

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AN54

Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and other Chronic B Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease)

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning presumptive service connection for certain diseases based upon the most recent National Academy of Sciences (NAS) Institute of Medicine committee report, Veterans and Agent Orange: Update 2008 (Update 2008). This proposed amendment is necessary to implement a decision of the Secretary of Veterans Affairs that there is a positive association between exposure to herbicides and the subsequent development of hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease, and ischemic heart disease. The intended effect of this proposed amendment is to establish presumptive service connection for these diseases based on herbicide exposure.

DATES: : Comments must be received by VA on or before [Insert date 30 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll free number.) Comments should indicate that they are submitted in response to “RIN 2900-AN54 - Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and other Chronic B Cell Leukemias, Parkinson’s Disease and Ischemic Heart Disease).” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Gerald Johnson, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 461- 9727 (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 3 of the Agent Orange Act of 1991, Public Law 102–4, 105 Stat. 11, directed the Secretary to seek to enter into an agreement with NAS to review and summarize the scientific evidence

concerning the association between exposure to herbicides used in support of military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between the suspect diseases and herbicide exposure, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association; (2) the increased risk of disease among individuals exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the suspect disease. Section 3 of Public Law 102–4 also required that NAS submit reports on its activities every 2 years (as measured from the date of the first report) for a 10-year period. The Veterans Education and Benefits Expansion Act of 2001 (Benefits Expansion Act), Public Law 107–103, § 201(d), extended through October 1, 2014, the period for submission of NAS reports. Section 1116(b) of title 38, United States Code, as enacted by the Agent Orange Act of 1991, Public Law 102–4, provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) exists between exposure of humans to an herbicide agent (i.e., a chemical in an herbicide used in support of the United States and allied military operations in the Republic of

Vietnam during the Vietnam era) and a disease, the Secretary will publish regulations establishing presumptive service connection for that disease.

Section 2 of the Agent Orange Act of 1991, Public Law 102–4, provided that the congressional mandate that the Secretary establish presumptions of service connection under 38 U.S.C. 1116(b) would expire 10 years after the first day of the fiscal year in which the NAS transmitted its first report to VA. The first NAS report was transmitted to VA in July 1993, during the fiscal year that began on October 1, 1992. Accordingly, under the Agent Orange Act of 1991, Public Law 102–4, the mandate for VA to issue regulatory presumptions as specified in section 1116(b) expired on September 30, 2002. In December 2001, however, Congress enacted the Benefits Expansion Act, section 201(d) of which extended the mandate under section 1116(b) through September 30, 2015. Pursuant to the Benefits Expansion Act, Public Law 107–103, VA must issue new regulations between October 1, 2002, and September 30, 2015, establishing additional presumptions of service connection for diseases that the Secretary finds to be associated with exposure to an herbicide agent.

The Secretary of Veterans Affairs has determined that the available scientific and medical evidence discussed in the “Veterans and Agent Orange Update 2008,” authored by the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, Institute of Medicine (IOM) of the NAS, and other information available to the Secretary, are sufficient to establish that a positive association exists between exposure of humans to a herbicide

agent and the occurrence in humans of Hairy Cell Leukemia (HCL) and other Chronic B-Cell Leukemias, Parkinson's disease (PD) and Ischemic Heart Disease (IHD). Consistent with that determination and as required by 38 U.S.C. 1116(b) and the Agent Orange Act of 1991, we propose to amend VA's adjudication regulations (38 CFR part 3) by revising section 3.309(e) to add these diseases to the diseases subject to presumptive service connection on the basis of herbicide exposure.

Hairy Cell Leukemia and Other Chronic B-cell Leukemias.

In delivering the charge to the IOM Committee, the Secretary specifically asked the IOM Committee, whether the occurrence of HCL should be regarded as associated with exposure to the chemical compounds in the herbicides used by the military in Vietnam. HCL is a chronic B-cell lymphoproliferative disorder. Because it is so rare, the Committee reported that HCL would never be studied epidemiologically on its own, and there are no studies of animals that describe HCL in animals exposed to the compounds of interest. The IOM Committee stated that HCL has been classified as a rare form of CLL and that both derive from B-cell neoplasms. Based on its biology, the Committee saw no reason to exclude HCL or any other chronic lymphoproliferative disease of B-cell origin from the overarching broader groupings for which positive epidemiologic evidence is available. Because HCL is related to chronic lymphocytic leukemia (CLL) (a disease that is already included on VA's regulatory list of diseases that qualify for presumptive service connection based upon herbicide exposure), the

Committee explicitly included HCL and other chronic B-cell leukemias in its discussions and conclusions regarding CLL. The Committee explicitly re-categorized HCL and other chronic B-cell leukemias along with CLL in Update 2008, which the Committee lists as a category clarification since Update 2006. Based on its review of the available scientific and medical literature, the Committee concluded that there is sufficient evidence of an association between exposure to herbicide agents and CLL, including HCL and all other chronic B-cell hematoproliferative leukemias.

The Secretary has determined that the available scientific and medical evidence presented in Update 2008 and other information available to the Secretary are sufficient to establish a new presumption of service connection for HCL and other chronic B-cell leukemias in veterans who were exposed to herbicides used in the Republic of Vietnam. The Secretary concludes that the credible evidence for an association between exposure to an herbicide agent and the occurrence of HCL and other chronic B-cell leukemias in humans outweighs the credible evidence against such an association. Accordingly, the Secretary has determined that a presumption of service connection for HCL and other chronic B-cell leukemias is warranted pursuant to 38 U.S.C. 1116(b). Because these leukemias are related to CLL and the evidence supporting an association is the same for these leukemias, we propose to refer to them as a group in VA's regulatory list in 38 CFR 3.309(e) of diseases associated with herbicide exposure. Specifically, we propose to establish a presumption of service

connection for “All chronic B-cell leukemias (including, but not limited to, hairy-cell leukemia and chronic lymphocytic leukemia).”

