CREW | citizens for responsibility and ethics in washington

August 28, 2020

VIA ACCESSDATA.FDA.GOV

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act Request

Dear FOIA Officer:

Citizens for Responsibility and Ethics in Washington ("CREW") makes this request for records pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and U.S. Food and Drug Administration ("FDA") regulations.

First, CREW seeks all emails sent or received by FDA Assistant Commissioner for Media Affairs Emily Miller regarding the use of convalescent plasma as a treatment for COVID-19.

Second, CREW seeks all emails sent or received by the following FDA officials between August 23, 2020 and the date this request is processed mentioning, referencing, or relating to Emily Miller:

- Commissioner Stephen M. Hahn, MD
- Principal Deputy Commissioner Amy Abernethy, MD, PhD
- Chief of Staff Keagan Lenihan
- Chief Counsel Stacy Cline Amin
- Office of the Executive Secretariat Director Martina H. Varnado

Please search for responsive records regardless of format, medium, or physical characteristics. We seek records of any kind, including paper records, electronic records, audiotapes, videotapes, photographs, data, and graphical material. Our request includes without limitation all correspondence, letters, emails, text messages, facsimiles, telephone messages, voice mail messages, and transcripts, notes, or minutes of any meetings, telephone conversations, or discussions. Our request also includes any attachments to emails and other records, as well as those who were cc'ed or bcc'ed on any emails.

If it is your position any portion of the requested records is exempt from disclosure, CREW requests that you provide it with an index of those documents as required under *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973). In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. *See* 5 U.S.C. § 552(b). If it is your position that a document contains non-exempt segments, but that those non-exempt segments are so dispersed throughout the

document as to make segregation impossible, please state what portion of the document is non-/*U.S. Dep't of the Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977).

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A) and FDA regulations, CREW requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures likely will contribute to a better understanding of relevant government procedures by CREW and the general public in a significant way. *See* 5 U.S.C. § 552(a)(4)(A)(iii). Moreover, the request primarily and fundamentally is for non-commercial purposes. *See, e.g.*, *McClellan Ecological v. Carlucci*, 835 F.2d 1282, 1285 (9th Cir. 1987).

On August 18, Emily Miller, a journalist and communications professional previously working for the conservative news outlet One America News Network, joined the FDA as the agency's chief communications official.[1]

Soon after, on August 23, the FDA issued an Emergency Use Authorization for the use of convalescent blood plasma as a treatment for COVID-19.[2] The granting of this EUA was announced to the public during a press conference featuring President Donald Trump and FDA Commissioner Dr. Stephen Hahn.[3]

The announcement was immediately criticized by scientists, who stated that the President and FDA Commissioner had misrepresented available data on the effectiveness of the treatment.[4] Subsequently, Miller defended the FDA Commissioner's misstatements on Twitter, despite Hahn himself later apologizing for overstating the known benefits of the treatment.[5]

---

[1] Dan Diamond and Adam Cancryn, Governors devise their own testing strategy, *Politico*, August 18, 2020, *available at* https://www.politico.com/newsletters/politico-pulse/2020/08/18/governors-devise-their-own-testing-strategy-790009.

[2] FDA Chief Scientist RADM Denise M. Hinton, *Response to Emergency Use Authorization Request for Convalescent Plasma for the Treatment of Patients with COVID-19*. August 23, 2020, *available at* https://www.fda.gov/media/141477/download.

[3] Sharon LaFraniere, Sheri Fink, Katie Thomas, and Maggie Haberman, F.D.A. Allows Expanded Use of Plasma to Treat Coronavirus Patients, *New York Times*, August 23, 2020, *available at* https://www.nytimes.com/2020/08/23/us/politics/fda-plasma-coronavirus.html.

[4] Katie Thomas and Sheri Fink, F.D.A. 'Grossly Misrepresented' Blood Plasma Data, Scientists Say, *New York Times*, August 24, 2020, *available at* https://www.nytimes.com/2020/08/24/health/fda-blood-plasma.html.

[5] Adam Cancryn and Dan Diamond, FDA ousts top spokesperson after 2 weeks, *Politico*, August 28, 2020, *available at* https://www.politico.com/news/2020/08/28/fda-top-spokesperson-leaves-404422.

