



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 27, 2020

The Honorable David P. Roe, M.D.
Ranking Member
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Roe:

In accordance with the requirements of the Further Consolidated Appropriations Act, 2020, Public Law 116-94, section 801, the Department of Veterans Affairs (VA), in consultation with Office of Management and Budget, submits the enclosed report. The report provides the status of any efforts by the Secretary to determine whether to promulgate new regulations to add to the list of diseases for which a presumption of service-connection is warranted for purposes of section 1110 of title 38, United States Code, by reason of having a positive association with exposure to an herbicide agent.

This report has also been sent to other leaders on the House and Senate Committees on Veterans' Affairs.

Sincerely,

A handwritten signature in cursive script that reads "Robert L. Wilkie".

Robert L. Wilkie

Enclosure



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 27, 2020

The Honorable Mark Takano
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In accordance with the requirements of the Further Consolidated Appropriations Act, 2020, Public Law 116-94, section 801, the Department of Veterans Affairs (VA), in consultation with Office of Management and Budget, submits the enclosed report. The report provides the status of any efforts by the Secretary to determine whether to promulgate new regulations to add to the list of diseases for which a presumption of service-connection is warranted for purposes of section 1110 of title 38, United States Code, by reason of having a positive association with exposure to an herbicide agent.

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Robert L. Wilkie

Enclosure



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 27, 2020

The Honorable Jon Tester
Ranking Member
Committee on Veterans' Affairs
United States Senate
Washington, DC 20510

Dear Senator Tester:

In accordance with the requirements of the Further Consolidated Appropriations Act, 2020, Public Law 116-94, section 801, the Department of Veterans Affairs (VA), in consultation with Office of Management and Budget, submits the enclosed report. The report provides the status of any efforts by the Secretary to determine whether to promulgate new regulations to add to the list of diseases for which a presumption of service-connection is warranted for purposes of section 1110 of title 38, United States Code, by reason of having a positive association with exposure to an herbicide agent.

This report has also been sent to other leaders on the House and Senate Committees on Veterans' Affairs.

Sincerely,

A handwritten signature in cursive script that reads "Robert L. Wilkie".

Robert L. Wilkie

Enclosure



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 27, 2020

The Honorable Jerry Moran
Chairman
Committee on Veterans' Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

In accordance with the requirements of the Further Consolidated Appropriations Act, 2020, Public Law 116-94, section 801, the Department of Veterans Affairs (VA), in consultation with Office of Management and Budget, submits the enclosed report. The report provides the status of any efforts by the Secretary to determine whether to promulgate new regulations to add to the list of diseases for which a presumption of service-connection is warranted for purposes of section 1110 of title 38, United States Code, by reason of having a positive association with exposure to an herbicide agent.

This report has also been sent to other leaders on the House and Senate Committees on Veterans' Affairs.

Sincerely,

A handwritten signature in black ink, reading "Robert L. Wilkie", is positioned above the printed name.

Robert L. Wilkie

Enclosure

Department of Veterans Affairs (VA)

Further Consolidated Appropriations Act, 2020 (Public Law 116-94)

Report to Congress on Disability Compensation and the Positive Association with Exposure to an Herbicide Agent

Bill Language: [Under Division P]

TITLE VIII—VETERANS AFFAIRS REPORT ON DISABILITY COMPENSATION AND THE POSITIVE ASSOCIATION WITH EXPOSURE TO AN HERBICIDE AGENT

SEC. 801. REPORT ON EFFORTS TO DETERMINE WHETHER TO ADD TO THE LIST OF DISEASES FOR WHICH PRESUMPTION OF SERVICE-CONNECTION IS WARRANTED FOR PURPOSES OF DISABILITY COMPENSATION BY REASON OF HAVING POSITIVE ASSOCIATION WITH EXPOSURE TO AN HERBICIDE AGENT.

(a) **IN GENERAL**—Not later than 30 days after the date of the enactment of this Act, the Secretary of Veterans Affairs, in consultation with the Director of the Office of Management and Budget, shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report setting forth the status of any efforts of the Secretary to determine whether to promulgate new regulations to add to the list of diseases for which a presumption of service-connection is warranted for purposes of section 1110 of title 38, United States Code, by reason of having positive association with exposure to an herbicide agent.

(b) **CONTENTS**—The report submitted under subsection (a) shall include the following:

(1) A detailed explanation of any delays in making a determination described in such subsection.

(2) An estimate of the cost of adding to the list of diseases described in such subsection.

(3) The date the Secretary anticipates on which the Secretary will promulgate new regulations as described in such subsection.

(c) **DEFINITION OF HERBICIDE AGENT**—For purposes of this section, the term "herbicide agent" has the meaning given such term in section 1116 of title 38, United States Code.