Parkinson’s Disease.

In Update 2008, the Committee placed Parkinson’s disease (PD) in the category “limited or suggestive evidence of an association.” This was a category change from IOM’s prior report, *Veterans and Agent Orange: Update 2006* (Update 2006). For Update 2008, the Committee selectively reevaluated all past epidemiologic studies that specifically assessed herbicide exposures and reviewed in detail those studies published since Update 2006. The older studies, taken as a group, suggest that there is a relationship between pesticide exposure and risk of PD, but generally did not contain sufficient exposure data to show an association specifically to the herbicides of interest. However, several studies published since Update 2006 now suggest a specific relationship between exposure to the herbicides of interest and PD. Three of the four studies published since Update 2006 showed a statistically significant odds ratio for development of PD and exposure to herbicides, most notably to 2, 4-D and 2, 4, 5-T and other chlorophenoxy herbicides. Accordingly, the recent studies are consistent with the body of epidemiologic and toxicologic data suggesting a relationship between exposure to pesticides and PD, but provide more specific evidence of an association between PD and the herbicides used in the Republic of Vietnam. The Committee noted that, to date, no studies have been done on Vietnam veterans to determine if an increased relative risk of developing PD

exists for this cohort, and the Committee recommended that such studies be done. Based upon the available scientific and medical evidence, the Committee placed PD in the category of “limited or suggestive evidence of an association.”

The Secretary requested expert opinion from the Parkinson’s and Associated Diseases Research and Education Clinical Center (PADRECC) network, a network of VA medical professionals designed to focus on care, research, and education relating to PD. These experts believe that there is an increasing body of evidence indicating exposure to herbicides increases the risk of developing PD and developing it at an earlier age. These experts also identified a September 2008 report by Tanner, et al., in Arch Neurol, 2008; 66(9):1106-1113, which found that the risk of Parkinsonism was increased by exposure to a variety of chemicals, including dioxin-like chemicals of interest in Update 2008. The Tanner study was published after Update 2008 was completed but provides additional support for an association between herbicide exposure and PD.

The Secretary has determined that the available scientific and medical evidence presented in Update 2008 and other information available to the Secretary are sufficient to establish a new presumption of service connection for PD in veterans exposed to herbicides, as the credible evidence for an association between exposure to an herbicide agent and the occurrence of PD in humans outweighs the credible evidence against such an association.

Ischemic Heart Disease.

The previous Committee responsible for Update 2006 was divided as to whether the evidence related to IHD and exposure to the compounds of interest was sufficient to advance IHD from the category of “inadequate or insufficient evidence to determine whether and association exists” to the category of “limited or suggestive evidence of an association.” Due to the lack of consensus, the 2006 Committee left IHD in the “inadequate or insufficient evidence” category.

For Update 2008, the Committee revisited the entire body of evidence relating herbicide exposure to heart disease risk and placed more emphasis on studies that had been rigorously conducted. These studies focused specifically on the chemicals of concern, compared Vietnam veterans to non-deployed Vietnam-era veterans, and had individual and reliable measures of exposure that permitted the evaluation of dose-response, to promote the interpretation of epidemiologic data. The Committee identified nine studies (including two new studies) that were deemed most informative. Of these nine studies, five showed strong statistically significant associations between herbicide exposure and ischemic heart disease. The studies considered by the Committee also included data from Agent Orange sprayers, occupationally exposed populations, and environmentally exposed populations that were either prevalence surveys or mortality follow-up studies. In situations where several alternative analyses were

presented the results with the greatest specificity in the dose-response relationship were given more weight.

The Committee stated that evidence of a dose-response relationship is especially helpful in interpretation of the epidemiological data, and the Committee was impressed by the fact that those studies with the best dose information all showed evidence for risk elevations in the highest exposure categories. The Committee noted that some of the study findings could be limited by the effect of selection bias or possible confounding factors. However, the Committee noted that one of the new studies showed an association that persisted after statistical adjustments for a large number of potential confounding risk factors, which is not generally available in studies of other dioxin exposed populations. The Committee also indicated that the major potential confounders were likely inadequate to explain away the high relative risks and dose-response relationships seen in the data for IHD. Further, the Committee noted that toxicologic data supports the biologic plausibility of an association between exposure to the compounds of interest and IHD.

After considering the relative strength and weaknesses of the evidence, and emphasizing in particular the numerous studies showing a strong dose-response relationship and good toxicology data regarding IHD, the Committee concluded that there was adequate information to advance IHD from the

“inadequate or insufficient evidence” category to the “limited or suggestive evidence” category.

The Secretary has determined that the available scientific and medical evidence presented in Update 2008 and other information available to the Secretary are sufficient to establish a new presumption of service connection for IHD in veterans exposed to herbicides. After considering all of the evidence, the Secretary has concluded that the credible evidence for an association between exposure to an herbicide agent and the occurrence of IHD in humans outweighs the credible evidence against such an association. Accordingly, the Secretary has determined that a presumption of service connection for IHD is warranted pursuant to 38 U.S.C. 1116(b).

