

# EXHIBIT N

Re: [EXTERNAL] Dr. Caleb Alexander 2019 FOIA Requests

Katherine Surma <katherine.surma@ylsclinics.org>

Mon 3/22/2021 6:30 AM

To: Udapi, Guruprasad <Guruprasad.Udapi@fda.hhs.gov>

Cc: David Schulz <david.schulz@ylsclinics.org>; Stephen Stich <stephen.stich@YLSClinics.org>

Dear Mr. Udapi,

We had hoped to receive a response from you by March 19th to discuss Caleb Alexander's FOIA requests, as we are perplexed by your March 3rd response to our inquiry.

In August 2019, the CDER FOIA Office told Dr. Alexander that his FOIA request 2019-4457 was then in the 4th or 5th position in the complex queue, and that a response might be expected in a matter of weeks or months, not years. We recently inquired about the status of his requests because it has been over 18 months since that estimate was provided, but no responses have been received. Your March 3rd email indicating that there are now about 200 requests that have priority over Dr. Alexander's requests was alarming, to say the least. This proposition is also impossible to reconcile with the fact that Dr. Alexander filed all six requests on the same day but received a response to just one of them (which an FDA FOIA officer told him was in the complex queue) approximately seven months ago.

We would very much prefer to sort out the status of Dr. Alexander's requests and develop an acceptable timeline for responses from the FDA without the need of litigation, but the inconsistent information that is being provided and the length of time that has already passed does not make sitting and waiting an acceptable option. Please let us know if we might arrange a time to speak with you about the status of these requests. We will do our best to make ourselves available at any time over the next couple of weeks that would work for you. We look forward to hearing from you.

Sincerely,

**Katherine Surma**

J.D. Candidate 2021 | Yale Law School

katherine.surma@yale.edu

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**From:** Katherine Surma <katherine.surma@ylsclinics.org>

**Sent:** Wednesday, March 10, 2021 9:53 PM

**To:** Udapi, Guruprasad <Guruprasad.Udapi@fda.hhs.gov>

**Cc:** David Schulz <david.schulz@ylsclinics.org>; Stephen Stich <stephen.stich@YLSClinics.org>

**Subject:** Re: [EXTERNAL] Dr. Caleb Alexander 2019 FOIA Requests

Dear Mr. Udapi,

Thank you for your recent correspondence regarding FOIA #2019-4428, #2019-4455, #2019-4457, #2019-4458, #2019-4465, and #2019-4472 filed by Dr. Caleb Alexander. We appreciated this information.

Might you be free to touch base by phone sometime over the coming week or two regarding this matter? Naturally, given the public health importance of the queries that Dr. Alexander proposes to examine, we would like to understand the process further, as well as to discuss with you potential means that might be used to resolve the current delay in processing his request.

Can you please let us know by Friday, March 19<sup>th</sup> whether you would be available, and if so, when might be convenient for you?

Thank you and best regards,

**Katherine Surma**

J.D. Candidate 2021 | Yale Law School  
katherine.surma@yale.edu

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**From:** Udapi, Guruprasad <Guruprasad.Udapi@fda.hhs.gov>  
**Sent:** Wednesday, March 3, 2021 1:08 PM  
**To:** Katherine Surma <katherine.surma@ylsclinics.org>  
**Subject:** FW: [EXTERNAL] Dr. Caleb Alexander 2019 FOIA Requests

Good afternoon Ms. Surma,

CDER processes FOIAs in date order priority. There are currently approximately 200 requests with priority over the 2019 requests identified below. While the general estimate processing time for such complex requests is typically 24 months, it is dependent on the size and complexity of the FOIAs in the queue. I will notify you when the requests approach the top of the processing queue. Thank you.

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**From:** Katherine Surma <[katherine.surma@ylsclinics.org](mailto:katherine.surma@ylsclinics.org)>  
**Sent:** Friday, February 26, 2021 3:28 PM  
**To:** Satchi, Sudarshini (Darshini) <[Sudarshini.Satchi@fda.hhs.gov](mailto:Sudarshini.Satchi@fda.hhs.gov)>  
**Cc:** David Schulz <[david.schulz@ylsclinics.org](mailto:david.schulz@ylsclinics.org)>; Stephen Stich <[stephen.stich@YLSClinics.org](mailto:stephen.stich@YLSClinics.org)>  
**Subject:** [EXTERNAL] Dr. Caleb Alexander 2019 FOIA Requests

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Dear Ms. Darshini Satchi,

The Yale Law School Media Freedom and Information Access Clinic represents Dr. Caleb Alexander with respect to the following FOIA requests he has submitted to the FDA:

- 2019-4428
- 2019-4455
- 2019-4457
- 2019-4458
- 2019-4465
- 2019-4472

I am writing to you because the FDA has not yet provided any records in response to five of these six requests, all of which have been pending since May 2019. Last November, Dr. Alexander timely filed an administrative appeal to the one request, 2019-4458, for which he did receive a response; the FDA has yet to address that appeal, nearly four months later.

Dr. Alexander has retained us to pursue litigation if necessary to obtain these records, which should have been provided long ago. Before proceeding down that path, we are reaching out to you to see if there is not some way

to get beyond this impasse without the time, effort and disruption of a lawsuit. Please let us know if we might arrange a time talk with you about what can be done to unloosen responses without further delay. We look forward to hearing from you.

Sincerely,

Katherine Surma  
J.D. Candidate 2021 | Yale Law School  
Media Freedom and Information Access Clinic