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Washington, D.C. 20036-4505

The Special Counsel

March 31, 2021

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

Re: OSC File No. DI-19-0931

Dear Mr. President:

I am forwarding a report transmitted to the Office of Special Counsel (OSC) by the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), in response to disclosures of wrongdoing at FDA's Team Biologics, Rockville, Maryland. The whistleblower, [redacted], a former FDA consumer safety officer, who consented to the release of his name, made several allegations concerning improprieties in FDA compliance inspections of pharmaceutical manufacturing facilities. Specifically, [redacted] alleged that Team Biologics management officials improperly downgraded several inspection conclusion reports without filing reclassification memoranda, as required in FDA's Regulatory Procedures Manual, and that the FDA did not follow proper procedures regulating the investigation of information provided by a Confidential Informant (CI). [redacted] asserted that these alleged deficiencies resulted in diminished compliance and could have placed public health at risk. I have reviewed the disclosure and the agency report, and in accordance with 5 U.S.C. §1213(e) provide the following summary of the agency investigation and my findings.[1] [redacted] provided comments to the report, which are summarized below.

Team Biologics is responsible for inspections of facilities that manufacture vaccine and blood products, to ensure that they are following established good manufacturing practices (GMPs). When Team Biologics inspects facilities, inspectors can recommend three different outcomes based on investigatory findings, which are articulated in inspection conclusion reports. A determination of No Action Indicated demonstrates that the facility is meeting GMPs. A finding of Voluntary Action Indicated (VAI) indicates that the facility should make non-urgent corrections to manufacturing processes. Finally, Official Action Indicated (OAI) suggests that the FDA is likely to restrict the plant's manufacturing and requires immediate corrective actions

[1]The allegations were referred to former Secretary Alex M. Azar II. FDA's Office of Regulatory Affairs was tasked with investigating the matter pursuant to 5 U.S.C. §1213(c) and (d). Former Secretary Azar delegated the authority to review and sign the report to Glenda F. Barfell, Director, Office of Management, Office of Regulatory Affairs.

to achieve compliance. If a plant still falls short, the FDA can issue a warning letter, or in less serious cases, a document known as an Untitled Letter that provides facilities with the opportunity to resolve issues before enforcement actions are taken.

Specifically, [redacted] alleged that the inspection conclusion report for the 2017 National Genetics Institute inspection was designated as OAI and subsequently reclassified as VAI without a required reclassification memorandum. Similarly, [redacted] asserted that the inspection conclusion report for the 2018 Baxalta US, Inc. inspection determined that the case should be considered OAI, with a recommended Untitled Letter, which would serve to notify the company of possible violations. He asserted that this finding was later downgraded to VAI without a reclassification memorandum. [redacted] also alleged that the inspection conclusion report for the 2018 CSL Behrin GmBH inspection was entered as OAI and subsequently downgraded to VAI without a reclassification memorandum.

Finally, [redacted] asserted that during the 2018 inspection of Merck Sharp and Dohme, he discovered that the company was intentionally destroying evidence of possible violations, which he asserted was confirmed by a CI. These possible violations included the improper presence of a biohazard bin used to collect employee uniforms soiled with urine and feces. The CI indicated that employees were soiling their uniforms rather than taking bathroom breaks which would have required them to disrobe and leave manufacturing areas. Similarly, employees were accused of moving between cleanrooms and uncontrolled rooms without gowning changes. [redacted] also asserted that FDA procedures for responding to the receipt of such information were not followed.

The agency report did not substantiate these allegations. The report noted that, during the time covered by the allegations, neither the agency's Regulatory Procedures Manual nor any other FDA policy required the issuance of a reclassification memorandum when FDA management chose to downgrade inspection findings. As such, in the case of the National Genetics Institute inspection, no reclassification memorandum was required, and the Compliance Officer/Acting Director of FDA's Compliance Branch reviewed the case and determined that VAI was appropriate. This revision was within the scope of this official's legal authority and discretion.