According to Harrison’s Principles of Internal Medicine (Harrison’s Online, Chapter 237, Ischemic Heart Disease, 2008), IHD is a condition in which there is an inadequate supply of blood and oxygen to a portion of the myocardium; it typically occurs when there is an imbalance between myocardial oxygen supply and demand. Therefore, for purposes of this regulation, the term “IHD” includes, but is not limited to, acute, subacute, and old myocardial infarction; atherosclerotic cardiovascular disease including coronary artery disease (including coronary spasm) and coronary bypass surgery; and stable, unstable and Prinzmetal’s angina. Since the term refers only to heart disease, it does not

include hypertension or peripheral manifestations of arteriosclerosis such as peripheral vascular disease or stroke.

Impact of the Nehmer Class Action Litigation.

Nehmer v. U.S. Department of Veterans Affairs, Civ. Action No. 86-6160 (N.D. Cal.) (TEH) (Nehmer) is a long-standing class action (originated in 1986) on behalf of all veterans and survivors of veterans eligible to claim VA disability compensation benefits based on exposure to herbicides in the Republic of Vietnam during the Vietnam era. In 1989, the U.S. District Court for the Northern District of California invalidated a 1985 VA regulation governing claims based on herbicide exposure. In 1991, the parties entered into a stipulation to provide for re-adjudication of class members' claims and payment of retroactive benefits, if warranted. Since that time, the district court has issued a series of orders interpreting the 1991 stipulation to impose ongoing duties on VA. Consistent with those orders, whenever VA identifies a new disease that is associated with herbicide exposure and adds a new disease to its regulatory list, it must identify and readjudicate any previously-filed claims by the class members involving that disease and, if warranted under VA regulations governing Nehmer awards, must pay benefits retroactive to the date the prior claim was received by VA to the veteran or, if the veteran is deceased, to the veteran's surviving spouse, child, or parents. In July 2007, the U.S. Court of Appeals for the Ninth Circuit rejected VA's position that its duties under the Nehmer stipulation have ended and held

that VA's duties extend through at least 2015. Nehmer v. U.S. Dept. of Veterans Affairs, 494 F.3d 846, 862-63 (9th Cir. 2007). Accordingly, the requirements of the Nehmer court orders for review of previously denied claims and for retroactive payment will apply to the proposed new presumptions, to the extent consistent with the court orders and 38 CFR 3.816, the VA regulation implementing those orders. The impact of these procedures is discussed in the Regulatory Impact Analysis below.

Paperwork Reduction Act

The collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521) that is contained in this document is authorized under OMB Control No. 2900-0001.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a regulatory action as a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, if it is a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector

of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this rulemaking and determined that it is an economically significant rule under this Executive Order, because it will have an annual effect on the economy of \$100 million or more. A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

Comment Period

Although under the rulemaking guidelines in Executive Order 12866 VA ordinarily provides a 60 day comment period, the Secretary has determined that there is good cause to limit the public comment period on this proposed rule to 30 days. This proposed rule is necessary to implement section 1116(c) of title 38 as enacted by the Agent Orange Act of 1991, Public Law 102-4, which sets forth time limits for rulemaking when the Secretary determines that a new presumption of service connection for veterans exposed to herbicides used in the Republic of

Vietnam is warranted. Those time limits include the requirement for issuance of final regulations “[n]ot later than 90 days after the date on which the Secretary issues proposed regulations.” 38 U.S.C. 1116(c)(2). The statute thus requires VA to act expeditiously to issue final rules, which will allow VA to begin providing benefits to veterans and their families based on this rule. A 30-day notice and comment period is necessary both to facilitate expeditious issuance of final regulations and to promote rapid action on affected benefits claims.

Regulatory Impact Analysis

VA followed OMB Circular A-4 to the extent feasible in this regulatory analysis. The circular first calls for a discussion of the Statement of Need for the regulation. As discussed in the preamble, the Agent Orange Act of 1991, as codified at 38 U.S.C. 1116 requires the Secretary of Veterans Affairs to publish regulations establishing a presumption of service connection for those diseases determined to have a positive association with herbicide exposure in humans.

Statement of Need: On October 13th, 2009, the Secretary of Veterans Affairs, Eric K. Shinseki, announced his intent to establish presumptions of service connection for PD, IHD, and hairy cell/B cell leukemia for veterans who were exposed to herbicides used in the Republic of Vietnam during the Vietnam era.

Summary of the Legal Basis: This rulemaking is necessary because the Agent Orange Act of 1991 requires the Secretary to promulgate regulations establishing

a presumption of service connection once he finds a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of any particular disease.

Alternatives: There are no feasible alternatives to this rulemaking, since the Agent Orange Act of 1991 requires the Secretary to initiate rulemaking once the Secretary finds a positive association between a disease and herbicide exposure in Vietnam during the Vietnam era.

Risks: The rule implements statutorily required provisions to expand veteran benefits. No risk to the public exists.

Anticipated Costs and Benefits: We estimate the total cost for this rulemaking to be \$13.6 billion during the first year (FY2010), \$25.3 billion for 5 years, and \$42.2 billion over 10 years. These amounts include benefits costs and government operating expenses for both Veterans Benefits Administration (VBA) and Veterans Health Administration (VHA). A detailed cost analysis for each Administration is provided below.

Veterans Benefits Administration (VBA) Costs

We estimate VBA's total cost to be \$13.4 billion during the first year (FY2010), \$24.3 billion for five years, and \$39.7 billion over ten years.

