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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

VIETNAM VETERANS OF AMERICA et al.,

No.: CV 09-0037-CW

Plaintiffs,

**DECLARATION OF
JOHN J. RESTA**

v.

CENTRAL INTELLIGENCE AGENCY, et
al.,

Defendants

Pursuant to 28 U.S.C. § 1746, I hereby declare as follows:

1. I am the Director, Army Public Health Center (APHC), U.S. Army Medical Command (MEDCOM), and the MEDCOM Field Operating Agency with responsibility for supporting the U. S. Army in relation to this litigation. I am familiar with this litigation based upon information received from my staff and legal advisors within MEDCOM as well as based on my review of the Army’s status reports submitted to the Court. I make this declaration to set forth the status of the Army’s efforts to comply with the Court’s injunction issued on November 19, 2013. ECF No. 545 (“Notice Injunction”). The Notice Injunction requires the Army to provide class members “with newly acquired information that may affect their well-being that it has learned since its original notification, now and in the future as it becomes available.” Notice Injunction at ¶ 1.
2. In accordance with the Notice Injunction, Army has executed contracts with third parties to search for “newly acquired information” that may affect the well-being of class members that could be then transmitted to the class members.

- 1 3. On 30 September 2014, the Army awarded a non-personal services contract to Blue
2 Earth Marketing Company, in accordance with federal procurement laws and
3 regulations, to perform an updated literature review to determine if new information
4 exists that would warrant notification to class members. The period of performance for
5 the contract was September 30, 2014 through September 29, 2015. Exhibit 1, Blue
6 Earth Performance Work Statement (“Blue Earth PWS”).
7
- 8 4. Blue Earth identified and evaluated information that could be relevant to the long-term
9 effects of exposure to the chemical and biological agents, drugs, medications, and
10 substances to determine if there was any significant impact on the potential long-term
11 health of test subjects who were exposed to these agents. Blue Earth then prepared a
12 report (“Blue Earth Report”) that summarized the findings and their significance
13 relative to the long-term health of the test participants. Exhibit 2, Blue Earth Report.
14
- 15 5. After reviewing the Blue Earth Report, an internal panel of MEDCOM subject matter
16 experts (“SMEs”) determined in April 2016 that the evidence gathered by Blue Earth
17 did not support reliable scientific conclusions regarding whether long-term health
18 effects could be associated with the exposure protocols used in the Army’s chemical
19 and biological research programs. In particular, the Blue Earth report did not provide
20 sufficient details regarding the subject or the manner of exposure in the cited studies
21 (e.g., human or animal subjects and relative dose/duration) nor did it provide an
22 assessment of the strength of the evidence. For example, the Blue Earth Report
23 identified organ systems potentially affected by exposure to substances without
24 addressing the significant differences between the cited exposure scenarios and the
25 specific testing protocols used in the relevant testing programs. In addition, the
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1 available scientific literature categorized in the report suffered from being both
2 overbroad by including test programs specifically excluded from this litigation (*i.e.*,
3 Shipboard Hazard and Defense and Project 112), and under-inclusive by failing to
4 address a large number of substances that were used in the testing programs (*i.e.*,
5 Dexedrine, tubocurarine, methylphenidate, and chlorpromazine).
6

7 6. From May to July 2016, MEDCOM considered options for addressing the deficiencies
8 in the Blue Earth Report. On August 3, 2016, MEDCOM decided to contract with the
9 National Academy of Sciences/Committee on Toxicology (“NAS/COT”) to review the
10 Blue Earth report and provide additional information regarding the potential long-term
11 health effects associated with participation in the Army’s chemical and biological agent
12 research programs.
13

14 7. Specifically, the Army requested NAS/COT provide its expert opinion on whether the
15 Blue Earth report contains any “newly acquired information” affecting class members’
16 well-being. Exhibit 3, W81K04-16-D-0036-0002 (NAS/COT SOW). Specifically,
17 MEDCOM tasked NAS/COT with reviewing the Blue Earth Report to determine
18 whether the report supported a conclusion that certain health conditions may be
19 proximately related to participation in the research programs. The Army also tasked
20 NAS/COT to characterize the strength of any association between agents and their
21 potential long-term health effects using a weight-of-evidence approach. Finally, Army
22 tasked NAS/COT to consider whether additional literature is available that would
23 suggest other potential long-term health effects.
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26 8. Upon completion of the NAS/COT review, MEDCOM will direct the U.S. Army
27 Medical Research Institute of Chemical Defense (“USAMRICD”), the U.S. Army
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1 Medical Research Institute for Infectious Diseases (“USAMRIID”), and the Army’s
2 Public Health Center to review the NAS/COT’s findings and recommendations. If there
3 is newly acquired information concerning potential health effects, MEDCOM will
4 develop an appropriate notice to disseminate this information to class members.
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6 9. The Army anticipates that the NAS/COT review of the Blue Earth Report will be
7 completed in early summer 2018 and it will take the Army 30 days to review the
8 NAS/COT findings and recommendations and determine whether newly acquired
9 information exists. If the Army determines that newly acquired information exists, the
10 Army will disseminate the information to affected class members within 120 days of
11 making this determination.
12

13 10. While the NAS/COT analysis of the Blue Earth literature search is ongoing, Army will
14 continue to search for more recent newly acquired information. The Army contracted
15 with the Oak Ridge National Laboratory (“ORNL”) for this purpose. Exhibit 4, SOW-
16 FY18-ORNL. Under the contract, ORNL will provide: (1) an overview of the available
17 literature related to long-term health effects associated with testing agents; (2) technical
18 support for estimating effects from the information concerning exposure; and (3)
19 technical support for evaluating potential long-term effects as a result of short-term
20 exposures to various agents.
21

22 11. ORNL will assist the Army Public Health Center (“APHC”) in searching available
23 literature for data pertaining to the health effects of exposures to specific agents of
24 concern. The proposed effort includes:
25

- 26 • Identification of dose-response relationship for toxicological effects and health
27 outcomes.
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- Identification of data gaps and associated uncertainty on exposure-response health outcome analyses.
- Performance of weight-of-evidence evaluations for relating exposure to health outcomes.

12. The Army anticipates that ORNL will complete its review by September 30, 2018.

Once ORNL completes its search and provides its report, MEDCOM will direct USAMRICD, USAMRIID, and the Army's Public Health Center to review ORNL's findings and recommendations and determine whether there is newly acquired information that potentially affects class members' well-being. It will take the Army 30 days to review the ORNL findings and recommendations and make a determination of whether newly acquired information exists. If there is newly acquired information concerning potential health effects, within 120 days of making this determination, MEDCOM will disseminate an appropriate notice to the affected class members.

I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on March 22, 2018.



JOHN J. RESTA