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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

VIETNAM VETERANS OF AMERICA, et al.,

Plaintiffs,

v.

CENTRAL INTELLIGENCE AGENCY, et al.,

Defendants.

Case No. CV 09-0037-CW

UPDATE TO DEPARTMENT OF THE ARMY REPORT PURSUANT TO THE COURT'S NOVEMBER 19, 2013 INJUNCTION

Pursuant to the Court's November 19, 2013 injunction, *see* Notice Injunction, ECF No. 545, the Department of the Army provides the following status report.

BACKGROUND

On November 19, 2013, the Court entered an injunction requiring Defendant Department of the Army to provide the members of the class "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 ¶ 1. As required by the Notice Injunction, the Army submitted an initial status report on March 6, 2014, *see* ECF No. 561, and a revised report on April 16, 2014, ECF No. 563, detailing Army's compliance efforts and a multi-step plan for periodically collecting "Newly Acquired Information" as defined in the Notice Injunction. At the time, the Army advised the Court that it was in the process of determining whether the search for such information—specifically, a literature search and health-effects assessment—could be executed in-house or through a contracted third party. *See* Revised Report, ECF No. 563, at 6.

On November 4, 2014, the Army filed another status report confirming that the Army Medical Command ("MEDCOM") concluded that "the scope and nature of the project favored the use of a third-party contract for these services." Third Status Report, ECF No. 566, at 1. After going through a multi-step contracting process, Army selected Blue Earth Marketing Company as the contractor tasked with this project. *Id.* at 2. Army's status report explained in detail the "nature of the contract, the work to be performed, and the deadlines contained in that contract." *Id.* at 2.

The Army hereby submits this further status report to provide an update on its efforts to comply with the Court's Notice Injunction—specifically, the results of the work performed by

the Blue Earth Marketing Company, deficiencies identified in the contractor's report, and Army's efforts to address those deficiencies to the benefit of the class members.

DISCUSSION

I. ARMY'S EFFORTS TO LOCATE NEWLY ACQUIRED INFORMATION THAT MAY AFFECT THE WELL-BEING OF TEST SUBJECTS.

In accordance with the Notice Injunction, the Army has executed contracts with third parties to search for "newly acquired information" that may affect the well-being of class members. Those contracts and related efforts are described below.

A. Blue Earth Contract for Literature Review (2014-16)

On September 30, 2014, the Army awarded a non-personal services contract to Blue Earth Marketing Company, in accordance with federal procurement laws and regulations, to perform an updated literature review to determine if new information exists that would warrant notification to class members. The period of performance for the contract was September 30, 2014 through September 29, 2015. *See* Declaration of John J. Resta ¶ 3, attached hereto as Exhibit A. As explained in an earlier status report, an Army Contracting Officer Representative ("COR") was assigned to monitor Blue Earth's work to ensure quality control in the contractor's literature searches and analysis of scientific and medical studies published between June 30, 2006 and December 1, 2015. *See* Third Status Report at 2 (describing qualifications and experience of the COR tasked with overseeing Blue Earth's performance).

Blue Earth identified and evaluated information to determine if there was any significant impact on the potential long-term health of test subjects who were exposed to the chemical and biological agents, drugs, medications, and substances used in the Army's testing programs encompassed by the Court's Notice Injunction. *See* Resta Decl. ¶ 4; Notice Injunction ¶ 1. Blue

Earth then prepared a report ("Blue Earth Report") that summarized the findings and their significance relative to the long-term health of the test participants. Resta Decl. ¶ 4 (attaching Blue Earth Report as Exhibit 2).

The Blue Earth Report first laid the background for its findings, noting that "several reviews of the health status of volunteers in these exposure experiments have been done [in] the years following the original studies and have found no conclusive evidence that receipt of investigational agents or substances was related to adverse health outcome." Blue Earth Report at 4. The same conclusion was reached in "follow-up studies," which could not point to any "consistent, clinically-significant groups of symptoms in those exposed." *Id.* In light of this background, Blue Earth conducted "[l]iterature searches and analyses of scientific and medical studies published between June 30, 2006 and December 1, 2015" to determine whether there was any new "information concerning the potential long-term health effects of the volunteer human exposures." *Id.*

The report found that "of the more than 100 agents and compounds researched for this study, 18 had evidence for potential long-term sequelae associated with exposure." *Id.* at 5. Blue Earth identified "16 different types of sequelae that ranged from neurological disorders to carcinomas," with neurological sequelae being the most common (occurring in 7 of the 18 compounds), with the next "types of sequelae [being] cognitive, cardiac, and cutaneous[,] which were each noted in 5 compounds." *Id.* The Blue Earth Report also examined the different types of sequelae by compound or substance. *See id.*

Notwithstanding these findings, Blue Earth identified important limitations concerning the results of the report. For example, the report noted that "evidence found in the literature for potential long-term health effects or sequelae does not necessarily mean that these symptoms

have occurred or will occur in subjects from the military testing programs. Evidence for potential sequelae only means that these conditions *could* occur in the soldiers who participated in the tests." *Id.* (emphasis in original). The report added:

> Although evidence for long-term sequelae associated with exposure to some agents and substances was found in the recent scientific literature, it is important to note that:
>
> - Volunteer exposures were low relative to many of the sequelae-inducing doses in the recent literature;
> - Volunteer exposures were single dose or short term, whereas many of the sequelae reported in the recent literature arose after long-term or chronic exposures;
> - Tests were terminated immediately if the volunteers experienced moderate-to-severe discomfort; and
> - The health impact of volunteers was assessed at several different time periods in the years following their exposures, and no significant sequelae were recorded in any of the follow-up health screenings.
>
> Furthermore, some of the information presented in this report about associated sequelae comes from animal studies. This information is informative, but should not be taken as indicative of sequelae associated with human exposure to these compounds. Rather the animal experiments should be regarded as, 'proof of concept,' of sequelae that might arise in humans after exposure, or as supportive of human epidemiological and medical data, if available.