Benefits Costs (\$000s)	1 st Year (FY10)	5 year	10 year
Retroactive benefits costs*	12,286,048	**12,286,048	**12,286,048
Recurring costs from Retroactive Processing	0	4,388,773	10,300,132
Increased benefits costs for Veterans currently on the rolls	415,927	2,188,784	4,864,755
Accessions	675,214	4,645,609	11,330,294
Administrative Costs			
FTE costs	4,554***	797,473	894,614
New office space (minor construction)		12,835	12,835
IT equipment		30,232	32,805
Totals:	13,381,743	24,349,746	39,721,476

*Retroactive benefits costs are paid in the first year only.

** Inserted for cumulative totals.

*** FTE costs in FY 2010 represent a level of effort of current FTE that will be used to work claims received in FY2010. New hiring will begin in 2011

Of the total VBA benefits costs identified for FY 2010, \$12.3 billion accounts for retroactive benefit payments. Ten-year total costs for ischemic heart disease is \$31.9 billion, Parkinson's disease accounts for \$3.5 billion, and hairy cell and B cell leukemia is the remaining \$3.4 billion.

Total Obligations by Presumptive Condition

(\$000's)	Retroactive Payments	1st year	5 year	10 year
Ischemic Heart disease	\$9,877,787	\$900,470	\$9,307,716	\$21,978,301
Parkinson's	\$692,204	\$166,300	\$1,189,143	\$2,796,852
Hairy Cell/B cell Leukemia	\$1,716,057	\$24,372	\$726,306	\$1,720,028
Sub-total	\$12,286,048	\$1,091,142	\$11,223,165	\$26,495,181
Total	\$12,286,048	*\$13,377,190	*\$23,509,213	*\$38,781,229

* Includes Retroactive Payments

Methodology

The cost estimate for the three presumptive conditions considers retroactive benefit payments for Veterans and survivors, increases for Veterans currently on the compensation rolls, and potential accessions for Veterans and survivors.

There are numerous assumptions made for the purposes of this cost estimate.

At a minimum, four of those could vary considerably and the result could be dramatic increases or decreases to the mandatory benefit numbers provided.

The estimate assumes:

- a prevalence rate of 5.6% for IHD based upon information extracted from the CDC's web site. Even slight variations to this number will result in significant changes.
- an 80% application rate in most instances. We have prior experiences that have been as low as in the 70% range and as high as in the 90% range.
- new enrollees will, on average, be determined to have about a 60% degree of disability for IHD. This would mirror the degree of disability for the current Vietnam Veteran population on VA's rolls. However, most of the individuals have had the benefit of VHA health care. We cannot be certain that the new population of Vietnam Veterans coming into the system will mirror that average.

- only the benefit costs of the presumptive conditions listed. Secondary conditions, particularly to IHD, may manifest themselves and result in even higher degrees of disability ultimately being granted.

Retroactive Veteran and Survivor Payments

Vietnam Veterans previously denied

In 2010, approximately, 86,069 Vietnam beneficiaries (as of August 2009 provided by PA&I) will be eligible to receive retroactive payments for the new presumptive conditions under the provisions of 38 C.F.R. 3.816 (Nehmer). Of this total, 69,957 are living Vietnam Veterans, of which 62,206 were denied for IHD, 5,441 were denied for hairy cell or B cell leukemia, and the remaining 2,310 for Parkinson's disease. Of those previously denied service connection for the three new presumptive conditions, 52,918, or nearly 76 percent, are currently on the rolls for other service-connected disabilities.

Compensation and Pension (C&P) Service assumes the average degree of disability for both Parkinson's disease and hairy cell/B cell leukemia will be 100 percent, and IHD will be 60 percent. Based on the Combined Rating Table, we assume Veterans currently not on the rolls would access at the percentages identified above. For those Veterans currently on the rolls for other service-connected disabilities, we assume they would receive a retroactive award based on the higher combined disability rating. For example, a Veteran who is on the rolls and rated 10 percent disabled who establishes presumptive service

connection for Parkinson's disease will result in a higher combined rating of 100 percent and receive a retroactive award for the difference. For purposes of this cost estimate, we assumed that Veterans previously denied service connection for one of the three new conditions who are currently receiving benefits were awarded benefits for another disability concurrently.

Based on the Nehmer case review in conjunction with the August 2006 Haas Court of Appeals for Veterans Claims (CAVC) decision, C&P Service identified an average retroactive payment of 11.38 years for Veterans whose claims were previously denied. Obligations for retroactive payments for Veterans not currently on the rolls were calculated by applying the caseload to the benefit payments by degree of disability, multiplied by the average number of years for Veterans' claims. For those who are on the rolls, based on a distribution by degree of disability, obligations were calculated by applying the increased combined degree of disability for those currently rated zero to ninety percent. Of the total 52,918 currently on the rolls, 8,348 are currently rated 100 percent disabled and, therefore, would not likely receive a retroactive award payment.

Of the total 86,069 Vietnam beneficiaries, a total of 69,957 are living Vietnam Veterans. Of this total, 52,918 are currently on the rolls for other service-connected disabilities and 17,039 are off the compensation rolls ($52,918 + 17,039 = 69,957$). Of the 52,918 Vietnam Veterans who are on the rolls, 8,348

are currently rated 100 percent disabled and would not likely receive a retroactive payment ($17,039 - 8,348 = 8,691 + 52,918 = 61,609$).

