

Timeline of White House efforts to block the Department of Veterans Affairs from expanding comprehensive health care and benefits to veterans suffering from illnesses due to Agent Orange exposure

- October 3rd, 2017: Then VA Secretary Shulkin decides to add to the list of certain diseases to the list of conditions eligible for Agent Orange benefits. Announcement is planned for Nov. 1st, 2017.
- November 1st, 2017: VA Secretary Shulkin meets with White House, Office of Management and Budget, and Office of Information and Regulatory Affairs officials after draft of announcement was circulated. VA Secretary Shulkin is asked not to announce the decision.
- November 14th, 2017: VA officials meet with White House, OMB, and OIRA officials, who ask the VA to produce more information and materials.
- January 31st, 2018: OMB and OIRA email VA Secretary Shulkin explaining the White House opposition to the inclusion of the certain diseases for expanded Agent Orange benefits.
- March 8th, 2018: VA Secretary Shulkin responded to OMB/OIRA asking to reverse their decision to block expanded benefits for certain veterans exposed to Agent Orange.
- March 28th, 2018: VA Secretary Shulkin is fired.

The Honorable Mick Mulvaney
Director
Office of Management and Budget
Washington, DC 20503

Dear Mick:

On October 3, 2017, VA sent an email to OMB/OIRA requesting your recommendation to add three new Agent Orange medical conditions, bladder cancer, hypothyroidism, and Parkinson's-like conditions, to the list of service-connected ailments presumed to be caused by exposure to certain herbicides, including Agent Orange, in Vietnam veterans. This email contained several relevant documents to support my regulatory proposal.

On November 14, 2017, VA met with several EOP/OMB/OIRA/OMB-OGC, DPC members and WH Counsel. It was my understanding that this meeting was very productive, resourceful and that OMB/OIRA would provide their recommendations to this proposal in the coming weeks. Following this meeting, OMB/OIRA requested several more documents to support my proposal. VA provided OMB/OIRA with over 40 supportive scientific study documents, peer-reviewed studies and other supportive Agent Orange studies/documents. We also provided OMB/OIRA with a much longer scientific single document supporting my regulatory proposal.

On January 31, 2018, we received an email from OMB/OIRA, stating the following:

Thank you for sharing information concerning the possibility of adding three new Agent Orange medical conditions, (b) (5)

The Honorable Mick Mulvaney

I understand your team, with your concurrence, listed several reasons for (b) (5)

[REDACTED]

Additionally, OMB/OIRA's January 31, 2018 email, did not contain any detailed evidence, refutable rationale and/or why OMB/OIRA implied that there was limitations in the scientific support for this regulatory proposal (rulemaking).

As we have discussed, Mick, I would like for you to direct your team to meet and have another discussion with our team, to specifically review our scientific support for this regulatory proposal and to conduct a secondary review of our scientific rationale and rebuttal to the fact that this regulatory proposal would be precedential in nature for other potential presumptions with a similar level of scientific support (including stroke and hypertension). Our scientific support and rationale that we plan to discuss with your team is provided in this letter below.

After this meeting, I would expect that your team provide a detailed explanation for their decision and/or recommendations.

We will address OMB's other (b) (5)

[REDACTED]

Given the research and scientific variables surrounding Agent Orange exposure and the significance of this matter to Veterans and their families, it is imperative to add these

(b) (5)
[REDACTED]

Thanks again for the time you and your team have put into this. Please advise your team to contact my Regulatory Policy Officer (b) (5) for a meeting and we look forward to a favorable decision on this issue. Our Veterans are counting on us. Thank you.

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Scientific Evidence to Support Three New Presumptions and Rebuttal to the Precedential Nature for other Potential Presumptions with a Similar Level of Scientific Support

1. Under contract with VA and IAW the Agent Orange Act (now expired), the National Academy of Medicine (NAM) has published periodic consensus reviews. In these reviews, NAM ranks the evidence in favor of an association with Agent Orange utilizing four categories of evidentiary strength. NAM goes out of its way to NOT make recommendations to VA for new presumptions. Being placed in a given NAM evidence category has not guaranteed that disease would eventually become a VA presumption.
2. Following VA Directive 0215, VA performed an independent review of all available information from the scientific literature. A series of working groups forwarded through channels recommendations to senior VA leaders for action. Using an approach similar to that used by NAM, VA found published research studies of the target population (i.e. Vietnam Veterans) to be the most useful. In making recommendations, we looked at the preponderance of scientific evidence for each of the five conditions to be discussed below.

