EMPOWER OVERSIGHT
Whistleblowers & Research

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January 21, 2022

VIA ELECTRONIC TRANSMISSION

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

RE: FOIA Request for Records Regarding Former FDA Employees Marion Gruber and Philip Krause, As Well As Government Authorization of COVID-19 Vaccines and Boosters

Dear FOIA Officer:

INTRODUCTION

Empower Oversight Whistleblowers & Research ("Empower Oversight") is a nonpartisan, nonprofit educational organization dedicated to enhancing independent oversight of government and corporate wrongdoing. We work to help insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities, and seek to hold those authorities accountable to act on such reports by, among other means, publishing information concerning the same.

BACKGROUND

Last August, several media outlets reported that Dr. Marion Gruber, the director of the Food and Drug Administration's ("FDA") vaccines office, would retire at the end of October, and her deputy, Dr. Philip Krause, would leave in November.[1][2] *EndPoints* released an email that Dr. Peter Marks, the agency's top vaccine regulator, sent to staff members that day. As reported by *EndPoints*:

> A former senior FDA leader told Endpoints that they're departing because they're frustrated that CDC and their ACIP committee are involved in decisions that they

[1] https://endpts.com/breaking-in-a-major-blow-to-vaccine-efforts-senior-fda-leaders-stepping-down-report/.

[2] https://www.nytimes.com/2021/08/31/us/politics/fda-vaccine-regulators-booster-shots.html.

> think should be up to the FDA. The former FDAer also said he's heard they're upset with CBER director Peter Marks for not insisting that those decisions should be kept inside FDA. What finally did it for them was the White House getting ahead of FDA on booster shots.[3]

According to *Business Insider*, the two FDA officials left the agency because the Biden administration planned to roll out the Pfizer COVID-19 booster shot before the agency had approved it.[4]

A few weeks later, on September 13, Drs. Gruber and Krause participated in a viewpoint published in *The Lancet* that argued, "Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high."[5] The viewpoint was signed by more than a dozen other experts including members of the World Health Organization. As reported by the *Associated Press*:

> After revelations of political meddling in the Trump administration's coronavirus response, President Joe Biden has promised to "follow the science." But the review raises the question of whether his administration is moving faster than the experts.[6]

Georgetown University's Larry Gostin told the *Associated Press*, "It's always a fundamental error of process to make a scientific announcement before the public health agencies have acted and that's exactly what happened here." *The Financial Times* reported:

> The FDA said in a statement: "As noted in the article, the views of the authors do not represent the views of the agency." It added: "We are in the middle of a deliberative process of reviewing Pfizer's booster shot supplemental approval submission, and FDA as a matter of practice does not comment on pending matters before the agency. We look forward to a robust and transparent discussion on Friday about that application."[7]

The Hill reported:

> White House chief medical adviser Anthony Fauci on Tuesday said he disagreed with a medical journal paper, co-authored by two outgoing federal vaccine regulators, that argued the science doesn't support giving COVID-19 booster shots to every American.
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> During an interview on MSNBC's *Morning Joe*, Fauci called the article "controversial" and said it conflates things that are not supposed to be connected.[8]

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[3] https://endpts.com/breaking-in-a-major-blow-to-vaccine-efforts-senior-fda-leaders-stepping-down-report/.

[4] https://www.businessinsider.com/2-top-fda-officials-resigned-biden-booster-plan-reports-2021-9.

[5] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02046-8/fulltext.

[6] https://www.nbcnews.com/health/health-news/fda-experts-oppose-u-s-plan-give-covid-boosters-all-n1279070.

[7] https://www.ft.com/content/af8da7d4-43ea-41d6-90ee-f959b3675cc5.

[8] https://thehill.com/policy/healthcare/572257-fauci-pushes-back-on-booster-criticism.

Some days after *Kaiser Health News* reported that Dr. Fauci of the National Institute of Allergy and Infectious Diseases ("NIAID"), which is within the National Institutes of Health ("NIH"), got ahead of the FDA and the CDC on vaccines by assembling a group of scientists to track and sequence COVID variants called "SAVE," or SARS-Cov-2 Variant Testing Pipeline.[9] According to *Kaiser Health News*:

> The SAVE group, active since February, was organized by NIH officials who in normal times track influenza epidemics. The 60 to 70 scientists are mostly from U.S. agencies such as the NIH, CDC, FDA and Biomedical Advanced Research and Development Authority, but also from other countries, including Israel and the Netherlands.
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> "This is very much the basic scientists who are in the weeds trying to figure things out," said Dr. Daniel Douek, chief of the human immunology section within NIAID. Douek said the larger SAVE group meets every Friday but several subgroups meet several times a week, focusing on different aspects of the virus, such as early detection of viral variants and testing suspicious variants for their ability to evade vaccine-induced immunity and sicken vaccinated mice and monkeys.[10]

On October 6, *Roll Call* reported that Peter Marks had supported the White House plan for boosters, over the objections of Drs. Gruber and Krause. According to *Roll Call*: "Krause bristled in a Sept. 17 public meeting with Pfizer, complaining that the drugmaker had not turned over much of its data for independent number crunching."[11] This was confirmed by others quoted for the article.