Veteran Caseload and Obligations for Retroactive Benefits

Presumptive Conditions	Caseload	Retroactive Payments (\$000's)
Ischemic Heart Disease	54,926	\$7,837,369
Parkinson's Disease	2,042	\$568,920
Hairy Cell/B Cell Leukemia	4,641	\$1,209,586
Total	61,609	\$9,615,875

Vietnam Veteran survivors previously denied

Survivor caseload was determined based on Veteran terminations. Based on data obtained from PA&I, of the 86,069 previous denials, 16,112 of the Vietnam Veterans are deceased. Of the deceased population, 13,420 were Veterans previously denied claims for IHD, 2,165 were denied for hairy cell or B cell leukemia, and 527 were denied for Parkinson's disease. We assumed that 90 percent of the survivor caseload will be new to the rolls and the remaining ten percent are currently in receipt of survivor benefits.

The 2001 National Survey of Veterans found that approximately 75 percent of Veterans are married. With the marriage rate applied, we estimate there are 12,084 survivors in 2010. Based on the Nehmer case review in conjunction with

the August 2006 Haas Court of Appeals for Veterans Claims (CAVC) decision, C&P Service identified an average retroactive payment of 9.62 years for Veterans' survivors. Under Nehmer, in addition to survivor dependency and indemnity compensation (DIC) benefits, survivors are also entitled to the Veteran's retroactive benefit payment to the date of the Veteran's death. Obligations for survivors who were denied claims were determined by applying the survivor caseload for each presumptive condition to the average survivor compensation benefit payment from the 2010 President's Budget and the average number of years for the survivor's claim (9.62 years). Veteran benefit payments to which survivors are entitled were calculated similarly with the exception of applying the survivor caseload for each presumptive condition to the difference between the average Veteran claim of 11.38 years and the average survivor claim of 9.62 years. The estimated remaining 4,028 deceased Veterans who were not married would have their retroactive benefit payment applied to their estate.

Of the 86,069 Vietnam beneficiaries, a total of 16,112 are Vietnam Veterans that are deceased. Of this total, an estimated 12,084 were married and an estimated 4,028 were not married (12,084 + 4,028 = 16,112).

Survivor Caseload and Obligations for Retroactive Benefits

Presumptive Conditions	Caseload	Retroactive Payments (\$000's)
Ischemic Heart Disease	13,420	\$2,040,418
Parkinson's	527	\$123,284

Disease		
Hairy Cell/B Cell Leukemia	2,165	\$506,470
Total	16,112	\$2,670,173

Recurring Veteran and Survivor Payments

Retroactive caseload obligations for both Veterans and survivors become a recurring cost and are reflected in out-year estimates. Mortality rates are applied in the out years to determine caseload.

Recurring Veteran and Survivor Caseload and
Obligations from Retroactive Processing

FY	Veteran Caseload	Survivor Caseload	Obligations (\$000s)
2010	N/A	N/A	N/A
2011	61,365	10,672	\$1,079,310
2012	61,243	10,570	\$1,084,209
2013	61,121	10,458	\$1,102,800
2014	61,000	10,336	\$1,122,454
2015	60,879	10,201	\$1,142,251
2016	60,758	10,052	\$1,162,167
2017	60,637	9,891	\$1,182,189
2018	60,517	9,716	\$1,202,298
2019	60,397	9,526	\$1,222,453
Total			\$10,300,132

Vietnam Veterans (Reopened Claims)

We expect Veterans who are currently on the compensation rolls and have any of the three presumptive conditions to file a claim and receive a higher combined disability rating beginning in 2010. We anticipate that Veterans receiving

compensation for other service-connected conditions will continue to file claims over ten years. Total costs are expected to be \$415.9 million the first year and approximately \$4.9 billion over ten years.

According to the Defense Manpower Data Center (DMDC), there are 2.6 million in-country Vietnam Veterans. With mortality applied, an estimated 2.1 million will be alive in 2010. C&P Service assumes that 34 percent of this population are service connected for other conditions and are already in receipt of compensation benefits. In 2010, we anticipate that 725,547 Vietnam Veterans will be receiving compensation benefits. This number is further reduced by the number of Veterans identified in the previous estimate for retroactive claims (52,918). C&P Service assumes an average age of 63 for all Vietnam Veterans. With prevalence and mortality rates applied, and an estimated 80 percent application rate and 100 percent grant rate, we calculate that 32,606 Veterans currently on the rolls will have a presumptive condition in 2010. Of this total, we anticipate 27,909 cases will result in increased obligations. Of the 27,909 Veterans, 25,859 are associated with IHD, 1,693 are associated with Parkinson's disease, and the remaining 357 are associated with hairy cell/ B cell leukemia. In future years, the estimated number of Veteran reopened claims decreases to almost one thousand cases and continue at a decreasing rate. The cumulative effect of additional cases with mortality rates applied is shown in the chart below.

The Vietnam Era caseload distribution by degree of disability provided by C&P Service was used to further distribute the total Vietnam Veterans who will have a

presumptive condition in 2010 by degree of disability for each of the three new presumptive conditions. We assume 100 percent for the average degree of disability for both Parkinson’s disease and hairy cell/B cell leukemia and 60 percent for IHD. Based on the Combined Rating Table, Veterans that are on the rolls for other service-connected conditions (with the exception of those that are currently receiving compensation benefits for 100 percent disability), would receive a higher combined disability rating if they have any of the three new presumptive conditions.

September average payments from the 2010 President’s Budget were used to calculate obligations. These average payments are higher than schedular rates due to adjustments for dependents, Special Monthly Compensation, and Individual Unemployability. The difference in average payments due to higher ratings was calculated, annualized, and applied to the on-rolls caseload to determine increased obligations. Because this particular Veteran population is currently in receipt of compensation benefits, survivor caseload and obligations would not be impacted.

