Comments of Peter M. Sullivan

Re: Proposed Information Collection
(Self-Assessment Questionnaire
for the
Airborne Hazards & Open Burn Pit Registry)
[OMB Control No. 2900-NEW]

These comments reflect my personal perspectives as the father of Marine, Sergeant Thomas Joseph Sullivan, who died in 2009 from complications of an illness related to his service in Iraq in 2004-2005. He developed multiple symptoms, the first of which involved rectal bleeding that began while he was deployed. Over time he developed severe intestinal and respiratory disease, accompanied by diffuse and intense pain and swelling, and non-alcoholic fatty liver disease and hypertension. After his death, the autopsy revealed serious heart disease.

His doctors could not explain the etiology of his illnesses. None raised even the possibility that his medical problems were linked to toxic exposures while he was deployed -- this despite his post-deployment health questionnaire noting his exposure to a burn pit (where feces were disposed), dust, and fumes from local chemical plants. He was given to believe that his array of symptoms was unusual and medically unexplained. After his death, we learned that some of his military doctors thought Tom had a psychosomatic disorder. We also learned from other military veterans and their families that are many Tom Sullivans among those who served in our post-9/11 wars and that much work remains to be done by the Veterans Administration and the Department of Defense to understand the illnesses that so many service men and woman developed after deployment.

So I welcome the long overdue project to develop a registry to help identify those who have deployment-related illnesses and to obtain information to improve capabilities to diagnose, treat and prevent such illnesses.

<u>Scope of Registry</u>

The VA should be commended for its decision to apply the registry to exposures of airborne hazards broadly. Burn pits pose only one of a variety of exposure risks from natural (e.g., metals and other toxins embedded in desert sand and particulate matter) and man-made hazards. This approach is consistent with Section 313 of the National Defense Authorization Act for Fiscal Year 2013 (Public Law 112-239, January 2, 2013) that requires the Secretary of Defense to facilitate the identification of members of the Armed Forces who have individual exposures to environmental hazards, including burn pits, dust or sand, hazardous materials, and waste.

Registry & Questionnaire Title

I think the title of the registry and questionnaire should clearly communicate its broad scope. However, confusing and inconsistent titles are used. One refers to "Open Burn Pit Registry Airborne Hazard Questionnaire." The other refers to Airborne Hazards and Open Burn Pit Registry Questionnaire." The latter should be consistently used as the title, as it properly reflects that open burn pits are a subset of airborne hazards.

Eligibility of Active Duty Service Members

I understand that the VA plans to make active duty military service members eligible for the Airborne Hazards and Open Burn Pit (AHOBP) Registry. This is a good idea and should enhance continuity of monitoring and tracking, which is very difficult when service members are discharged (especially the 50% or so who do not enroll in the VA health care system). The new registry will serve to partially fill a gap in the Gulf War Illness registry for which OEF (Afghanistan) veterans are not now eligible.

Eligibility of Gulf War Veterans

I endorse the VA's decision to make 1991 Gulf War veterans eligible for the new registry. However, there many exposures besides oil well fires that these veterans faced that are not referred to in the questionnaire. I think a proper check list of exposures should be added to the questionnaire.

Maximizing Registration

To encourage the maximum possible participation in the registry, the VA needs to make the enrollment as simple as possible. In contrast to the Gulf War Illness Registry enrollment process, which involves personal interface with a VA professional, the prospective respondents for the new AHOBP Registry will be left to their own devices in preparing the draft "self-assessment" questionnaire.

Moreover, the draft questionnaire is more than twice as long as the initial enrollment data sheet for the GWI Registry (compare Gulf War Phase I Worksheet, VA Form 10-9009A).

The draft also contains many awkwardly or oddly worded questions and potential answers and, in some cases, seeks information of no conceivable value. For example, **Q2.4 asks, Have you ever experienced an emotional event that you would consider very stressful?** There appear to be far more detailed questions about non-deployment and even non-military related factors that those linked to deployment. A war veteran is likely to find these questions off-putting and to question the value of the registry process. I can tell you that 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.

