CREW | citizens for responsibility and ethics in washington

April 2, 2020

**BY 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 March 12, 2020 to the present between FDA 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 approval or potential approval of possible coronavirus treatments.

Second, CREW seeks all internal FDA communications from March 12, 2020 to the present regarding any directives, instructions, requests, or inquiries from President Trump or White House employees regarding the approval or potential approval of possible coronavirus treatments.

Both of the foregoing requests include but are not limited to FDA's Emergency Use Authorization for hydroxychloroquine and chloroquine (also known as hydroxychloroquine sulfate and chloroquine phosphate) and the potential approval of the drug Avignan.

Third, CREW seeks all communications from March 12, 2020 to the present between FDA 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 import alert on Ipca Laboratories as it relates to hydroxychloroquine and chloroquine (also known as hydroxychloroquine sulfate and chloroquine phosphate).

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-exempt, and how the material is dispersed throughout the document. *See Mead Data Central v. 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 March 19, 2020, President Donald J. Trump declared at a news briefing that the anti-malarial drugs chloroquine and hydroxychloroquine had shown "very, very encouraging early results" against Covid-19 and "could be a game changer."[1] Although President Trump indicated that the drugs would be "available almost immediately" and had "gone through the approval process," FDA Commissioner Stephen Hahn clarified at the same briefing that FDA planned to take a "closer look" at the anti-malarials "in the setting of a clinical trial – a large, pragmatic clinical trial – to actually gather that information and answer the question that needs to be answered."[2] President Trump continued to publicly tout the anti-malarials, noting that the government had ordered "millions of units" and awaited "one final approval from the FDA."[3] Soon after, the federal government awarded a pharmaceutical company a contract to conduct a one-month study on the use of the anti-malarials in patients with Covid-19.[4]

On March 28, 2020—almost a month before the completion of the clinical study on chloroquine and hydroxychloroquine—FDA authorized the distribution of the anti-malarials for

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[1] Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, Mar. 19, 2020, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-6/.
[2] *Id.*
[3] Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, Mar. 20, 2020, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-c-oronavirus-task-force-press-briefing/; *see also* Donald J. Trump (@realDonaldTrump), *Twitter*, Mar. 21, 2020, https://twitter.com/realDonaldTrump/status/1241367239900778501.
[4] Jason Leopold, Anthony Cormier, and John Templon, After Trump's Tweet, The Government Is Funding A Coronavirus Study of Hydroxychloroquine, *Buzzfeed News*, Mar. 28, 2020, https://www.buzzfeednews.com/article/jasonleopold/new-government-study-of-chloroquine-after-trump-comments.

use against Covid-19.[5] Scientists have criticized the decision, noting the lack of scientific evidence that the anti-malarials are beneficial in treating patients with Covid-19.[6] Around the same time, FDA lifted an import alert on Indian manufacturer Ipca Laboratories, which FDA imposed in 2015 over quality issues, so that Ipca could ship the active pharmaceutical ingredients of hydroxychloroquine and chloroquine to the United States.[7] *Politico* is now reporting that the White House is encouraging FDA to approve another drug, Avigan, for coronavirus treatment—even though there is limited evidence that the drug will be effective against Covid-19.[8] FDA reportedly has begun exploring potential clinical trials of Avigan in the United States.[9]

The requested records will shed light on whether political influence has impacted FDA's decisionmaking with regard to the approval of drugs for use against Covid-19. FDA has a significant role in protecting the public from dangerous and ineffective medical treatments, as well as from low-quality manufacturers. Especially in times of uncertainty and crisis, the public deserves to know whether FDA is basing its drug-approval decisions on scientific evidence or political pressure. In this way, the requested records would reveal important information about the functioning and decisions of FDA.

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.

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

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[5] Letter from Denise M. Hinton, Chief Scientist, FDA, to Rick Bright, Director, Biomedical Advanced Research and Development Authority, Dep't of Health and Human Servs., Mar. 28, 2020, https://www.fda.gov/media/136534/download.
[6] Dan Diamond, FDA issues emergency authorization of anti-malaria drug for coronavirus care, *Politico*, Mar. 29, 2020, https://www.politico.com/news/2020/03/29/fda-emergency-authorization-anti-malaria-drug-155095.
[7] Eric Palmer, FDA frees India's Ipca from import ban so it can ship unproven COVID-19 treatments, *FiercePharma*, Mar. 23, 2020, https://www.fiercepharma.com/manufacturing/fda-lifts-ban-so-india-s-ipca-so-can-ship-unproven-covid-19-treatments; *see also* Sarah Owermohle and Dan Diamond, Trump's push for risky malaria drugs disrupts coronavirus response, *Politico*, Mar. 27, 2020, https://www.politico.com/news/2020/03/27/trump-malaria-coronavirus-152498.
[8] Dan Diamond and Nahal Toosi, White House pressures FDA on unproven Japanese drug, *Politico*, Mar. 31, 2020, https://www.politico.com/news/2020/03/31/white-house-pressures-fda-japanese-drug-157587.
[9] *Id.*

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 (202) 408-5565 or jlutkenhaus@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 jlutkenhaus@citizensforethics.org or at Jessica Lutkenhaus, 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,

Jessica Lutkenhaus
Legal Fellow