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The Special Counsel

December 15, 2022

The President
The White House
Washington, DC 20500

Subject: OSC File Nos. DI-20-0372

Dear Mr. President:

I am forwarding to you a report transmitted to the Office of Special Counsel (OSC) in response to the Special Counsel's referral of disclosures of wrongdoing at the U.S. Department of Health and Human Services, U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP) Office of Science (OS) Division of Nonclinical Science (DNCS).¹ The whistleblower, [REDACTED] consented to the release of [REDACTED] name. I have reviewed the agency report and whistleblower comments and, pursuant to 5 U.S.C. § 1213(e), have determined that the report contains the information required by statute and that its findings appear reasonable.

The whistleblower alleged that CTP—to speed up reviews of e-cigarette premarket authorization applications—had relaxed its standards of review potentially allowing more harmful tobacco products to enter the market. Specifically, the whistleblower cited a February 21, 2019 memorandum [HPHC Memo]³ that CTP's DNCS issued to its scientists revising the process for evaluating substantial equivalence (SE) tobacco applications—i.e., the process of measuring and comparing the harmful and potentially harmful ingredients, or constituents, in a proposed tobacco product to determine if that product poses more health risks than other tobacco products already on market.⁴ The HPHC Memo, according to the whistleblower, directed scientists to stop using objective, quantitative data (the full quantitative risk assessment or "QRA") to evaluate applications and to instead use a more subjective ("qualitative or semi-qualitative") approach which, according to the whistleblower, was more akin to "eyeballing it"

¹ See 5 U.S.C. § 1213(c) and (e). The Special Counsel referred the whistleblower's allegations to former Secretary Alex M. Azar II to investigate pursuant to 5 U.S.C. § 1213(c) and (d). Former Secretary Azar directed FDA to investigate. Former Secretary Azar reviewed and signed the report before transmitting it to OSC. OSC then requested a supplemental report and FDA's former Director, Office of Scientific Integrity, George M. Warren, reviewed and signed the agency's supplemental response.

² [REDACTED]

³ The full title is "Harmful and potentially harmful constituent (HPHC) comparison and evaluation procedure for comparing two tobacco products in the substantial equivalence reports" (February 21, 2019).

⁴ According to the whistleblower, if the proposed tobacco product is *more* harmful to human health than existing products on the market, CTP rejects the application; if the proposed product is less harmful, or is 'substantially equivalent,' to existing products on the market, CTP approves the application.

and resulted in unclear standards of review and less reliable decisions. The whistleblower further alleged that flaws in CTP’s internal scientific dispute resolution (SDR) process effectively prevented the whistleblower and several other concerned scientists from raising and possibly resolving these issues within the agency.

FDA’s Office of the Commissioner, through its Office of Scientific Integrity (OSI), oversaw the investigation into the whistleblower’s allegations and its report largely substantiated the allegations. I have included a brief summary of the findings and corrective actions below.

i. Substantial Equivalence Tobacco Product Application Reviews

OSI convened a panel of independent scientific experts (“Expert Panel”) to evaluate the whistleblower’s allegations concerning the new SE application review process as outlined in the HPHC Memo. The panel largely agreed with the whistleblower’s concerns, finding that the HPHC Memo lacked “quantifiable standards or criteria” and “sufficient detail and guidance to be enacted as a scientific methodology in its current form.”⁵ The Expert Panel echoed the whistleblowers’ concerns that the new method could yield different results than the previous method when applied to the same tobacco product application. The panel made six recommendations, including that the agency create “clear decision rules which guide the review and dictate the integration of the ‘qualitative or semi-quantitative’ evaluation with quantitative risk assessment,” create a “process for resolving discrepancies” and regularly train reviewers.⁶

The agency ultimately agreed that these revisions were necessary.⁷ The agency further acknowledged that different regulatory decisions were possible when scientists used the new qualitative or semi-qualitative method in the HPHC Memo versus the previously used quantitative or QRA method. However, the agency determined that the approach in the HPHC Memo “*as it was intended to operate and as we plan to revise the HPHC Memo to describe it*” (emphasis added) would ultimately be more protective of public health because it would resolve any “uncertainty” in favor of withholding a tobacco product from the market.⁸ Citing this, along with its limited resources and statutory authority to exercise discretion in addressing SE applications, the agency still concluded that a qualitative or semi-qualitative approach—as it would be articulated in the forthcoming HPHC Memo—was the best regulatory approach.

The agency has taken the following corrective actions:

- Revised the HPHC Memo, with assistance from the whistleblower, to: (1) establish three tiers of review for SE applications; (2) incorporate those tiers more explicitly into the review process and explain which SE applications fall into which tier; (3) clarify how CTP will resolve scientific uncertainty within each tier, including how QRAs may be used in evaluating those SE applications;⁹

⁵ See Appendix 3 to Agency Report, pp. 3 and 4.

⁶ *Id.* at 4.