Reopened Caseload and Obligations

FY	Veteran Caseload	Obligations (\$000s)
2010	27,909	\$415,927
2011	28,340	\$418,928
2012	29,051	\$431,726
2013	29,746	\$451,042
2014	30,425	\$471,161
2015	31,086	\$491,648
2016	31,746	\$512,767

2017	32,404	\$534,529
2018	33,061	\$556,958
2019	33,716	\$580,070
TOTAL		\$4,864,755

Vietnam Veteran and Survivor Accessions

We anticipate accessions for both Veterans and survivors beginning in 2010 and continuing over ten years. Total costs are expected to be \$675.2 million in the first year and total just over \$11.3 billion from the cumulative effect of cases accessing the rolls each year.

To identify the number of Veteran accessions in 2010, we applied prevalence rates to the anticipated living Vietnam Veteran population of 2,133,962, and reduced the population by those identified in the previous estimates for retroactive and reopened claims. Based on an expected application rate of 80 percent and a 100 percent grant rate, 28,934 accessions are expected. Of the 28,934 Veteran accessions, 25,505 are associated with IHD, 3,074 are associated with Parkinson’s disease, and the remaining 355 are associated with hairy cell/B cell leukemia. In the out years, anticipated Veteran accessions drop to approximately 3,400 cases in 2011, and continue at a decreasing rate. The cumulative effect of additional cases coupled with applying mortality rates is shown in the chart below.

To calculate obligations, the caseload was multiplied by the annualized average payment. We assumed those accessing the rolls due to IHD will be rated 60

percent disabled and those with either Parkinson's disease or hairy cell/B cell leukemia will be rated 100 percent disabled. Average payments were based on the 2010 President's Budget with the Cost of Living Adjustments factored into the out years.

The caseload for survivor compensation is associated with the number of service-connected Veterans' deaths. There are two groups to consider for survivor accessions: those survivors associated with Veterans who never filed a claim and died prior to 2010; and survivors associated with the mortality rate applied to the Veteran accessions noted above.

To calculate the survivor caseload associated with Veterans who never filed a claim and died prior to 2010, general mortality rates were applied to the estimated total Vietnam Veteran population (2.6 million). We estimate that almost 500,000 Vietnam Veterans were deceased by 2010. Prevalence rates for each condition were applied to the total Veteran deaths to estimate the number of deaths due to each condition. With the marriage rate and survivor mortality applied, we anticipate 20,961 eligible spouses at the end of 2010. We assume that half of this population will apply in 2010 and the remaining in 2011. Obligations were calculated by applying average survivor compensation payments to the caseload each year.

The second group of survivors associated with Veteran accessions was calculated by applying mortality rates for each of the presumptive conditions to the estimated eligible Veteran population (28,934). In 2010, 57 Veteran deaths are anticipated as a result of one of the new presumptive conditions. With the marriage rate applied and aging the spouse population (and assuming spouses were the same age as Veterans), we calculated 42 spouses at the end of 2010. Average survivor compensation payments were applied to the spouse caseload to determine total obligations.

Veteran and Survivor Accessions
Cumulative Caseload and Total Obligations

FY	Veteran Caseload	Survivor Caseload	Total Obligations
2010	28,934	10,416	\$ 675,214
2011	32,270	20,265	882,974
2012	35,541	20,693	955,525
2013	38,744	20,487	1,028,467
2014	41,874	20,283	1,103,429
2015	44,928	20,081	1,179,725
2016	47,900	19,881	1,257,259
2017	50,787	19,682	1,335,922
2018	53,583	19,485	1,415,601
2019	56,285	19,290	1,496,178
Total			\$ 11,330,294

Estimated Claims from Veterans Not Eligible

Based on program history, we anticipate that we will also receive claims from Veterans who will not be eligible for presumptive service connection for the three new conditions.

These claims will be received from two primary populations:

- Veterans with a presumptive disease who did not serve in the Republic of Vietnam
- Claims from Vietnam Veterans with hypertension who claim “heart disease”

We applied the prevalence rate of IHD, Parkinson’s disease and hairy cell/B cell leukemia to the estimated population of Veterans who served in Southeast Asia during the Vietnam Era (45,304, 32, and 6 respectively), and assumed that 10 percent of that population will apply for presumptive service connection.

Review of data obtained from PA&I shows that 23 percent of Vietnam Veterans who have been denied entitlement to service connection for hypertension also have nonservice-connected heart disease. We applied the prevalence rate of hypertension to the living Vietnam Veteran population, and then subtracted 23 percent who are assumed to also have IHD. We assumed that 10 percent of the remaining population would apply for presumptive service connection to arrive at an estimated caseload of 111,256.

We then assumed that 25 percent of the ineligible population would apply in 2010, 25 percent would apply in 2011, and the remaining population would apply over the next 8 years. For purposes of claims processing, anticipated claims are

as follows. The chart below reflects workload, which is not directly comparable to the preceding caseload charts.

Total Claims

FY	Retroactive Claims	Reopened Claims	Accessions	Claims not Eligible	Total Claims
2010	86,069	32,606	39,350	27,814	185,839
2011		1,069	13,806	27,814	42,689
2012		1,051	3,386	6,954	11,391
2013		1,032	3,329	6,954	11,314
2014		1,011	3,267	6,954	11,232
2015		989	3,201	6,954	11,143
2016		989	3,129	6,953	11,071
2017		989	3,053	6,953	10,995
2018		989	2,971	6,953	10,913
2019		989	2,885	6,953	10,827

VBA Administrative Costs

Administrative costs, including minor construction and information technology support are estimated to be \$4.6 million during FY2010, \$841 million for five years and \$940 million over ten years.