Id. at 5-6.

An internal panel of MEDCOM subject-matter experts ("SMEs"), convened pursuant to a Quality Assurance Surveillance Plan, *see* Third Status Report at 2, evaluated Blue Earth's final report from February to April 2016. In April 2016, these SMEs determined that the evidence gathered by Blue Earth did not support reliable scientific conclusions regarding whether long-term health effects could be associated with the exposure protocols used in the Army's chemical and biological research programs. *See* Resta Decl. ¶ 5. In particular, the SMEs determined that the Blue Earth report did not provide sufficient details regarding the subject or the manner of

exposure in the cited studies (*e.g.*, human or animal subjects and relative dose/duration), nor did it provide an assessment of the strength of the evidence. For example, the Blue Earth Report identified organ systems potentially affected by exposure to substances without addressing the significant differences between the cited exposure scenarios and the specific testing protocols used in the relevant testing programs. *Id.* In addition, the SMEs determined that the available scientific literature categorized in the report suffered from being both overbroad by including test programs specifically excluded from this litigation (*i.e.*, Shipboard Hazard and Defense and Project 112), and under-inclusive by failing to address a large number of substances that were used in the testing programs (*i.e.*, dexedrine, tubocurarine, methylphenidate, and chlorpromazine). *Id.*

B. National Academy of Sciences/Committee on Toxicology Review (2017-Present)

From May to July 2016, MEDCOM considered options for addressing the deficiencies in the Blue Earth Report. *See* Resta Decl. ¶ 6. On August 3, 2016, MEDCOM decided to contract with the National Academy of Sciences/Committee on Toxicology ("NAS/COT") to review the Blue Earth Report and provide additional information regarding the potential long-term health effects resulting from exposure to a substance associated with participation in the Army's chemical and biological agent research programs. *Id.*[1]

[1] Federal law requires the NAS to investigate, examine, experiment and report upon any subject of science whenever called upon by any department of the U.S. Government. *See* 36 U.S.C. § 150303. The primary resources for addressing the relevant needs of the Department of Defense are the National Research Council Committee on Toxicology, its professional staff, and the staff and collection of the Toxicology Information Center. The Army has been responsible since 1982 for contracting toxicology services with the NAS on behalf of the Department of Defense.

The Army has requested that NAS/COT provide its expert opinion on whether the Blue Earth report contains any "newly acquired information" affecting the class members' well-being. Resta Decl. ¶ 7. Specifically, MEDCOM tasked NAS/COT with reviewing the Blue Earth Report to determine whether the report supported a conclusion that certain health conditions may be proximately related to participation in the research programs. *Id.* The Army also tasked NAS/COT to characterize the strength of any association between agents and their potential long-term health effects using a weight-of-evidence approach.

Upon completion of the NAS/COT review, MEDCOM will direct the U.S. Army Medical Research Institute of Chemical Defense ("USAMRICD"), the U.S. Army Medical Research Institute for Infectious Diseases ("USAMRIID"), and the Army's Public Health Center to review the NAS/COT findings and recommendations. Resta Decl. ¶ 8. If there is newly acquired information concerning potential health effects, MEDCOM will develop an appropriate notice to disseminate such information. *Id.*

The Army anticipates that the NAS/COT review of the Blue Earth report will be completed in early summer 2018, and it will take the Army 30 days to review the NAS/COT findings and recommendations and make a determination of whether newly acquired information exists. Resta Decl. ¶ 9. If the Army determines that newly acquired information exists, the Army will disseminate the information to affected class members within 120 days of making this determination. *Id.*

C. Oak Ridge National Laboratory Review (2018-Present)

While the NAS/COT analysis of the Blue Earth literature search is ongoing, Army will continue to search for more recent newly acquired information. Resta Decl. ¶ 10. The Army has contracted with the Oak Ridge National Laboratory ("ORNL") to provide: (1) an overview of the

available literature related to long-term health effects associated with testing agents; (2) technical support for estimating effects from the information concerning exposure; and (3) technical support for evaluating potential long-term effects as a result of short-term exposures to various agents. *Id.* ORNL will assist the Army Public Health Center ("APHC") in searching available literature for data pertaining to the health effects of exposures to specific agents of concern. Resta Decl. ¶ 11. The proposed effort includes:

- Identification of dose-response relationship for toxicological effects and health outcomes.
- 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.

Id.

The Army anticipates that ORNL will complete its review by September 30, 2018. *See* Resta Decl. ¶ 12. Once ORNL completes its search, MEDCOM will direct USAMRICD, USAMRIID, and the Army's Public Health Center to review ORNL's findings and recommendations. Resta Decl. ¶ 12. If there is newly acquired information concerning potential health effects, MEDCOM will develop an appropriate notice to disseminate such information. It will take the Army 30 days to review the ORNL findings and recommendations and make a determination of whether newly acquired information exists. *Id.* ¶ 10. If the Army determines that newly acquired information exists concerning potential health effects, MEDCOM will disseminate the information to affected class members within 120 days of making that determination.

Dated: March 22, 2018

Respectfully submitted,

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