SERGEANT SULLIVAN CENTER

NAMED FOR A MARINE WHO FELL TO ILLNESS, IMPROVING POST-DEPLOYMENT HEALTH THROUGH AWARNESS, RESEARCH, AND CONNECTION

August 20, 2013

Ms. Cynthia Harvey-Pryor
Veterans Health Administration (10B4)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

RE: OMB Control No. 2900-NEW, Open Burn Pit Registry Airborne Hazard Self-Assessment Questionnaire – SSC Preliminary Comments

Dear Ms. Cynthia Harvey-Prior:

Following are Preliminary Comments from The Sergeant Thomas Joseph Sullivan Center ("SSC") in response to Federal Register Notice on June 5, 2013, "Proposed Information Collection (Open Burn Pit Registry Airborne Hazard Self-Assessment Questionnaire) Activity: Comment Request."

These Preliminary Comments are offered as prelude to Final Comments that SSC will submit at the end of a second 30-day comment period, which will follow publication of a revised proposed data collection questionnaire, per announcement by Dr. Paul Ciminera, Director, VA Post-9/11 Era Environmental Health Program, at the Joint DoD/VA Airborne Hazards Symposium August 13, 2013.

SSC

The SSC is the only private, not for profit 501(c)(3) organization in the nation dedicated to confronting and eradicating post-deployment illnesses. Named for a Marine who fell to post-deployment illnesses, The SSC is dedicated to improving health outcomes for current and former military personnel, especially those who are suffering from emerging, complicated, or currently unexplained post-deployment health concerns, through awareness, research, and connection. More information is available at www.sgtsullivancenter.org.

SCOPE OF PRELIMINARY COMMENTS

The Department of Veterans Affairs ("VA"), per the June 5, 2013 Federal Register Notice referenced above, has solicited "comments for information needed to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits ... [specifically:] (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology."

The SSC will confine its Preliminary Comments to these four subject areas. However, the SSC may submit Supplementary Preliminary Comments to VA during the period in which the data collection and associated

public information campaign are being developed and will also submit Final Comments after the revised data collection is made available for review. The SSC Preliminary Comments focus on the language, wording, and strategies of the proposed data collection from a lay perspective informed by opinions from scientific, Veteran, and Caregiver communities.

BACKGROUND

On January 10, 2013, President Barack Obama signed into law the Open Burn Pits Registry Act ("the Act"), which includes four central provisions, including to "(A) establish and maintain an open burn pit registry for eligible individuals who may have been exposed to toxic airborne chemicals and fumes caused by open burn pits; (B) include any information in such registry that the Secretary of Veterans Affairs determines necessary to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits; (C) develop a public information campaign to inform eligible individuals about the open burn pit registry, including how to register and the benefits of registering; and (D) periodically notify eligible individuals of significant developments in the study and treatment of conditions associated with exposure to toxic airborne chemicals and fumes caused by open burn pits."

In its Preliminary Comments, the SSC will endeavor to provide comments that address the VA proposed data collection and justification as proposals for agency implementation the four provisions of the Act, in reference to the four focus areas delineated in the Federal Register Notice.

SSC PRELIMINARY COMMENTS

Focus Area (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility

The VHA is responsible for the healthcare of Veterans as well as for biomedical research under the Office of Research and Development. Establishing and maintaining registries to examine the short- and long-term impacts of deployment exposure hazards would seem to be essential to the proper performance of VHA's functions. The practical utility is potentially enormous. The proposed Registry, at first, will be a list of Veterans and Service members who are suffering from complicated post-deployment illnesses that began after airborne exposures, a core group of sick warriors who require innovative and adaptable healthcare for emerging, poorly understood illness.[1] Over time, better understanding post-exposure diseases through registries will lead to more informed healthcare delivery to exposed Veterans, consistent with the VHA Vision for patient-centered, evidence-based care in an environment that supports learning, discovery, and continuous improvement.