In view of the foregoing, I am concerned that potential respondents will be turned off by the questionnaire in its current form. Moreover, the VA's estimate that 50,000 will responds reflects low expectations. It is estimated that about 250,000 Gulf War veterans developed Gulf War Illnesses. The IOM's January 2013 report said preliminary data show similar pattern of illness appears to be emerging in Iraq and Afghanistan war veterans. The probabilities are that hundreds of thousands of these recent (post 9/11) war veterans will be affected. The VA needs to find them and evaluate them, look for patterns and learn something about their complex illnesses and the exposures that might explain them. The registry and the questionnaire need to be user friendly so these veterans can be monitored and tracked.

Streamline and Focus Questionnaire

I recommend that the draft be streamlined to focus on essential threshold data to enable respondents to enroll on the registry. This would serve as a Phase I of the registry process. Once registered, the VA can follow up with additional detailed questions and, I hope, medical screenings.

In my opinion, the essential data points include

--Name/Identification/Contact Info (residential mailing address, email and telephone)

--Current Employment (e.g., occupation, full-time/part-time)

--Military and Deployment History (Demographics in the draft)
>> All deployments should be listed, not just OEF, OIF, ND, 1991 Gulf War

--Deployment Exposures (for each deployment)

--Health Status Before Deployment (info should be requested for each deployment)

--Health History & Problems During and/or After Each Deployment
>Symptoms
>Any diagnoses
>Current condition
>Current medications
>Trend line (stable, improving, worsening)

>Impact of any health problems on quality of life (ability to work, activities of daily living, medical discharge, DOD/VA disability rating for specified conditions)

Symptoms/Diagnoses/Health History and Exposures

It is recommended that Symptoms and Health History be revised to be more comprehensive. The draft is focused on respiratory and heart health and cancer, but needs to be broadened to permit respondents to disclose symptoms and diagnoses covering all organs and bodily systems, that is to say, all significant aspects of health.

Respondent can list symptoms they have and diagnoses they have received, but cannot be expected to say whether a particular condition or health problem is a cause of an inability to run or job a mile, etc. (See Q6.1.F.) The questionnaire should be revised to provide a robust list of symptoms and conditions and diagnoses. In this connection, there should also be a question whether respondent had been informed by a health care provider that a symptom or condition he/she has experienced is medically unexplained or its etiology (origin/cause) is unknown. According to the VA's Analysis of VA Health Care Utilization by post-9/11 war veterans, over half of the diagnoses call in this category.

I think it would be useful for the respondent to indicate where he received his medical care, particular whether any diagnoses received were from a military, VA or private doctor.

The questions under Health Conditions Q6.2 are cast in terms of have you ever been told you had a certain condition (hay fever, asthma, chronic bronchitis, COPD, various heart conditions, etc.). These questions need a temporal framework and, for the first round questionnaire, it should be focused on before and after each deployment. If the condition existed before deployment, then the follow-up would be, did the condition worsen, stay same or improve?

In the draft questionnaire's listing of diseases, there is a conspicuous omission of constrictive bronchiolitis and some other rare lung diseases that are known to have afflicted several veterans of OIF and OEF.

In this listing of exposures, there is also an omission of a significant known exposure – a major sulphur mine fire in Iraq.

Again, a more robust list is required and it must deal with more than respiratory, heart and cancer diseases. For example, many veterans who have deployment related respiratory illnesses, also experience gastrointestinal illnesses, kidney and liver diseases, neurological illness, severe rashes and other symptoms; in many cases, conditions/symptoms are characterized as ill-defined, or medically unexplained. As noted above, my son Tom's health problems included major intestinal disease and diffuse pain and swelling, as well as respiratory and heart

disease. Informal surveys, including one by Burn Pits 360, show a high incidence of intestinal or digestive illnesses and other co-morbidities among persons with deployment related respiratory illnesses.

The 2010 IOM report on burn pits (Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan) lists many pathologies that might be associated with exposure to toxins released by burn pits.[1] All of these should be on the check list.

