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The Special Counsel

June 9, 2016

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-13-3318

Dear Mr. President:

Pursuant to my duties as Special Counsel, I am transmitting a Department of Health and Human Services (HHS) report based on disclosures of wrongdoing regarding the implementation and management of the National Institutes of Health (NIH), National Institute on Aging (NIA), Baltimore Longitudinal Study on Aging (BLSA). I received these allegations from Dr. Nazli McDonnell, a former staff clinician in the NIA Clinical Unit, who consented to the release of her name. I have reviewed the report and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the agency investigation and my findings.[1]

Dr. McDonnell alleged that NIA research staff violated NIH standard operating procedures (SOPs) and failed to follow good clinical practices in the administration of the BLSA. Specifically, she alleged that BLSA participants were not timely informed of abnormal medical test results and that the notification participants did receive was inadequate because it did not include information that the BLSA protocol required, such as an explanation of the medical test results. The investigation did not substantiate any violation of law, rule, or regulation, or find that there was a substantial and specific danger to public health or safety, but it did conclude that some corrective actions were warranted.

I referred the allegations to then-Secretary Kathleen Sebelius for investigation pursuant to 5 U.S.C. § 1213 (c) and (d). Secretary Sebelius delegated the authority to

[1]The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c). Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

review and sign the report to Dr. Michael M. Gottesman, NIH deputy director for Intramural Research. The NIH review team (review team), comprised of the Office of Human Subjects Research Protections and the Office of Management Assessments, investigated the allegations and Dr. Gottesman submitted the report the Office of Special Counsel in October 2014. Dr. McDonnell did not comment on the report.

BLSA is a longstanding study that gathers data to address questions on aging and the factors that contribute to healthy aging. Study participants undergo testing for research, not for clinical purposes, and receive information on the study design, their participation, the evaluations of tests that are part of the study, as well as the potential risks associated with those tests. The BLSA protocol includes the formal description and design of the study and requires that participants execute an informed consent form at each visit. The tests and evaluations set forth in the protocol are conducted during a three-day visit at the NIA Clinical Research Unit. The BLSA study visit includes a review of participants' medical history, a physical examination, as well as completion of tests and questionnaires to gather research data. Follow-up visits are scheduled at intervals of one to four years in accordance with the protocol.

The report explains in detail the role of NIA/BLSA staff and presents a series of tables that describe the criteria, methodology, summary of evidence, and conclusion regarding the allegations referred by OSC as well as the additional allegations Dr. McDonnell raised in her interview. The investigation found that NIA/BLSA staff reported advising patients verbally of medical test results, particularly those requiring immediate attention, and entering this information in each participant's medical records, but that these communications with study participants were frequently not documented. An audit of medical records found that the first documented notification of abnormal test results was frequently a letter dated weeks after the visit. The report notes that the protocol requires that participants be informed to follow-up with their primary care physicians. The audit of the letters sent to study participants concluded that this correspondence met the requirement of the protocol because it advised study participants to follow-up with their primary care physician on the abnormal test results. The report notes that the BLSA protocol requires that staff mail test results to participants "shortly" after the visit. BLSA leadership indicated that their goal is to mail the results within four weeks of the participant visit; however, this goal was frequently not met.

In response to the investigative findings, NIA took numerous corrective actions, including NIA training on the regulations and policies that protect human subjects in research and mailing participant packages that include the final test results within three-to-four weeks after each participant's visit. In addition, the NIA clinical director instructed BLSA research staff to increase documentation of the discussion and reporting of test results with participants. Discussions on preliminary lab results are now documented with a stamp signed by both the nurse practitioner and the participant acknowledging that the lab results were provided and discussed. BLSA staff also received training on the appropriate way to correct written documents.

Following discussions with the NIH review team on the investigation, NIA also developed and implemented a policy on participant medical charts, and created an electronic BLSA visit summary form that standardizes the format for key findings as well as tests completed and not completed. The visit summary form will be included in the study participants' charts. NIA also developed and implemented a policy for the classification and return of test results. Because some test results may suggest the need for follow-up with the participant's primary care physician, NIA will classify the research results into the following three groups—immediate alert, clinically significant, and courtesy—with communication requirements commensurate for each level of urgency.

NIA will revise the language in the BLSA protocol and informed consent form to reflect these changes and current practices. The agency also proposed amendments to the informed consent form that highlight that participants will be notified if the medical staff determines that the research test results show new or clinically significant findings. Finally, Dr. Gottesman will monitor the corrective actions and obtain annual progress reports from NIA.

The Special Counsel's Findings and Conclusions

I have reviewed the original disclosure and the agency report. Based on that review, I have determined that the report contains all of the information required by statute and that the findings appear reasonable. While the allegations were not substantiated, the agency has taken significant steps to improve its processes related to the administration of the BLSA.

As required by 5 U.S.C. § 1213(e)(3), I have sent a copy of this letter and the agency report to the Chairmen and Ranking Member of the Senate Committee on Health, Education, Labor and Pensions, and to the Chairman and Ranking Member of the House Committee on Energy and Commerce. I have also filed a copy of this letter and the agency report and in OSC's public file, which is available at www.osc.gov. This matter is now closed.

Respectfully,

Carolyn Lerner

Carolyn N. Lerner

Enclosures