Focus Area (2) the accuracy of VHA's estimate of the burden of the proposed collection of information

Number of registrants: The estimated number of respondents, per the VA Justification, is 50,000. This seems low based on projections of the number of Veterans impacted by post-deployment illnesses after exposure to airborne hazards. Note here that VA intends the registry to be open to active duty personnel as well Gulf War

[1] The list will also include veterans who may not currently experience any symptoms but who could develop them later.

and Iraq and Afghanistan Veterans. According to estimates from a noted VA war related illness specialist, up to 35% of Gulf War and post-911 era Veterans may have been exposed, or are concerned about exposure, to deployment environmental hazards, suggesting an at risk population of over one million possible Veteran registrants. It has been reported that nearly 52% of Iraq and Afghanistan Veterans suffer from post-deployment "symptoms, signs, and ill-defined conditions," which may have been caused, in whole or in part, by exposure to airborne hazards. To facilitate identifying causes for their illnesses, each of these Veterans (est. 478,276) would be encouraged to register via the self-assessment questionnaire during the public information campaign component of the implementation of the Act.[2]

Cost: The estimated expense of $70,000 for Veteran outreach does not on its face appear to be a realistic or reasonable assessment of the actual burden of conducting a public information campaign on behalf of over 2.2 million post-9/11 era Veterans and Service members and 700,000 Gulf War Veterans potentially exposed to airborne hazards from burn pits plumes, dust, oil well fires, and particulate matter. The estimated cost of $1.5 million to develop information technology for the self-assessment questionnaire versus $70,000 on the public information campaign is suggestive of an unbalanced approach to the implementation of one of the central provisions of the Act – educating Veterans about their health risks and the benefits and purposes of registering. As a reference point in re-evaluating cost, the VA may consider that the Department of Housing and Urban Development has funded public information campaign that has comparable features the one proposed by the Act at $1.2 million, certainly a more reasonable estimate of the true burden of effective outreach to the at-risk populations who should register.[3]

Focus Area (3) ways to enhance the quality, utility, and clarity of the information to be collected

The Act requests VA to "include any information in such registry ... necessary to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits." The possible health effects of specific chemicals in burn pit plumes and associated airborne hazards has been documented in published scientific literature, yet the data collection fails to collect information about many of these documented health effects.

For example, the data collection fails to request information on whether a respondent has been diagnosed with constrictive bronchiolitis, an objectively reportable and documented unique health impact of exposure to deployment airborne hazards.

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[2] Various references: "The exact number of new veterans of OEF/OIF/OND who have been exposed to environmental hazards, are concerned about having been exposed, or both is unknown, but is likely to be between 20% and 35%...." **[pg. 658, JOEM Volume 54, No. 6, June 2012 (Health Hazards of Exposure)]. Institute of Medicine (IOM):** "Estimates of the numbers of 1991 Gulf War veterans who have CMI [Chronic Multisymptom Illness] range from 175,000 to 250,000 (about 25–35% of the 1991 Gulf War veteran population), and there is evidence that CMI in 1991 Gulf War veterans may not resolve over time. Preliminary data suggest that CMI is occurring in veterans of the Iraq and Afghanistan wars as well." **Gulf War and Health, Volume 9, Treatment for Chronic Multisymptom Illness**, Committee on Gulf War and Health: Treatment of Chronic Multisymptom Illnesses, Board on Health of Select Populations, Institute of Medicine of the National Academies, January 2013. "One of the more common diagnoses among veterans of the Iraq and Afghanistan wars (nearly 52% of the veterans) is symptoms, signs, and ill-defined conditions (that is, conditions that do not have an immediately obvious cause or isolated laboratory test abnormalities) (VA, 2012a) **Gulf War and Health,** Characterizing Chronic Multi-symptom Illness, pg. 27. VA Healthcare Utilization Records.