BACKGROUND

Concerns from Vietnam Veterans returning to the United States in the 1960s and 1970s regarding potential exposures to Agent Orange and other dioxin contaminants led Congress to pass Public Law (P.L.) 102-4, the "Agent Orange Act of 1991." P.L. 102-4 directed the Secretary of Veterans Affairs to contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct comprehensive review and evaluation of scientific and medical information regarding the health effects of exposure to Agent Orange, other herbicides used in Vietnam, and the various components of those herbicides, including 2,3,7,8-tetrachlorodibenzop-dioxin (TCDD). These herbicides and their components will be referred to as Chemicals of Interest (COI) in

this report. P.L. 102-4 also required the Secretary to contract NASEM to conduct updates every 2 years for 10 years from the date of the first report in order to review newly available literature and draw conclusions from the overall evidence.

The first NASEM report, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam (VAO)*, was published in 1994. Subsequent statutes extended through September 30, 2020, the requirement for VAO biennial updates from NASEM. Overall, NASEM published a total of 11 reports between 1994 and 2018 as mandated by law and also by the Department of Veterans Affairs' (VA) authority to request reports.

To the extent that scientific data permitted, NASEM was charged to determine:

- 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;
- The increased risk of disease among individuals exposed to herbicides while in service in Vietnam during the Vietnam era; and
- Whether there is a plausible biologic mechanism or other evidence of a causal relationship between herbicide exposure and a suspect disease.

In carrying out its work, NASEM reviews peer-reviewed scientific studies concerning associations between various health outcomes and exposure to the COIs. NASEM weighed the importance of the reviewed studies in the following order: Vietnam Veterans, occupationally exposed workers, and people who were exposed environmentally. Exposures collected from case-control designs were considered separately by NASEM. Vietnam Veterans (U.S. Veterans and those from allied countries including Australia, Korea, and New Zealand) were presumed by NASEM to have been exposed to all the COIs. NASEM, however, acknowledged in its reports the limitations of its reviews due to "most health studies of Vietnam Veterans were hampered by relatively poor measures of exposure to herbicides or TCDD and by other methodological problems. Most of the evidence on which the findings regarding associations are based, therefore, comes from studies of people exposed to TCDD or herbicides in occupational and environmental settings rather than from studies of Vietnam Veterans." Additionally, NASEM indicated that "Vietnam Veterans were exposed to other agents and stressors—such as tobacco smoke, insecticides, therapeutics, drugs, diesel fumes, alcohol, hot and humid conditions, and combat—that may increase or decrease the ability of chemicals in herbicides to produce a particular adverse health outcome. Few, if any, studies either in humans or in experimental animals have examined those interactions."

NASEM classifies the evidence regarding exposure to the COIs and health outcomes into four categories: sufficient, limited or suggestive, inadequate or insufficient, and no association. The classifications are based on the committee's evaluation of the epidemiologic literature and reflect the committee members' judgement of the relative

certainty of the association between the outcome and exposure to the herbicides that were used in Vietnam or to any of their components or contaminants (with no intention of specifying particular chemicals). As mandated by P.L. 102-4, the distinctions among categories in NASEM's review are based on statistical association and not on strict causality.

Upon receiving a report and briefing from NASEM, VA's NASEM Technical Working Group (TWG) would carry out the formal review process of the report findings as prescribed by VA Directive 0215. TWG is co-chaired by the Director of Environmental Health and the Deputy Director of Epidemiology and comprises of experts in health care; occupational and environmental medicine; public health; toxicology; epidemiology; disability compensation; policy; regulations; and legal. In carrying out its review of the findings, TWG also considers other related research studies and reports that were not reviewed by NASEM. TWG is responsible for recommending course of actions to VA senior leaders based on its review of the NASEM report and other relevant evidences.

As enacted, P.L. 102-4 imposed stringent rulemaking requirements for VA to establish presumptions of service-connection for new diseases. The statutory standard required VA to focus narrowly on certain factors, while ignoring other factors that ordinarily would be a usual and necessary component of a decision regarding establishment of presumptions. Those rulemaking requirements expired on September 30, 2015.

CONCERNS REGARDING SUFFICIENCY OF EVIDENCE TO SUPPORT NEW PRESUMPTION RULEMAKING

Based on the review of VAO Volume 11 and research studies not covered by NASEM, VA experts noted significant concerns and limitations regarding the evidence and NASEM's analysis and whether they support adding new conditions to the list of diseases for which presumption of service-connection is warranted due to exposure to herbicide agent.