C&P Service, along with the Office of Field Operations, estimated the FTE that would be required to process the anticipated claims resulting from the new presumptive conditions using the following assumptions:.

1. 185,839 additional claims in addition to the projected 1,146,508 receipts during FY2010. This includes:

- 86,069 retroactive readjudications under Nehmer
- 89,354 new and reopened claims from veterans
- 10,416 new claims from survivors.

2. The average number of days to complete all claims in FY2010 will be 165.

3. Priority will be given to those Agent Orange claims that fall in the Nehmer class action.

In FY2010, we will leverage the existing C&P workforce to process as many of these new claims as possible, once the regulation is approved, but especially the Nehmer cases. However, to fully accommodate this additional claims volume with as little negative impact as possible on the processing of other claims, we plan to add 1,772 claims processors to be brought on in the FY2011 budget and timeframe. This approximate level of effort will be sustained through 2012 and into 2013 in order to process these claims without significantly degrading the processing of the non-presumptive workload.

- Net administrative costs for payroll, training, additional office space, supplies and equipment are estimated to be \$4.6 million in FY2010, \$165 million in FY2011, \$798 million over five years, and \$895 million over 10 years. Additional support costs for minor construction are expected to be \$12.8 million over the five and ten year period. Information Technology

(computers and support) are assumed to require \$30.2 million over five years and \$32.8 million over ten years.

Veterans Health Administration (VHA) Costs

We estimate VHA's total cost to be \$236 million during the first year (FY2010), \$976 million for five years, and \$2.5 billion over ten years.

FY2010 and FY2011 Summary:

- FY2010 new enrollee patients are expected to number 8,680.
- FY2011 additional new enrollees are expected to number 1,018.
- FY2010 costs for C&P examinations are expected to be \$114M.
- FY2011 costs for C&P examinations are expected to be \$23M.
- FY2010 health care costs (inclusive of travel) are expected to be \$236M (using cost per patient of 13,500).
- FY2011 health care costs (inclusive of travel) are expected to be \$165M (using cost per patient of 14,100).
- Combined costs are as follows:
 - FY2010: \$236M
 - FY2011: \$165M

Assumptions:

- 30% of Veterans newly determined to be service-connected will enroll and will use VA health care.

- Newly enrolled Veterans will be Priority Group 1 Veterans.
- The cost per patient is arrived at using the average cost per Priority Group 1 patient aged between 45-64.
- Every VBA case will require a new exam.
- It is assumed that 100% of newly enrolled Veterans will request mileage reimbursement. The average amount of mileage reimbursement claims per Veteran is \$511 (this amount reflects to the FY2009 actual average amount).

Distribution of Disability Claims:

VBA has established estimates for claims workload for Veterans. Figure 1 provides breakdown of disability claims.

Overall, VBA anticipates 69,957 claims. Of these, 17,039 will be for Veterans whose previous claims for disability compensation were denied. Additionally, VBA anticipates reopened claim volume of 32,606 claims in FY2010 with subsequent decreases to 1,069 per year in FY2011. VBA anticipates 28,934 accessions in FY2010. These are new disability compensation awards – for Veterans who did not previously have an award for service connected disability compensation. Additionally, in FY2010 VBA anticipates disability claim volume associated with the presumptive SC determination to be 159,311 and to exceed 270,000 through FY2019.

Figure 1

FY	Retroactive Claims	Retroactive Claims Representing New SC Disability Award	Reopened Claims	Accessions	Total Disability Claim Volume
2010	69,957	17,039	32,606	28,934	159,311
2011			1,069	3,393	31,207
2012			1,051	3,335	10,289
2013			1,032	3,273	10,227
2014			1,011	3,207	10,161
Subtotals			36,769	42,142	221,195
2015			989	3,137	10,091
2016			989	3,062	10,016
2017			989	2,983	9,937
2018			989	2,898	9,852
2019			989	2,809	9,763
Totals	69,957		41,714	57,031	270,854

New Enrollments and Changed Enrollments:

The disability compensation workload, the resulting increases in service-connected patients, and the increased combined service connected percents will both add new patients to VA's health care system and will change the priority levels of Veterans currently enrolled in VA's health care system.

For purposes of estimation, it is assumed that 30% of Veterans "Accessions" will enroll in the system each year. For FY2010, this means that 8,680 of the 28,934 Veteran "Accessions". Figure 2 provides the estimate of new enrollments per year for the ten year period. In all, it is estimated that 17,109 new Veterans will enroll in VA's health care system.

Figure 2

FY	New Enrollees per Year	New Enrollees Cumulative
2010	8,680	8,680
2011	1,018	9,698
2012	1,001	10,699
2013	982	11,681
2014	962	12,643
Subtotals	12,643	
2015	941	13,584
2016	919	14,502
2017	895	15,397
2018	869	16,267
2019	843	17,109
Totals	17,109	17,109

It is assumed that Veterans enrolling will be Priority Group 1 Veterans and that they will use VA health care services.

For purposes of estimation, it is assumed that 40% of the Veterans whose claims are reopened will have been enrolled in VA's health care system and that their Priority Group will move from a copay required status to a copay exempt status. Additionally, it is assumed that their third party collections will be lost. It is assumed that 10% of the accessions will result in changes to Veterans who are currently enrolled. These Veterans would be enrolled in a copay required status and would move to copay exempt status. In FY2010 it is estimated that 43,919 Veterans would have their enrollment status changed, and FY 2011 it is estimated that an additional 767 Veterans would have their enrollment status changed. Figure 3 provides these estimated changes in enrollment status per year and cumulatively.