[3] HUD's national media campaign for fair housing awareness is funded at **$1,249,885.00**. See link: http://portal.hud.gov/hudportal/HUD?src=/states/district_of_columbia/news/HUDNo.2012-05-16

In fact, rather than documenting objectively reportable exposure health impacts (diseases/symptoms), the data collection appears to focus questions on Veteran perception of disease and causation. For example, there are ten questions (Questions 2.5 B-K) asking Veterans, in various forms, to report whether they believe something they breathed during deployment made them sick. These questions do not, on their face, appear to be relevant to the scientific and legal purpose of the Registry. That purpose, as defined by the Act, is to monitor the diseases themselves, not Veteran beliefs about disease. If Congress, in the future, wishes the VA to conduct a questionnaire on Veteran beliefs about disease, then these questions may be useful at that time, and could be reserved that purpose, but they have no apparent utility here.

Certain questions in the "Symptoms, Health History" section (6) present related utility problems. Questions under 6.1 enable to Veterans to report certain health problems (F01-F18) only if they first report one of five functional limitations related to running and walking. (Note: running and walking are by no means the only functional limitations associated with airborne hazard exposures, but they are the only options for Veteran reporting in the current Registry.) The question following report of a functional limitation is, "What condition or health problem causes you to have difficulty [emphasis added] with these [running and walking] activities?" (6.1.F.). Answers to this question may yield information on what Veterans believe to be the cause for running and walking limitations, which might be useful for a Veteran psychology of disease survey, but will not advance the purpose of the Registry.

That purpose, to assess and monitor the health impacts of toxic chemical exposures from deployment airborne hazards, calls for the questionnaire to permit respondents to disclose objectively reportable symptoms, diagnosis, and functional limitations covering all organs and bodily systems potentially impacted by airborne exposures (heart, lung, gastrointestinal, immune, etc.). These diseases and functional limitations have been documented in scientific literature, such as *Long Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan* (Institute of Medicine of the National Academies, 2011), *Constrictive Bronchiolitis in Soldiers Returning from Iraq and Afghanistan* (New England Journal of Medicine, 2011), or the numerous papers summarizing known health impacts of such chemicals and metals by the Agency for Toxic Substances and Disease Registry (http://www.atsdr.cdc.gov). The data collection for post-exposure symptoms and diseases could be accomplished, in a preliminary fashion, with a simple but comprehensive checklist and an open field for additional comments and concerns.

As a kind of grassroots "beta registry," the Veteran and Caregiver-operated Burnpits360.org website has received 2,000 anecdotal entries by enabling simple Veteran reports of the objective symptoms from which they are suffering from and for which they seek relief, such as shortness of breath, memory loss, t-cell cancers, fatigue, pain, digestive disorders, fibromyalgia, and swelling. Veterans and Caregivers associated with Burnpits360 were instrumental in advocating for passage the Act, and the symptoms tracked by the Burnpits360 registry are among those that the VA would monitor if it were to implement the Act in a manner consistent with the VHA mission to provide patient-centered, evidence-based care. (Burnpits360 is essentially an evidence-collecting association of patients and caregivers asking for help from the VA with a health crisis.)

Finally, it is worth noting that not a single question in the data collection directly and clearly asks Veterans to report on diseases they have now that they did not have before deployment. Instead, questions ask for Veteran subjective perceptions of disease and exposure and for general health conditions without reference to whether

deployment exposure preceded the conditions, a tactic which will not yield information useful for assessing how deployment exposures actually impact health.

Focus Area (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology

Based on an initial review of some Veteran and Caregiver comments on the proposed data collection, it is reasonable to consider whether the most significant burden of the proposed data collection for respondents will be the emotional and psychological burden of completing a questionnaire that may generate feelings of mistrust and betrayal through its wording and chronology of questions, to the point at which completing the questionnaire, in its current form, could present a threat to the psychological and physical health of at-risk Veterans and Service members.

For example, the present questionnaire asks multiple questions about non-deployment exposures before addressing functional limitations, including such questions as, "Have you ever worked for a year or more in any dusty job outside the military?" (4.3. A.), and "Have you ever removed mold in your home because of its effect on your health?" (5.1.B.). These questions appear to undermine the Veterans concerns about the highly toxic deployment exposures they have undeniably endured and the pressing physical diseases that they did not have before they were deployed, but are now suffering since their return.