Additionally, the FDA's press release announcing the EUA for convalescent plasma, which billed the authorization as "Another Achievement in Administration's Fight Against Pandemic," has been described as "a breach of FDA's historic focus on science."[6]

During the ongoing pandemic, President Trump has publicly pressured the FDA to accelerate its testing of potential vaccines and treatments for COVID-19. One day prior to the press conference announcing the granting of an EUA for convalescent plasma, the president posted on Twitter that "[the] Deep State, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics… [The FDA must] focus on speed, and saving lives!"[7] This post was made after top health officials "questioned whether the data was sufficient" to support expanded use of convalescent plasma as a treatment for COVID-19.[8]

This public pressure, as well as the granting of an EUA for convalescent plasma despite limited evidence from clinical trials, has raised concerns about political interference in the FDA's approval process for the treatment.[9]

Following the backlash over the announcement of the EUA for convalescent plasma, on August 28, FDA Commissioner Hahn removed Miller from her position at the agency.[10]

The requested records will shed light on whether political influence has impacted the FDA's decision-making regarding this authorization, including Miller's role in communicating the authorization to the public. The requested records will also illuminate the details surrounding Miller's ouster from the agency. Especially in times of uncertainty and crisis, the public has a right to know whether public health decisions and communications are being made based on scientific evidence or political pressure.

CREW is a non-profit corporation, organized under section 501(c)(3) of the Internal Revenue Code. CREW is committed to protecting the public's right to be aware of the activities of government officials, to ensuring the integrity of those officials, and to highlighting and working to reduce the influence of money on politics. CREW uses a combination of research, litigation, and advocacy to advance its mission. CREW intends to analyze the information

---

[6] *Id.*

[7] Tweet by @realDonaldTrump, August 22, 2020, *available at* https://twitter.com/realDonaldTrump/status/1297138862108663808.

[8] LaFraniere, Fink, Thomas, and Haberman, *NYT*, August 23, 2020.

[9] New York Times Editorial Board, Politicizing Medical Science Will Cost American Lives, *New York Times*, August 24, 2020, *available at* https://www.nytimes.com/2020/08/24/opinion/trump-fda-coronavirus.html.

[10] Sheila Kaplan and Katie Thomas, Two P.R. Experts at F.D.A. Have Been Ousted After Blood Plasma Fiasco, *New York Times*, August 29, 2020, *available at* https://www.nytimes.com/2020/08/28/health/blood-plasma-fda.html.

responsive to this request and to share its analysis with the public through reports, press releases, or other means. In addition, CREW will disseminate any documents it acquires from this request to the public through its website, www.citizensforethics.org. The release of information obtained through this request is not in CREW's financial interest.

CREW further requests that it not be charged search or review fees for this request pursuant to 5 U.S.C. § 552(a)(4)(A)(ii)(II) because CREW qualifies as a member of the news media. *See Nat'l Sec. Archive v. U.S. Dep't of Defense*, 880 F.2d 1381, 1386 (D.C. Cir. 1989) (holding non-profit a "representative of the news media" and broadly interpreting the term to include "any person or organization which regularly publishes or disseminates information to the public").

CREW routinely and systematically disseminates information to the public in several ways. CREW's website receives tens of thousands of page views every month. The website includes blogposts that report on and analyze newsworthy developments regarding government ethics, corruption, and money in politics, as well as numerous reports CREW has published to educate the public about these issues. In addition, CREW posts documents it receives under the FOIA on its website, and those documents have been visited hundreds of thousands of times.

Under these circumstances, CREW satisfies fully the criteria for a fee waiver.

Conclusion

If you have any questions about this request or foresee any problems in fully releasing the requested records, please contact me at (914) 671-3052 or elee@citizensforethics.org. Also, if CREW's request for a fee waiver is not granted in full, please contact our office immediately upon making such a determination.

Where possible, please produce records in electronic format. Please send the requested records to me either at elee@citizensforethics.org or at Eli Lee, Citizens for Responsibility and Ethics in Washington, 1101 K Street, N.W., Suite 201, Washington, D.C. 20005. Thank you for your assistance in this matter.

Sincerely,

Eli Lee
Research Associate