⁷ The CTP Director—despite helping select the panel and provide it with information—initially alleged that the panel lacked expertise and information and disagreed with its findings. However, following additional requests by FDA’s Office of the Commissioner, and later by OSC, CTP agreed to revise the HPHC Memo and related guidance.

⁸ FDA Report, titled “Review of Whistleblower Allegations,” p. 4.

⁹ See Attachment C to Agency Supplemental Report.

- Clarified that scientists have discretion to use a QRA in certain SE applications, as opposed to relying solely on the qualitative or semi-qualitative method;
 - Developed a decision tree, included as an appendix to the HPHC Memo, guiding scientists through various steps of the SE application review process;¹⁰
 - Agreed to continue to evaluate and revise the HPHC Memo and SE application review process as scientific developments occur.
- ii. CTP’s Internal Scientific Dispute Resolution (SDR) Process

OSI investigated the whistleblower’s allegations concerning CTP’s SDR process. OSI found that “confusion . . . ambiguity in CTP’s written process . . . and a lack of experience . . . by CTP staff at all levels undermined CTP’s efforts to resolve the scientific disagreement in [the whistleblower’s] case. . . .”¹¹ For over a year, OSI found, the whistleblower and several other concerned scientists had attempted to decipher and invoke their agency’s SDR process to resolve their concerns with the HPHC Memo. They utilized both formal and informal means, including by writing to DNCS and CTP leadership; to the CTP Ombudsman; and through a detailed appeal to the DNCS Office of Science which the Deputy Director denied. OSI found that all of the above parties were in a position to direct the whistleblower and fellow scientists to the appropriate SDR process—according to OSI, the scientists’ concerns “fall[] squarely” within that process—but they all failed to do so.¹² OSI further found that DNCS leadership, as the whistleblower alleged, had stopped routing work to the whistleblower and to the other scientists who raised concerns about the new SE review process and HPHC Memo; but OSI stated that it found no evidence that management took these actions to prevent the scientists from elevating their scientific dispute.

In response to these findings, the agency has taken the following corrective actions:

- Issued an updated SDR-Tobacco Policy and Procedure (SDR-ToPP) Guide outlining CTP’s policy and procedures for resolving internal scientific disputes;¹³
- Created an agency-wide point of contact for SDR issues within the Office of Scientific Integrity, Office of the Chief Scientist, available at SDR@fda.hhs.gov;
- Designed and delivered a mandatory training program for all CTP staff involved in scientific decision-making on the SDR policy and process.

The whistleblower commented on the agency’s report and supplemental report. In response to the first report, the whistleblower accurately noted that CTP’s defense of the HPHC Memo relied largely on the memo as it was “intended,” rather than as it had been implemented to date and urged the agency to revise it consistent with the Expert Panel’s recommendations.¹⁴ The whistleblower also warned that the agency’s internal processes for handling scientific disputes had been used to quash dissent and delay resolution of critical issues, citing how CTP leadership had prevented the whistleblower and colleagues from raising their concerns in meetings such that

¹⁰ See Attachment E to Agency Supplemental Report.

¹¹ *Id.* at 4-5.

¹² *Id.* at 56.

¹³ See Attachment F to Agency Supplemental Report.

¹⁴ “Whistleblower Response to FDA Report,” p.1.

they “lost trust in management, and even before departing CTP, continued to fear retaliation.”¹⁵ OSC shared many of the whistleblower’s concerns and requested a supplemental report from the agency. In comments to the supplemental report, the whistleblower acknowledged the agency’s progress in revising the HPHC Memo—specifically, in giving scientists discretion to consider risk drivers or quantitative data in reviewing harmful chemical compounds in SE applications—but stated that the revised memo did not contain all of the whistleblower’s recommended changes and that “scientists will still need courage to challenge a system that places great importance on collaboration and meeting deadlines” and “discourages dissenting voices.”¹⁶

I have determined that the report contains the information required by statute and that its findings appear reasonable. I am deeply troubled that FDA’s own scientific dispute process—designed to identify and resolve public health concerns like those identified here—failed our whistleblower and fellow concerned scientists when they repeatedly tried to invoke it with the highest levels of CTP and DNCS leadership; and that, as a result, much-needed guidance, clarity, and structure initially were not provided to CTP DNCS scientists reviewing harmful tobacco product applications. I do, however, commend the agency for ultimately convening an independent Expert Panel to review the whistleblower’s concerns and for taking necessary steps to repair its processes moving forward. Finally, and critically, I commend the whistleblower for persevering in raising these issues despite the unnecessary obstacles. The public depends on the FDA, with the support of scientists like the whistleblower, to vigorously implement and enforce our nation’s health and safety laws.

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

Respectfully,

A handwritten signature in black ink, appearing to read "Henry J. Kerner", with a stylized flourish at the end.

Henry J. Kerner
Special Counsel

Enclosures

¹⁵ *Id.* at 10.

¹⁶ *Id.* at 1 and 3.