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The Special Counsel

June 5, 2014

The President
The White House
Washington, D.C. 20510

Re: OSC File No. DI-12-1098

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find agency reports based on disclosures made by a whistleblower at the Department of Veterans Affairs (VA), VA Boston Healthcare System (VABHS), Department of Dermatology, Boston, Massachusetts. The whistleblower, Ms. Carolyn Bogal, a former nurse practitioner in the Department of Dermatology, alleged that employees engaged in conduct that constituted a violation of law, rule, or regulation and a substantial and specific danger to public health by manipulating the research process and falsifying the data recorded in a VA skin cancer prevention clinical trial. Ms. Bogal consented to the release of her name.

The agency investigation found that Dr. Nellie Konnikov, chief of dermatology, engaged in research impropriety by failing to comply with VA rules set forth in VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research*. Among corrective actions taken, the VABHS chief of medicine verbally counseled Dr. Konnikov and the research compliance officer (RCO) monitored and audited all research involving Dr. Konnikov for a period of six months. In addition, VABHS presented live training regarding regulatory requirements associated with the conduct of drug studies and clinical trials to all investigative staff. The agency investigation did not substantiate the allegation that Dr. Konnikov engaged in research misconduct or that her actions resulted in a substantial and specific danger to public health. I have determined that the agency reports contain all of the information required by statute and that the findings appear to be reasonable.

On April 4, 2012, OSC referred Ms. Bogal's allegations to then-Secretary of Veterans Affairs Eric Shinseki to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d).[1] Secretary Shinseki asked the Under Secretary for Health to conduct the

[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

investigation, who in turn requested the assistance of the Office of Research Oversight. On August 9, 2012, Secretary Shinseki submitted the agency's report to OSC. In response to OSC's request for additional information, the agency submitted supplemental reports on October 5, 2012, December 21, 2012, and May 31, 2013. Pursuant to 5 U.S.C. § 1213(e)(1), Ms. Bogal submitted comments on the agency's reports on November 14, 2012, February 14, 2013, and June 19, 2013. As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the reports and the whistleblower's comments to you.

The Whistleblower's Allegations

Ms. Bogal was employed as a nurse practitioner in the Department of Dermatology from 2004 to 2011, during which time Dr. Konnikov was her direct supervisor. Beginning in 2009, both Dr. Konnikov and Ms. Bogal were involved in CSP #562 – The VA Keratinocyte Carcinoma Chemoprevention Trial (the clinical trial), a study to determine whether 5-fluorouracil skin cream can be used to prevent the growth of new skin cancers on the face and ears. Dr. Konnikov was involved as a lead investigator and Ms. Bogal as a sub-investigator.

Ms. Bogal disclosed that from the onset of the clinical trial in 2009 through 2010, Dr. Konnikov improperly instructed her to conduct initial skin examinations on individuals seeking to be participants. Ms. Bogal indicated that she examined between 10 and 15 individuals, all of whom were admitted into the clinical trial and randomized. According to Ms. Bogal, the study protocol indicated that the lead investigator was to conduct all initial and follow-up skin examinations of study participants, but Ms. Bogal was not eligible to be the lead investigator because the study protocol required lead investigators to be board-certified dermatologists. In addition, Ms. Bogal disclosed that Dr. Konnikov falsely recorded data in the study to reflect that she, rather than Ms. Bogal, conducted these initial skin examinations.

In Veterans Health Administration (VHA) Handbook 1058.2, research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results," and falsification includes "manipulating research…processes, or changing or omitting data…such that the

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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) and (g).

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).

research is not accurately represented in the research record." VHA Handbook 1058.2, *Research Misconduct,* § 3.a. According to Ms. Bogal, by instructing her to perform initial skin examinations in the clinical trial and falsely recording data regarding these examinations, Dr. Konnikov engaged in research misconduct as described in VHA Handbook 1058.2.

The Agency Reports

The Office of Research Oversight (ORO) did not substantiate the allegations that Dr. Konnikov engaged in research misconduct or that her actions could lead to improper FDA- approval of the study drug. On April 16, 2012, ORO made a threshold determination that Ms. Bogal's allegations did not fall within the federal and VA policy definition of research misconduct. In reaching this determination, ORO stated that in order to constitute research misconduct under VHA Handbook 1058.2, the falsification alleged must result in the inaccurate representation of the "*data or results* that embody the facts *resulting from scientific inquiry.*" ORO explained, "[f]alsification of *who* conducted the procedure by itself would not necessarily result in an inaccurate representation of the "research record." Thus, ORO determined that because Ms. Bogal did not allege that the results of her examinations were inaccurately represented in the research record, the allegations did not meet the threshold for opening a research misconduct inquiry. Instead, ORO investigated the allegations as possible research impropriety as defined in VHA Handbook 1058 § 6.g.