Bladder Cancer: (b) (5)

Yi et al. in 2014 reported a statistically significant two-fold increase in bladder cancer-specific mortality comparing high- and low-exposure groups (of self-reported exposure history). According to the NAM 2014 Report: "The evidence for bladder cancer mortality found in the Korean Vietnam Veterans Health Study is consistent with some previous mortality studies in occupationally exposed cohorts that had reasonable numbers of cases and exposure assessments." These studies include: Kogenivas et al. (1997); Steenland et al. (1999); Manuwauld et al. (2007); and, Reveld et al. (2001). Bladder cancer risk rises rapidly with age. The average annual incidence of urinary bladder cancer is 182.9 at ages 70-74 (the age of many Vietnam Veterans).

Hypothyroidism: (b) (5)

Two studies by Yi et al. (2014a/b) found evidence of an increased occurrence of clinical hypothyroid disease, possibly associated with autoimmune hypothyroidism, in association with higher estimated potential herbicide exposure. Chevier et al. (2014) analyzed data from the Seveso Women's Health Study and found an inverse relationship between serum TCDD level and total T4 in exposed pre-menarchal women. Animal studies also provide biologic plausibility to this association. The symptoms of

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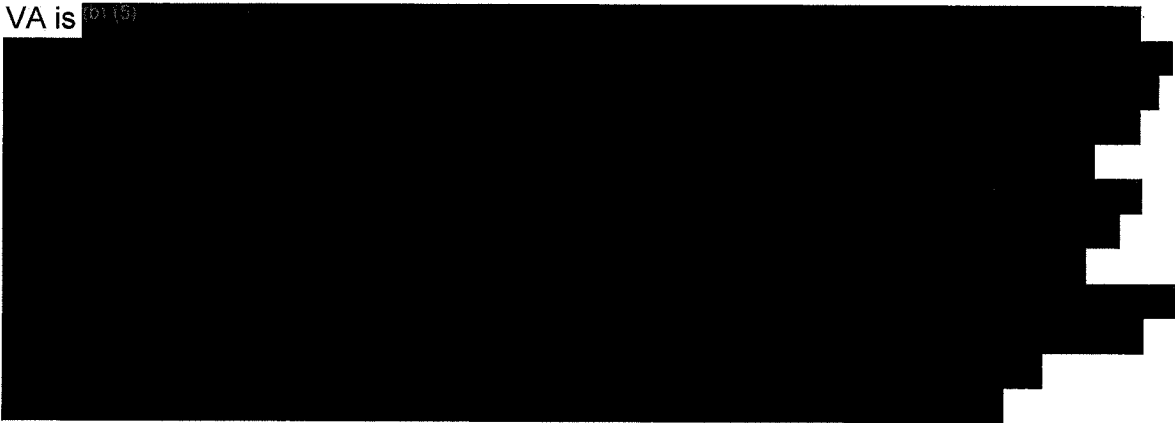
hypothyroidism are known to be easily treated in most cases with thyroid replacement. Without identification and treatment, it can, however, result in significant morbidity. An estimated 4.6 percent of the U.S. population has hypothyroidism; prevalence increases with age (~10% adults >65 years).

Parkinsonism: (b) (5) .

Parkinson's Disease is already accepted as a presumption. At the time the rule was made to include it, Parkinsonism - which is the correct term for Parkinson's Disease with a known cause (e.g., Agent Orange) - was omitted. This recommendation will correct that oversight; in fact, Parkinson's Disease has no known cause by definition. Many times these terms are confused and used interchangeably. By including "Parkinsonism, in the setting of dementia, multiple system atrophy, and progressive supra-nuclear palsy", this will correct that error. This language was recommended by the NAM.

Hypertension and Stroke: (b) (5) .

VA is (b) (5)



Sincerely,

David J. Shulkin

From: Murphy, Thomas, Acting Under Secretary
for Benefits </o=va/ou=vba
philadelphia/cn=recipients/cn=(b) (6), (b) (5)>

To: Tucker, Brooks </o=va/ou=exchange
administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6), (b) (5)> DJS
</o=va/ou=exchange administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6), (b) (5)> Wright, Vivieca
(Simpson) </o=va/ou=va
martinsburg/cn=recipients/cn=(b) (6), (b) (5)>

Cc: Bowman, Thomas </o=va/ou=exchange
administrative group (fydibohf23spdlt)/cn=recipients/cn=(b) (6), (b) (5)>
(b) (6), (b) (5) Byrne, Jim (OGC) </o=va/ou=exchange administrative
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Ullyot, John </o=va/ou=exchange administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6), (b) (5)> Tran, Dat VACO
</o=va/ou=va martinsburg/cn=recipients/cn=(b) (6), (b) (5)>

Bcc:

Subject: RE: Important

Date: Wed Nov 01 2017 07:26:47 CDT

Attachments:

Normal Process for the last several presumptive condition decisions:

VA receives a report from NAM or other scientific evidence

VA follows the presumptive condition recommendation review process led by Dat Tran, involving VACO, VHA, and VBA,

Committee, led by Dat Tran, presents recommendations to the SecVA. SecVA decides.

