CREW | citizens for responsibility and ethics in washington

August 25, 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 communications from June 11, 2020 to the date this request is processed between the Office of the Commissioner and (1) President Trump; (2) White House employees, including anyone with an "*.eop.gov" email domain; or (3) attorneys or representatives acting on behalf of President Trump, regarding the granting of an Emergency Use Authorization (EUA) for the use of convalescent plasma as a treatment for the novel coronavirus (COVID-19).

Second, CREW seeks all communications from June 11, 2020 to the date this request is processed between the Office of the Commissioner and the Office of the Secretary of Health and Human Services regarding the granting of an EUA for the use of convalescent plasma as a treatment for COVID-19.

Third, CREW seeks all internal FDA communications from June 11, 2020 to the date this request is processed regarding any directives, instructions, or guidance relating to the granting of an EUA for the use of convalescent plasma as a treatment for COVID-19.

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 April 3, 2020, the FDA and the Mayo Clinic opened an expanded access program seeking to study the use of convalescent plasma, a blood component containing antibodies extracted from recovered patients, as a treatment for COVID-19.[1] On June 11, the program released a report tentatively linking early administration of plasma to reduced mortality in COVID-19 patients.[2] The program issued another report, with similar findings, on August 12.[3]

In early August, based on results from the expanded access program, the Department of Health and Human Services issued an Emergency Use Authorization request for the use of convalescent plasma as a treatment for COVID-19.[4] On August 23, in response to the request from HHS, the FDA issued an EUA for plasma treatment.[5] The granting of this EUA was

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[1] *Coronavirus (COVID-19) Update: FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19.* U.S. Food and Drug Administration. April 3, 2020, *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19.

[2] Michael Joyner, Katelyn Bruno, Stephen Klassen, et al., Safety Update: COVID-19 Convalescent Plasma in 20,000 Hospitalized Patients. *Mayo Clinic Proceedings*, June 11, 2020, *available at* https://els-jbs-prod-cdn.jbs.elsevierhealth.com/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp_ft95_6_8.pdf.

[3] Michael Joyner, Jonathon Senefeld, Stephen Klassen, et al., Effect of Convalescent Plasma on Mortality among Hospitalized Patients with COVID-19: Initial Three Month Experience. August 12, 2020, *available at* https://www.medrxiv.org/content/10.1101/2020.08.12.20169359v1.full.pdf.

[4] *Emergency Use Authorization Request for Convalescent Plasma for the Treatment of Patients with COVID-19*. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. August 2020, *available at* https://www.fda.gov/media/141481/download

[5] 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.

announced to the public during a press conference featuring President Donald Trump and FDA Commissioner Dr. Stephen Hahn.[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]

The requested records will shed light on whether political influence has impacted the FDA's decision-making regarding this authorization. Especially in times of uncertainty and crisis, the public has a right to know whether public health decisions 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 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.

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[6] 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.

[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.

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