Veterans with these life-threatening post-deployment illnesses, looking for a place to register these diseases to get help, will be unable to report these specific diseases because the questionnaire provides no vehicle to collect such reports. Instead, sick Veterans will be faced with answering questions such as, "During your pre-deployment, deployment, or post-deployment integration period, did you experience an emotional event that you would consider very stressful?" (2.4), followed by a series of mental perception questions, such as, "Do you **currently** have a sickness or condition you think [emphasis added] began or got worse because of something you breathed during deployment(s)?" (2.5.C.).

The use of language and order of questions appears to locate responsibility for the disease in the Veteran's thinking process, rather than on an external cause, and, in light of the historically dysfunctional relationship between VA and Veterans on exposure issues, this is likely to create feelings of dread, confusion, and betrayal in some respondents.

Consider this excerpt from the comments of Peter Sullivan, father of Marine Corps Veteran Sgt. Tom Sullivan, who died of post-deployment illnesses after being exposed to dust and smoke during his deployment: "A war veteran is likely to find these questions off-putting ... I can tell you that [my son] Tom would have considered the many detailed questions about non-deployment related matters as an indication that the authors were seeking to minimize the impact of deployment exposures on his health and to maximize the non-deployment related exposures or find psychological explanations of health problems. The history of Agent Orange and Gulf War Illness has conditioned veterans to think that the government's denial and minimization efforts will likely carry over to the illnesses of our post-9/11 wars."

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Captain Rebecca Selby, a sick post-9/11 era Service member comments: "The purpose of the burn pit registration is ascertain & monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals & fumes caused by open burn pits, yet many of the questions asked have nothing to do with exposure … I have been diagnosed with 38 illnesses/conditions since I was medivac'd out of Afghanistan 2.5 years ago ... right now my whole body is effected ... No where [sic] on the survey do you allow someone like me & there are thousands of us ... "

Alice Daniel, surviving parent of SSG William Austin Daniel, who died of cancer after burn pit exposure in Iraq, comments: "After reading the proposed burn pit "registry", it appears to be slanted toward proving the health of military personnel was not affected by the burn pits rather than locating all who became ill due to exposure ... This is not a registry but instead a questionnaire to place blame for illness elsewhere."

Whether or not the proposed Registry questionnaire is intended to place blame elsewhere, or to brush aside the pressing health concerns of hundreds of thousands of Veterans, the perception of this intent will become a real hurdle for effectiveness of the data collection. Additionally, mitigating the emotional and psychological burden of completing the questionnaire is essential to rebuilding the trust between the VA and Veterans and focusing on the healing process.

For the VA, this may mean simply refining the Registry questionnaire to collect information on what Veterans were exposed to, and what diseases they have now that they did not have before deployment. A lifetime environmental exposure history could be conducted in a clinical setting after initial deployment exposure and post-deployment disease data is collected through a trust-building questionnaire. Arguably, an emphasis on rebuilding trust, focusing on facts over perceptions, and emphasizing healing is more important than automated collection techniques and information technology in reducing the burden on respondents.

CONCLUSION

In its proposed plan to implement the Act, the VA has developed a Registry Questionnaire as a "self-assessment" rather than as a data collection of objectively reportable symptoms, diseases, and deployment exposures. The current Questionnaire may yield results useful for those examining Veteran psychology of exposure risk perception, but will not apparently yield results to answer the central scientific issue the Act prompts VA to investigate: the relationship between the airborne exposures and the post-exposure diseases themselves.

Despite this setback, The SSC looks forward to reviewing the VA's revised symptoms, diseases, and exposures questionnaire and seeing an expanded budget assessment for the true cost of the critically important public information campaign.

Sincerely,

Daniel Sullivan

Daniel Sullivan
President, The Sergeant Thomas Joseph Sullivan Center