Figure 3

FY	Upgraded Enrollees per Year	Upgraded Enrollees Cumulative
2010	43,919	43,919
2011	767	44,686
2012	754	45,439
2013	740	46,180
2014	725	46,905
Subtotals	46,905	46,905
2015	709	47,614
2016	702	48,316
2017	694	49,010
2018	685	49,695
2019	677	50,372
Totals	50,372	50,372

Disability Exams Associated Costs:

It is assumed that each VBA case will result in disability examinations for the Veteran. In all, it is estimated that 270,854 disability examinations will need to be performed. An escalation factor of 4% is applied to cost of disability examinations.

Figure 4

FY	Total Disability Claim Volume	Cost per Disability Exam*	Annual Cost Per Disability Exams
2010	159,311	\$719	\$114,544,609
2011	31,207	\$748	\$23,335,346
2012	10,289	\$778	\$8,001,451
2013	10,227	\$809	\$8,271,365
2014	10,161	\$841	\$8,546,705
Subtotals	221,195		\$162,699,475
2015	10,091	\$875	\$8,827,339
2016	10,016	\$910	\$9,112,200
2017	9,937	\$946	\$9,401,942
2018	9,852	\$984	\$9,694,379
2019	9,763	\$1,023	\$9,991,075
Totals	270,854		\$209,726,410

*Source: Allocation Resource Center

Health Care and Total Costs:

Figure 5 provides extended health care costs per year and includes costs for C&P disability examinations and travel associated with C&P examinations. The cost per patient is arrived at using the average cost per Priority Group 1 patient aged between 45-64. It is assumed that 100% of newly enrolled Veterans will request mileage reimbursement. The average amount of mileage reimbursement claims per Veteran is \$511 (this amount reflects to the FY2009 actual average amount). Total costs over the 10-year period are estimated to be in excess of \$2.4B.

Figure 5

FY	Annual Cost Per Disability Exams	Cost per BT Mileage Claim	Beneficiary Travel Costs (41.5 Cents/Mile)	Cost Per Patient	Health Care Costs per Patient	Extended Annual Costs
2010	\$114,544,609	\$511	\$4,435,582	\$13,500	\$117,182,700	\$236,162,891
2011	\$23,335,346	\$511	\$4,955,729	\$14,100	\$136,743,210	\$165,034,285
2012	\$8,001,451	\$511	\$5,466,985	\$14,700	\$157,269,420	\$170,737,855
2013	\$8,271,365	\$511	\$5,968,736	\$15,100	\$176,375,550	\$190,615,650
2014	\$8,546,705	\$511	\$6,460,369	\$15,700	\$198,488,820	\$213,495,893
Subtls	\$162,699,475		\$27,287,400		\$786,059,700	\$976,046,575
2015	\$8,827,339	\$511	\$6,941,271	\$16,300	\$221,414,310	\$237,182,919
2016	\$9,112,200	\$511	\$7,410,675	\$17,100	\$247,989,330	\$264,512,205
2017	\$9,401,942	\$511	\$7,867,969	\$17,900	\$275,609,880	\$292,879,791
2018	\$9,694,379	\$511	\$8,312,233	\$18,800	\$305,812,080	\$323,818,692
2019	\$9,991,075	\$511	\$8,742,852	\$19,800	\$338,764,140	\$357,498,068
Totals	\$209,726,410		\$66,562,400		\$2,175,649,440	\$2,451,938,251

Summary:

Combined estimated increases in health care costs and lost revenues are presented in Figure 6.

Figure 6

FY	Extended Annual Costs
2010	\$236,162,891
2011	\$165,034,285
2012	\$170,737,855
2013	\$190,615,650
2014	\$213,495,893
Subtotals	\$976,046,575
2015	\$237,182,919
2016	\$264,512,205
2017	\$292,879,791
2018	\$323,818,692
2019	\$357,498,068
Totals	\$2,451,938,251

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This rulemaking would have no such effect on State, local, and tribal governments, or on the private sector.

Regulatory Flexibility Act

The Secretary certifies that the adoption of this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule would not directly affect any small entities; only individuals could be directly

affected. Therefore, under 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Congressional Review Act

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts. We have determined this rulemaking to be a major rule under the Congressional Review Act.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this proposed rule are 64.109, Veterans Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, veterans, Vietnam.

Approved: December 23, 2009

John R. Gingrich,
Chief of Staff, Department of Veterans Affairs

For the reasons set out in the preamble, VA is proposing to amend 38 CFR part 3 as follows:

PART 3 — ADJUDICATION

Subpart A-Pension, Compensation, and Dependency and Indemnity

Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

§ 3.309 [Amended]

2. In § 3.309(e) the listing of diseases is amended as follows:

- a. By removing “Chronic lymphocytic leukemia” and adding, in its place, “All chronic B-cell leukemias (including, but not limited to, hairy-cell leukemia and chronic lymphocytic leukemia)”.
- b. By adding “Parkinson’s disease” immediately preceding “Acute and subacute peripheral neuropathy”.
- c. By adding “Ischemic heart disease (including, but not limited to, acute, subacute, and old myocardial infarction; atherosclerotic cardiovascular disease including coronary artery disease (including coronary spasm) and coronary bypass surgery; and stable, unstable and Prinzmetal’s angina)” immediately following “Hodgkin’s disease”.

[FR Doc. 2010-6549 Filed 03/24/2010 at 8:45 am; Publication Date: 03/25/2010]