VA goes to OMB with SecVA decision.

OMB "ADVISES" VA what it is willing to support.

Following SecVA decision, VA starts the rulemaking process.

Normally a 12-18 month process. An Interim Final Rule is a kind of Fast Track that bypasses the normal public notice and comment period and is very rarely approved by OMB.

The issue OMB has is with the press release (b) (5)

We followed a very similar process for brain cancer and 7 other GW conditions. OMB would not support (b) (5)

From: Tucker, Brooks
Sent: Tuesday, October 31, 2017 7:01 PM
To: DJS; Wright, Vivieca (Simpson)
Cc: Bowman, Thomas; Byrne, Jim (OGC); Ulyot, John; Murphy, Thomas, Acting Under Secretary for Benefits; Tran, Dat VACO
Subject: RE: Important

Adding Tom Murphy and Dat Tran.

Sent with Good (www.good.com)

From: DJS
Sent: Tuesday, October 31, 2017 3:57:59 PM
To: Wright, Vivieca (Simpson)
Cc: Bowman, Thomas; Tucker, Brooks; (b) (5) Byrne, Jim (OGC); Ulyot, John
Subject: Important

For All- We apparently have confusion around the agent orange presumptive.

This is my first time through this process so I need to rely upon the advice given.

We decided we would notify Omb, 8 corners, vsos and then tomorrow a press release.

I am told that Omb was (b) (5)

Apparently there is confusion so We are going to have an urgent meeting tomorrow with Omb and doc at 1030 am- details to follow

In preparation I need to understand what is the normal process in the past. 1 or 2)?

1. (b) (5) [Redacted] Or [Redacted]

2. (b) (5) [Redacted]

Sent with Good (www.good.com)

From: Bowman, Thomas </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED] (b) (6), (b) (5)>
To: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED] (b) (6), (b) (5)>
Cc: Wright, Vivieca (Simpson) </o=va/ou=va martinsburg/cn=recipients/cn=[REDACTED] (b) (6), (b) (5)>
Bcc:
Subject: FW: Guidance for AO meeting with OMB and DPC
Date: Sun Nov 12 2017 13:39:37 CST
Attachments:

Sir: This is part and parcel of the follow-on actions arising out of the WH meeting we had with DPC and OMB Director.....I believe that we should stand [REDACTED] (b) (6), (b) (5)

Additionally I recommend that we stand [REDACTED] (b) (6), (b) (5)

Tom

From: Tran, Dat VACO
Sent: Sunday, November 12, 2017 1:54 PM
To: Bowman, Thomas
Cc: Devine, Danny C.
Subject: Guidance for AO meeting with OMB and DPC
Importance: High

Sir:

This coming Tuesday afternoon, a team from VA will be meeting with a team from the WH to begin the Agent Orange regulation/rulemaking discussion. The VA team consists of the Director of Regulations Management, VHA, VBA, OGC, OM, and OCLA. I will be the overall senior executive lead for the VA team. For the WH team, there will be representatives from OMB Budget, Office of Information and Regulatory Affairs (OIRA), DPC (Darin Selnick), WH Counsel, and OMB OGC. The VA team will have a prep session at 2:00 pm tomorrow afternoon. Prior to the meeting, we would like to seek guidance from you and the Secretary regarding VA's position in a couple of areas that I have outlined below.

Based on email exchanges between VA Office of Regulations Management and WH OIRA, we believe the WH team will ask VA to justify SECVA's decision to seek presumptions in the following order -- (1)

[REDACTED] (b) (6), (b) (5)

(1) The Secretary's specific authority to grant additional AO presumption under the Agent Orange Act of 1991 expired on September 30, 2015. However, VA OGC believes under (b) (5)

[REDACTED]

(2) In the scientific justification, we believe the WH team will push (b) (5)

[REDACTED]

(3) Assuming that VA can get past (b) (5)

[REDACTED]

Please let me know yours and SECVA's guidance on #1 and #2.

v/r

Dat