ORO was unable to substantiate Ms. Bogal's specific allegations that Dr. Konnikov instructed her to conduct initial skin examinations on individuals seeking to be participants the clinical trial or that Dr. Konnikov falsely recorded data in the research record to reflect that she, rather than Ms. Bogal, conducted the initial skin examinations. Dr. Konnikov and Mark Zacheis, R.N., the study coordinator, both denied Ms. Bogal's allegations in their interviews with ORO. Further, although ORO found that at least three case records originally reflected that Ms. Bogal conducted the initial skin exam in violation of the approved protocol, and that those case records were subsequently amended on March 16, 2010, to reflect that Dr. Konnikov conducted the exam, ORO could not establish by a preponderance of the evidence that Dr. Konnikov engaged in intentional falsification of the data.

However, ORO substantiated the allegation that Dr. Konnikov engaged in activity that violated a law, rule, or regulation in failing to comply with VA rules set forth in VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research*, and thus, engaged in research impropriety. Specifically, ORO found that Dr. Konnikov did not oversee research staff sufficiently to ensure the clinical trial was implemented in accordance with the approved protocol. For example, she did not ensure the initial skin examination was documented prior to the enrollment of an individual in the clinical trial; she did not ensure adherence to the "un-blinding" procedures set forth in

the protocol; and she did not ensure that the study drug was prescribed only by an authorized provider. In addition, ORO found that Dr. Konnikov failed to identify and report the protocol deviations identified above, as required by VHA Handbook 1200.05 § 9.q.

In response to its findings, ORO required the VABHS to: (1) ensure that all research involving Dr. Konnikov and Mr. Zacheis adheres to Institutional Review Board (IRB)-approved protocol and complies with VA research requirements by implementing a monitoring plan; (2) ensure that all research studies are conducted in accordance with IRB-approved protocols and all relevant federal regulations and VHA policies; (3) ensure that pharmacy personnel dispense study medications only when prescribed by authorized prescribers; and (4) determine whether any disciplinary action is warranted in light of ORO's findings.

As noted, in response to OSC's request for additional information on the corrective actions taken, the agency provided supplemental reports on October 5, 2012, December 21, 2012, and May 31, 2013. The supplemental reports confirm that the VABHS took immediate action to audit each study involving Dr. Konnikov for a period of six months beginning the week of October 15, 2012. The audit has been completed and there were no reportable findings of non-compliance. In addition, VABHS began auditing Dr. Konnikov's reports of "Unanticipated Problems Involving Risks to Subjects and Others" and "Adverse Events" quarterly rather than annually, as was the past practice. Further, Dr. Konnikov was instructed to establish permanent weekly lab meetings with research personnel under her supervision and provide minutes of those meetings for a period of six months for review. The research pharmacist was required to submit monthly drug accountability reports, subject to bimonthly audits, verifying that only authorized prescribers had dispensed study medications. The reviews of meeting minutes and drug accountability reports did not reveal information suggesting that Dr. Konnikov or the research pharmacist were out of compliance with regulations. VABHS also presented live training regarding regulatory requirements associated with the conduct of drug studies and clinical trials to investigative staff on February 14, 2013, and March 18, 2013.

As this was Dr. Konnikov's first incident of wrongdoing, the VABHS chief of medicine determined counseling was the appropriate disciplinary response, and reviewed the findings of the ORO report and discussed the seriousness of the identified deficiencies with her. VABHS indicated that Dr. Konnikov has changed her research practices to prevent any future occurrences.

The Whistleblower's Comments

Ms. Bogal commented on the reports pursuant to § 1213(e)(1). In her comments, Ms. Bogal reiterated her assertions that Dr. Konnikov instructed her to conduct initial skin examinations on individuals seeking to be participants the clinical trial and that Dr.

Konnikov knowingly falsified the research records. She questioned ORO's inability to substantiate these allegations, stating that the numerous inconsistencies ORO identified in the research record call into question the credibility of Dr. Konnikov's claim that she conducted all of the initial skin examinations herself. Ms. Bogal also expressed dissatisfaction with the decision to limit the disciplinary action taken against Dr. Konnikov to a verbal counseling and questions whether the VABHS should have reported her actions to the state licensing board.

The Special Counsel's Findings

I have reviewed the original disclosure, the agency reports, and the whistleblower's comments. Based on that review, I have determined that the reports contain all of the information required by statute and that the findings appear to be reasonable.

As required by 5 U.S.C. § 1213(e)(3), I have sent copies of the unredacted agency reports and the whistleblower's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed copies of the redacted agency reports and whistleblower's comments in OSC's public file, which is available online at www.osc.gov.[2] This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosures

[2] The VA provided OSC with reports containing employee names (enclosed), and redacted reports in which employees' names were removed. The VA has cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the reports produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the reports in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version of the reports as an accommodation.