- In general, there was no definitive causal link between COIs and the conditions identified in the VAO report.
- One of the conditions identified by NASEM, hypertension (HTN), has many alternative risk factors (including diet, tobacco use, genetics, race) and commonly occurs at a high rate among elderly populations, so most Vietnam Veterans would probably already have HTN from another cause or at least a combination of causes.
- Many of the studies for another condition identified by NASEM, bladder cancer, are not conclusive because of the small numbers of exposed cases, low exposure specificity, and a lack of ability to control for a major confounding factor. For example, cigarette smoking is a major risk factor for bladder cancer but was not controlled in any of the studies reviewed by NASEM. According to cancer research experts, "the most common risk factor for bladder cancer is

cigarette smoking, although smoking cigars and pipes can also raise the risk of developing bladder cancer. Smokers are 4 to 7 times more likely to develop bladder cancer than nonsmokers.”

- The most rigorous study cited by NASEM was conducted on members of the Army Chemical Corps, those with known high occupational exposure, but the exposure experience of this group does not necessarily reflect the experience of the general population of Veterans deployed to Vietnam.

ESTIMATED COST FOR POTENTIAL PRESUMPTION CONDITIONS

Potential Retroactive Benefits based on Nehmer

VA had significant responsibilities as a result of compliance obligations associated with rulings issued by Federal Courts in the *Nehmer v. U.S. Department of Veterans Affairs* class action litigation (which began in 1987 and is ongoing with regard to prior presumptions). Specifically, each time VA established a new presumption of service-connection under the rulemaking provisions of the Agent Orange Act 1991, VA was required to (1) identify and re-adjudicate all claims by Vietnam Veterans or their survivors in which entitlement to service-connection for the new presumptive disease was denied by VA between September 1985 and the effective date of the new presumption; and (2) award retroactive benefits based on the original claim if re-adjudication results in an award of service-connection. This result accorded the class of Vietnam Veterans covered by the *Nehmer* court orders numerous adjudicatory advantages not available to any other Veterans.

The rulemaking requirements of the Agent Orange Act of 1991 expired on September 30, 2015. As a result, it is VA's position that the judicially imposed *Nehmer* re-adjudication and retroactivity requirements would not apply to new presumptions. Rather, any new regulation to add to the list of diseases for which a presumption of service-connection is warranted would be subject to the traditional effective date rule. However, that issue will likely be litigated and there is a risk that courts will find the *Nehmer* requirements applicable to new presumptions. Accordingly, for the purpose of this report, cost estimates are being provided for two scenarios: one with *Nehmer* re-adjudication requirements and one where *Nehmer* requirements do not apply.

Year	Estimated # Cases (Veterans & Survivors)	Without Nehmer (\$ in billion)	With Nehmer (\$ in billion)
1	190,900	\$1.3	\$3.5
2	344,250	\$2.0	\$2.8
3	498,400	\$2.7	\$3.5
4	524,250	\$2.5	\$2.6
5	546,200	\$2.8	\$2.8
Total	2,104,000	\$11.2	\$15.2

Notes: Cost estimates do not include Blue Water Navy cases; total may not add up due to rounding.

WAY FOWARD

Since the enactment of the Agent Orange Act of 1991, VA had previously established a presumption of service connection for fourteen diseases associated with Agent Orange exposure. VA is awaiting the results of two studies -- the Vietnam Era Health Retrospective Observational Study (VE-HEROeS) and the Vietnam Era Mortality Study -- currently being carried out by VA's Office of Research and Development that could potentially provide definitive association of certain diseases to herbicide agent exposure.

VE-HEROeS was initiated in 2014 to study the overall health of Vietnam-era Veterans. The study is a rigorously conducted survey of 45,000 Veterans randomly selected from 9.9 million who served from 1961-1975. VE-HEROeS compares Veterans who served in the Vietnam theater of operations to Veterans who served concurrently in other parts of the world, as well as same-age and same-gender civilians on measures of health, physician-diagnosed diseases, and other health related characteristics. The survey was fielded in 2016-2017, and the results are now being analyzed and prepared for submission to peer-reviewed literature in 2020.

The Vietnam-era Veteran Mortality study compares overall mortality and specific causes of death between theater and era Veterans as well as comparison to standardized U.S. mortality rates published by the Centers for Disease Control and Prevention. The overall Vietnam-era Veteran population data were recently obtained and will be matched to the mortality data from the Department of Defense (DoD)-VA Joint Mortality Data Repository (MDR) for use in the study. The mortality data used for the study encompass all domestic deaths available from 1979 through 2017. It is the most current cause of death data available to VA and DoD investigators. The mortality data analysis and the research findings are expected to be available for peer-review and

publication in late 2020. The soonest the Secretary would be able to consider any addition of new presumptive conditions is in late 2020, pending the results from the Vietnam studies having cleared peer-reviews.

VA remains committed to the care of Vietnam Veterans and the continued study of Agent Orange and its associated adverse health effects as well as regular review of all emerging evidence of adverse impacts to Veterans from Agent Orange.

U.S. Department of Veterans Affairs
January 2020