Also, the IOM report and other studies note the very high particulate matter levels that contain, not only particles from burn pits, but local pollutants and metals, bacteria, viruses and fungi found naturally in the desert dust. The pathologies associated with those toxins should also be listed.

It is recommended that, for symptoms, conditions and diagnoses, an "Other" open field be added in which the respondent can add something that is not in the check list.

In addition, after each question or series/section of questions, there should be a field for the respondent to add any explanation of answers given or not given. It is difficult to capture all relevant information in a series of questionnaire items. Flexibility is needed to provide context and clarity.

The Health History should also note whether the respondent has suffered any conventional wounds from bombs or other weapons or accidents (e.g., loss of limbs, eyesight, hearing, etc.) and list the respondent's surgical history and current medications.

Many questions offer answer options that seem inappropriate. For example, Cancer History Q6.3, asks "Have you ever been told by a doctor…that you had Cancer or a malignancy (tumor) of any kind?" The answer options are "Yes;" "No;" "I do not

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[1] The following are among the long-term health effects of chemicals of interested detected at Joint Base Balad, per the IOM report referenced above: increased liver weight, increased cholesterol, vascular disorders, and degeneration in the internal organs and central nervous system; lung and liver cancers; stomach and respiratory tract tumors; lung and skin tumors; liver effects; carcinomas and malignant lymphoma; nephropathy; hematological alterations; blood effects; increased liver, spleen, and kidney weights; liver necrosis; renal tubular degeneration; defatting of skin; chronic bronchitis; impaired neurobiological test performance; hypochromic anemia; maternal and developmental]toxicity; eye and respiratory tract irritation; neurobehavioral and neurological effects (e.g. reduced nerve conduction velocity, increased reaction time); respiratory and inflammatory responses, nasal lesions, increased heart and kidney weights, liver necrosis, decreased body weight gain; leukemia and hematologic neoplasms; progressive deterioration of hemotopoeitic function; suppression of circulating B-lymphocytes, menstrual disorders, limited evidence of reproductive toxicity and neurotoxicity; liver, lung, ovary, and mammary tumors; lymphohematopoietic cancers and leukemia; reproductive and developmental effects (e.g. ovarian and testicular atrophy, fetal skeletal variations, decreased fetal weight); etc. See IOM, Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan, Health Effects of Air Pollutants, (Health Effects of Air Pollutants Detected at Joint Base Balad, Table 5-1), pp.50-54

wish to answer;" or "Don't know." Whether a prospective respondent chooses to enroll in the registry or answer any or all of the questionnaire questions is a voluntary act. It does not make sense to prompt a respondent in some answer options to refrain from answering (assuming that the question is properly re-worded to avoid the "have your ever" formulation).

In addition, "Don't know" seems to be a rather unlikely answer to this any many other questions. Perhaps, "Not sure" might fill the bill for the occasional respondent who needs to check to make sure what a doctor actually said before committing to an answer. This is yet another reason to give respondents a field in which to provide clarifying explanations of answers (or inability to answer).

The questions on deployment-related dust exposures are quite limited relative to the extensive questions concerning non-deployment related exposures. One wonders whether the authors of the questions under stand the unusual nature of dust in Iraq and Afghanistan. It is very fine and hollow; it can penetrate deep into the small airways and carry bacteria, viruses, fungi, as well as metal particles found naturally in the desert sand and particles from local pollution (industry, burn pits, etc.) This is very different from any dust that would be found in the domestic U.S. More detailed questions concerning deployment dust exposures should be added, including the extent to which dust migrated into sleeping, eating and work place facilities.

Delete Questions on Non-Deployment Related Exposures

It is recommended that the following sections of the draft questionnaire be deleted from the initial questionnaire: Residential History Q3, Non-Military Dust Exposures Q4.3, Non-Military Gas, Smoke, Vapors or Fumes Exposures Q4.4, Non-Military Asbestos Exposure Q4.5, Non-Deployment Environmental Exposures, Tobacco Exposure Q6.5, Q6.6 (except for basic info on whether respondent is currently or formerly a smoker and whether he/she smoked while deployed), Alcohol Use Q6.7.

