbicide regulations, then the prior claim is considered to have been denied under former section 3.311 a(d) regardless of whether the claimant specifically alleged herbicide exposure as the cause.

Under Judge Henderson's decision, VA may be required to pay retroactive benefits in cases where a disability or death is currently service connected under 38 C.F.R. §§ 3.307(a)(6) and 3.309(e), and a prior claim of service connection for the same condition was denied between 1985 and 1989. (The Nehmer decision may also affect cases where a prior claim was denied after 1989.)

Judge Henderson did not order VA to pay any specific amount of payments. Rather, VA will have to determine, on a case-by-case basis, whether a particular claimant is entitled to retroactive benefits as a result of the order. VA's Compensation and Pension Service will provide specific guidance as to who qualifies for the retroactive benefits.

The plaintiffs in Nehmer have stated that Judge Henderson's decision will require VA to pay an estimated $70 million in retroactive benefits. The basis for that estimate is unknown.

**VA Agent Orange Fact Sheet Series to Be Revised and Updated**

The Environmental Agents Service (EAS) in VA headquarters in Washington, DC, is updating a series of Agent Orange fact sheets, known as "Agent Orange Briefs." The updated fact sheets will soon be sent to all VA medical centers and to many other interested parties. EAS anticipates release of the revised "Briefs" in August or shortly thereafter. The revised "Briefs" will describe a wide range of Agent Orange-related matters. The following twenty-one "Briefs" will be available:

A1. Agent Orange - General Information
A2. Agent Orange Class Action Lawsuit
B1. Agent Orange Registry
B2. Agent Orange - Health Care Eligibility
B3. Agent Orange and VA Disability Compensation
B4. VA Information Resources on Agent Orange and Related Matters
C1. Agent Orange - The Problem Encountered in Research
C2. Agent Orange and Vietnam Related Research - VA Efforts
C3. Agent Orange and Vietnam Related Research - Non-VA Efforts
D1. Agent Orange and Birth Defects
D2. Agent Orange and Chloracne
D3. Agent Orange and Non-Hodgkin's Lymphoma
D4. Agent Orange and Soft Tissue Sarcomas
D5. Agent Orange and Peripheral Neuropathy
D6. Agent Orange and Hodgkin's Disease
DT. Agent Orange and Porphyria Cutanea Tarda
D8. Agent Orange and Multiple Myeloma
D9. Agent Orange and Respiratory Cancers
D10. Agent Orange and Prostate Cancer
D11. Agent Orange and Spina Bifida
D12. Agent Orange and Diabetes

Changes in law, research developments, and policy have necessitated changes. The revised fact sheets will incorporate the latest report of the National Academy of Sciences' Institute of Medicine, plus the 1999 Agent Orange Task Force report and the Secretary's action on the Task Force report. Most of the "Briefs" will be modified. Earlier versions of the "Briefs" were released in October 1988, October 1989, September 1990, July 1991, February 1992, January 1993, September 1994, January 1997, and December 1997. Copies of these outdated issues are no longer available.

For additional information or a copy of some or all of the fact sheets, contact the Agent Orange Registry Coordinator at the nearest VA medical center or write to Agent Orange Briefs, Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

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### Air Force Investigators: No Increased Cancer Risk in Ranch Hand Personnel

Air Force Health Study investigators who are studying veterans of Operation Ranch Hand, the Air Force unit responsible for the aerial spraying of herbicides in Vietnam
from 1962 to 1971, recently reported that they found "no significant increase in cancer risk" among those individuals in the "high dioxin exposure category." The Air Force Health Study is a 20-year prospective study of the health, mortality, and reproductive outcomes of Ranch Hand veterans.

The report's authors, Norma S. Ketchum, Joel E. Michalek, and Joseph E. Burton, of the Air Force Research Laboratory at Brooks Air Force Base, explained that a comparison group of Air Force veterans who served in Southeast Asia during the same period who were not involved with herbicide spraying were matched to Ranch Hand veterans on age, race and military occupation.

Investigators measured dioxin levels in 1987 or 1992, extrapolated the result to the time of service in Southeast Asia, and assigned each Ranch Hand veteran to background, low, or high exposure categories. The statistical power of this study was limited by the small size of the Ranch Hand group. The study had no power to detect small or moderate increases in the risk of rare cancers, such as soft tissue sarcoma and non-Hodgkin's lymphoma in the high or low Ranch Hand exposure categories.

Investigators concluded that the risk of cancer at sites other than the skin within twenty years of service was increased in Ranch Hand veterans with elevated dioxin levels, but the pattern was inconsistent with that of another study, suggesting that the excess risk may not have been caused by dioxin exposure. Overall, they found no consistent increase in cancer risk in the high dioxin exposure category.

The report was published in the American Journal of Epidemiology. The citation is Am J Epidemiol 1999; 249:630-9. Article reprint requests should be referred to Dr. Joel E. Michalek, AFRL/HEDB, 2606 Doolittle Road, Building 807, Brooks AFB, TX 78235-5250.

Gulf War Review Newsletter Available for Desert Shield/Storm Veterans and Other Interested Groups and Individuals

Organizations and individuals who wish to get on the mailing list for the "Gulf War Review" newsletter, should send their name and address, to Gulf War Review, Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, N.W., Washington, DC 20420. As with the "Agent Orange Review," there is no subscription charge. Individuals are encouraged to include their Social Security Number with their request.

Conditions Recognized as Service-Connected for Vietnam Veterans Based on Exposure to Agent Orange or Other Herbicides

1. Chloracne
2. Non-Hodgkin's lymphoma
3. Soft tissue sarcoma
4. Hodgkin's disease
5. Porphyria cutanea tarda
6. Multiple myeloma
7. Respiratory cancers (including cancers of the lung, larynx, trachea, and bronchus)
8. Prostate cancer
9. Peripheral neuropathy (transient acute or subacute)

Condition Recognized in Children of Vietnam Veterans

Spina bifida

Condition Under Consideration Pending Special IOM Review and Decision of the Secretary of Veterans Affairs

Diabetes

Condition Recognized Pending Legislation

Birth Defects in Children of Women Vietnam Veterans