EXHIBIT Q

MFIA MEDIA FREEDOM & INFORMATION ACCESS CLINIC

ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION

Yale Law School

April 29, 2021

Director, Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Re: Request for Prompt Determination on Appeal File No. 21-0006AA, FOIA Request No. 2019-4458

Dear FOIA Appeals Officer,

We, the Yale Law School Media Freedom & Information Access Clinic, represent Dr. G. Caleb Alexander in this matter. We hereby request that the FDA promptly make a determination on Dr. Alexander's outstanding above-captioned administrative appeal.

On May 21, 2019, Dr. Alexander submitted six FOIA requests to the FDA. These requests sought records relating to the FDA's decision to impose, modify, retain, or terminate Risk Evaluation and Mitigation Strategy (REMS) requirements for six drugs: zolpidem (Request No. 2019-4472), prasugrel (Request No. 2019-4465), mifepristone (Request No. 2019-4457), clopidogrel (Request No. 2019-4455), salmeterol-fluticasone (Request No. 2019-4428), and varenicline (Request No. 2019-4458). The FDA has not responded to the zolpidem, prasugrel, mifepristone, clopidogrel, and salmeterol, fluticasone requests, and thus constructively denied them. Dr. Alexander is administratively appealing these constructive denials in a separate letter.

On August 17, 2020, the FDA responded to Dr. Alexander's varenicline request. The FDA's cover letter to its August 17, 2020 response did not state that the FDA had withheld any documents in their entirety. Most of the documents it provided were publicly available. The FDA also did not provide several documents Dr. Alexander specifically requested. Missing from the production were, among other documents:

- "FDA's initial evaluation assessing whether a REMS is needed for varenicline";
- "the May 2008 FDA letter to Pfizer requiring a REMS and issuing a post marketing requirement for a clinical trial";
- "[t]he 18-month [REMS Assessment] Report submitted [by Pfizer] in or around April 2011";
- "the 3-year [REMS Assessment] Report submitted [by Pfizer] in or around October 2012";

- "the 7-year [REMS Assessment] Report submitted [by Pfizer] in or around October 2016";
- "Pfizer's proposed modifications, including elimination, to the approved REMS plan . . . including those submitted on November 8, 2013 and September 3, 2014"; and
- "FDA's review of Pfizer's 18 Month Report, 3 Year Report, and 7 Year Report."

On November 17, 2020, Dr. Alexander administratively appealed the FDA's response to his varenicline request. The next day, the FDA acknowledged receipt of this administrative appeal. The FDA specified that "[p]ursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. 5.24(f) of the HHS FOIA regulations, [Dr. Alexander's] appeal falls under the 'unusual circumstances' in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal."

On November 20, 2020, the FDA emailed Dr. Alexander, indicating that "CDER is going to reopen [Dr. Alexander's] request for processing" and asking whether Dr. Alexander "[w]ould like to withdraw the appeal until CDER sends another response with new appeal rights or keep it open." On November 22, 2020, Dr. Alexander responded to this email and indicated that he "would like to continue to keep the appeal that [he] ha[d] filed open."

Since November, the FDA has neither provided additional documents for Dr. Alexander's varenicline request nor responded to his administrative appeal. It has also not been receptive to our several attempts to discuss the matter. On February 26, 2021, we emailed Sudarshini Satchi, CDER Freedom of Information Branch Chief, to request a call on both the varenicline request and the five other requests to which the FDA had not responded. On March 3, 2021, Guruprasad Udapi, a Supervisory Government Information Specialist at CDER, responded to our email but addressed (in boilerplate fashion) only the five other requests. He did not acknowledge the pendency of the varenicline appeal or our request for a call to discuss the matter.

On March 11, 2021, we responded to Mr. Udapi requesting a call to discuss how to resolve the delay in processing Dr. Alexander's requests, including the varenicline request, but received no response. We again emailed Mr. Udapi on March 22 requesting a call, and again received no response.

As you know, FOIA requires agencies to make a determination on an administrative appeal within twenty business days of its receipt. 5 U.S.C. § 552(a)(6)(A)(ii). Agencies may extend that deadline for "unusual circumstances" under 5 U.S.C. § 552(a)(6)(B), but only for ten business days unless they provide the requester an opportunity to limit the scope of the request, which the FDA did not do here. The FDA's response to Dr. Alexander's administrative appeal was therefore due several months ago.

By failing to provide a determination and responsive records with respect to Dr. Alexander's varenicline appeal within the statutory deadline, the FDA is in violation of its obligations under FOIA. Dr. Alexander respectfully requests that the FDA promptly make a determination on his appeal and produce responsive records.

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If you have any questions regarding this appeal, please do not hesitate to call me at (520) 488-0486 or email me at stephen.stich@ylsclinics.org. I look forward to your response.

Sincerely,

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