In the case of the Baxalta US, Inc. inspection, the inspection classification was modified by the Team Biologics Manager with the concurrence of compliance officials. While no memorandum explaining this decision was required under agency policy, a "Memo to File" was included in the administrative file explaining why the findings were modified. With respect to CSL Behrin GmBH, OAI findings were downgraded to VAI upon the review of FDA's Center for Biologics Evaluation and Research Consumer Safety Officer, with an accompanying memorandum explaining that this decision was appropriate in light of corrective actions taken by the company at issue. With respect to allegations concerning the Merck Sharp and Dohme inspection and the associated CI, the report noted appropriate agency procedures were followed during the course of the inspection. Notably, the agency provided support from FDA's Office of Regulatory Affairs, in the form of an action plan, to direct the inspection to critical areas of

review, and gather evidence to substantiate the informant's complaint. The report noted that ultimately, the informant's allegations could not be corroborated.

In comments to the report, [redacted] strongly objected to the FDA's conclusions, asserting that the agency focused narrowly on procedural issues and failed in its mission to protect public health. He noted that while reclassification memos may not have been required, the reclassification of the inspections at issue occurred after significant time had elapsed. With respect to the National Genetics Institute, Baxalta, and CSL Behrin GmBH inspections, he noted that he discovered significant issues at these facilities, and that in downgrading the inspection reports, the FDA was disregarding both significant potential safety issues and its public health mandate.

[redacted] took significant issue with the agency's findings concerning Merck Sharp and Dohme. Specifically, he explained that despite multiple formal requests for additional inspection resources, he was instructed to inspect the 850,000 square foot facility by himself in under a week. He provided information indicating that the inspection of similar facilities typically involved four investigators and 21 inspectional days. Further, he explained that while the FDA was contacted by the CI via letter in September 2018, over a month before the inspection was conducted, he was not provided with the letter or aware of the CI until he had initiated his inspection in late October. He explained that once he was notified of the CI's existence and assertions, FDA management increased the scope of complexity of the inspection without providing [redacted] with additional resources or time to complete it. Most concerningly, he provided information indicating that the FDA's assertions regarding his inability to corroborate the CI's allegations were not true. In fact, [redacted] substantiated the presence of a biohazard bin where uniforms soiled with urine, feces, and blood were disposed of. He also determined that personnel were moving between cleanrooms and uncontrolled areas without properly ungowning. Further, there was an absence of required environmental monitoring documentation in firm records. [redacted] summarized his position by emphasizing that the FDA's demonstrated unwillingness to hold firms accountable for significant safety issues could dramatically compromise public health.

I am troubled by many aspects of this matter. I concur with [redacted] in his assertion that the agency narrowly focuses on procedural issues, and in so doing, disregards the fact that inspection reports detailing serious concerns were downgraded in a manner that may compromise compliance and safety efforts. While these downgrades appear within the authority of agency management, questions remain about their suitability. I am most concerned by the agency's conduct involving the 2018 Merck Sharp and Dohme inspection. [redacted] was not afforded sufficient resources to appropriately conduct this review, in a break with prior practice, and particularly in light of the CI's disclosures. These disclosures were also made well in advance of his inspection, and the agency's failure to timely inform him of their existence potentially compromised his planning and execution of the inspection. Additionally, [redacted] determined that the CI had written a prior letter to the FDA concerning the same issues, and that this prior letter was also not given to the FDA inspection team. Finally, it appears that [redacted] substantiated serious misconduct in the Merck Sharp and Dohme facility, which the agency seems to deny.

I have reviewed the original disclosure, agency report, and [redacted] comments. Based on this review, I have found that the report meets all the statutory requirements but that the findings do not appear reasonable. I urge the agency to closely examine compliance matters like these where inspectors identified serious compliance concerns, but where the agency reclassified their findings after significant time had elapsed.

As required by 5 U.S.C. § 1213(e) (3), I have sent a copy of this letter and the agency report to the Chairs and Ranking Members of the Senate Committee on Health, Education, Labor and Pensions, and the House Committee on Energy and Commerce. I have also filed redacted copies of these documents and the redacted referral letter in our public file, which is available at www.osc.gov. This matter is now closed.

Respectfully,

Henry J. Kerner
Special Counsel

Enclosures