U.S. OFFICE OF SPECIAL COUNSEL
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October 29, 2009

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

Re: OSC File No. DI-08-2680

Dear Mr. President:

The Office of Special Counsel (OSC) received a disclosure from a former employee at the Department of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), Bethesda, Maryland. The whistleblower, Arnaldo Quinones, M.D., a former Medical Officer at NIAID, alleged that a drug study's April 12, 2005, Quarterly Safety Report did not include all known Serious Adverse Events (SAEs) and that serious unexpected adverse events possibly associated with the drug were not reported to the U.S. Food and Drug Administration (FDA) within 15 days of discovery as required by federal regulation. Dr. Quinones also alleged that some participants did not provide informed consent for their participation.

On January 29, 2009, OSC referred the whistleblower's allegations to the Honorable Michael O. Leavitt, former Secretary of Health and Human Services, to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). The Honorable Kathleen Sebelius, Secretary of Health and Human Services, submitted the agency's report on September 2, 2009. Secretary Sebelius delegated the authority to approve the investigation to Leslie K. Ball, M.D., Division Director, Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA. OSC forwarded the report to Dr. Quinones, pursuant to 5 U.S.C. § 1213(e)(1), on September 9, 2009. However, he did not respond to our multiple requests for comments.

The agency's report did not substantiate Dr. Quinones' allegations. The investigators reviewed archived documentation provided by NIAID. The report described one participant's eligibility for the drug study as a "judgment call" with "confounding" factors that did not allow a clear determination to be made. The investigators were unable to substantiate the existence of factors that would have excluded participants from the study. The adverse event that Dr. Quinones believed to be serious and unexpected was determined to be consistent with the drug's labeling. Consequently, it was not required to be reported in an expedited timeframe. In some cases, consent to participate in the study was received from family members. The investigators' review of the relevant notes indicated that the risks and benefits of participation in the study were discussed before obtaining informed consent from participants' family members.

OSC has reviewed the original disclosure and the agency's report. Based on that review, OSC has determined that the agency's report contains all of the information required by statute and the findings of the agency head appear reasonable.

As required by law, 5 U.S.C. § 1213(e)(3), OSC has sent a copy of the report to the Chairmen and Ranking Members of the Senate Committee on Health, Education, Labor, & Pensions and the House Committee on Energy and Commerce. OSC has also filed a redacted copy of the agency's report in our public file and closed the matter. OSC's public file is now available online at www.osc.gov.

Respectfully,

William E. Reukauf
Associate Special Counsel

Enclosure