Detailed questions like these may be relevant to taking a detailed health history of a respondent as a follow-up to the initial questionnaire. It would make more sense to obtain such information in a clinical context, where a health professional elicits the information and can explain the potential relevance of the info to a diagnosis of the respondent's health problems.

The typical respondent to this questionnaire will be a veteran who was in good to excellent health before initial deployment and experienced a decline in health during/after deployment. The immediate objective should be (and presumably) is to find veterans who have experienced a decline in their health since deployment

and identify the nature of the diseases they have and likely or possible exposures that could explain these conditions.[2]

Critical Evaluation of Questionnaire

There needs to be a comprehensive critical evaluation of the questions and answer options in the questionnaire. Previously, I noted the question about whether the respondent experienced a stressful event. This will not produce any useful information. Similarly, the question whether respondent believes he/she is sick because of something he breathed.

Again, the questionnaire should obtain useful information regarding exposures, symptoms, conditions and diagnoses, treatment and health trend lines.

It would also be helpful to test run/sanity check the revised questionnaire with about 100 to 200 veterans. Napoleon used to have his Corporal test read his draft orders before giving it to his generals. If the Corporal did not understand them, neither would his generals.

Open Fields for Respondent Comments

In addition to fields after each questions or series/section of questions for respondent's to clarify or elaborate on any answer (or correct Demographic data obtained from the VA Defense Information Repository), I recommend an open field be provided at the end of the questionnaire for the respondent to note any other information that he/she believes is important to understand his/her health concerns.

The suggestion for this and other open fields was inspired in part by remarks Veterans Support Organizations recently made by VA Under Secretary of Health Petzel. He said the key to delivering effective health care is listening to patients.

Medical Screening and Other Questionnaire Follow-Up

If the registry is to have any real value, it will be important for the VA to offer medical screenings similar to those offer to persons enrolled on the Gulf War Illness Registry. In addition to offering such screenings, it is recommended that respondents be asked if they would be interested in obtaining a registry medical screening. This would provide an opportunity to obtain more detailed health history information and build a more reliable database for more effective

[2] This is not to say the registry has no value for those veterans who have remained in good health after deployment. Some of the effects could be latent. As indicated in some of the comments on the questionnaire thus far, some veterans want to be registered in the event they become ill and so they can be notified of significant research findings that become available.

monitoring, analysis and research. When the final version of the registry questionnaire is launched, the VA's plan for follow-up questionnaires and screenings should be explained.

It would also make sense to ask respondents if they would be interested in participating in research studies.

Disabled Respondents and Outreach

I am concerned about the ability of some disabled veterans to respond to the questionnaire. They may not be able to use computers because of blindness or other limitations. It is recommended that the VA provide assistance to such veterans or their representatives.

In this connection, the VA says it has allocated only about $70,000 to outreach to implement the questionnaire. This seems grossly inadequate to publicize the questionnaire and registry and provide assistance to those who will need it.

Deceased Veterans

There does not seem to be any provision for registering veterans who suffered from illnesses possibly related to toxic exposure while deployed, but have since died. My son, SGT Tom Sullivan, is one of them. I know of others.

Right now, the VA has no readily accessible data on veterans who have died as a result of deployment-related illnesses.[3] This is an opportunity to remedy that problem.

It is recommended that the VA made provision to allow next of kin or other appropriate representatives of such veterans to respond to the questionnaire and register on behalf of such deceased veterans.

[3] A review of surrogate data obtained by a news organization under the FOIA on persons enrolled in the VA system showed at least 4200 Iraq and Afghanistan veterans had died as of early 2011. Since about half of these veterans are not enrolled in the VA system, the number of deaths is likely to be much higher.

Conclusion

As indicated above, I think the questionnaire needs careful reconsideration and revision. I am pleased that the VA plans to have another round of public comment on a revised questionnaire that takes into account the comments on the first draft.

Respectfully submitted,

Peter Sullivan

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NOTE: The views expressed in these comments are mine personally and not necessarily those of The Sergeant Thomas Joseph Sullivan Center, with which I am associated.