Then on November 29, Drs. Gruber, Krause, and Paul Offit published an essay in *The Washington Post* that stated, "While boosting can further increase already very high levels of protection against even mild illness, the only people who really need an additional dose of vaccine are those who are at high risk of serious disease (including the elderly) or who might expose vulnerable household or workplace contacts if they got infected."[12]

About two weeks later, *STAT News* reported that the FDA approved vaccine booster without consulting its independent vaccine advisers, the Vaccines and Related Biological Products Advisory Committee, or VRBPAC.[13] The outlet also reported that Dr. Rochelle Walensky of the CDC "sidestepped CDC's independent vaccine experts, the Advisory Committee on Immunization Practices, or ACIP — an unusual move that is already drawing criticism."

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[9] https://www.modernhealthcare.com/politics-policy/how-fauci-and-nih-got-ahead-fda-and-cdc-backing-boosters.

[10] https://www.modernhealthcare.com/politics-policy/how-fauci-and-nih-got-ahead-fda-and-cdc-backing-boosters.

[11] https://www.rollcall.com/2021/10/06/fdas-internal-turmoil-could-impact-boosters-shots-for-kids/.

[12] https://www.washingtonpost.com/outlook/2021/11/29/booster-shots-universal-opinion/.

[13] https://www.statnews.com/2021/12/09/fda-expands-authorization-for-pfizers-covid-19-booster-to-cover-16-and-17-year-olds/.

RECORDS REQUEST

To shed light on why Drs. Gruber and Krause left the FDA and the controversy around COVID-19 vaccines and boosters, we respectfully request pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, copies of:

1. All emails at the FDA regarding Dr. Gruber and/or Dr. Krause, their concerns about COVID-19 boosters, and discussions about them leaving the FDA. The time span of this request covers August 1, 2021 to the present. In responding to this request, please search all email mailboxes assigned or formerly assigned to Marion Gruber, Philip Krause, Peter Marks, FDA Chief of Staff Julia Tierney, and FDA Acting Director Janet Woodcock.

2. All emails between reporters and the FDA's Office of Media Affairs regarding Dr. Gruber and/or Dr. Krause, to include all FDA internal emails discussing any response to one or more reporter's(s') question(s) or request(s) for comment. The time span of this request covers August 1, 2021 to the present.

3. All records at the FDA regarding Drs. Gruber and Krause and the September 13, 2021, viewpoint published in *The Lancet* reference above, which argued, "Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high." The time span of this request covers September 1, 2021 to the present. In responding to this request, please search all email mailboxes assigned or formerly assigned to Marion Gruber, Philip Krause, Peter Marks, FDA Chief of staff Julia Tierney, and FDA Acting Director Janet Woodcock.

4. All emails between reporters and the FDA's Office of Media Affairs regarding the viewpoint published in *The Lancet* on September 13, 2021, to include all FDA internal emails discussing any response to one or more reporter's(s') question(s) or request(s) for comment. The time span of this request covers September 12, 2021, to the present.

5. All FDA records regarding the SAVE group and its meetings. The time span of this request covers January 1, 2021. In responding to this request, please search all email mailboxes assigned or formerly assigned to Marion Gruber, Philip Krause, Peter Marks, FDA Chief of staff Julia Tierney, and FDA Acting Director Janet Woodcock.

6. All emails at the FDA regarding Drs. Gruber and Krause's essay published on November 29, 2021, in *The Washington Post*. The time span of this request covers November 15, 2021, to the present. In responding to this request, please search all email mailboxes assigned or formerly assigned to Marion Gruber, Philip Krause, Peter Marks, FDA Chief of staff Julia Tierney, and FDA Acting Director Janet Woodcock.

7. All emails between reporters and the FDA's Office of Media Affairs regarding Drs. Gruber and Krause's essay published in *The Washington Post* on November 29, 2021, to include all FDA internal emails discussing any response to one or more reporter's(s') question(s) or request(s) for comment. The time span of this request covers November 29, 2021 to the present.

8. All emails discussing COVID-19 vaccines and boosters with Jeffrey Zientz and/or other personnel in the White House or Executive Office of the President. In responding to this

request, please search all email mailboxes assigned or formerly assigned to Peter Marks, FDA Chief of staff Julia Tierney, and FDA Acting Director Janet Woodcock. The time span of this request covers August 1, 2021 to the present.

DEFINITIONS

"COMMUNICATION(S)" means every manner or method of disclosure, exchange of information, statement, or discussion between or among two or more persons, including but not limited to, face-to-face and telephone conversations, correspondence, memoranda, telegrams, telexes, email messages, voice-mail messages, text messages, Slack messages, meeting minutes, discussions, releases, statements, reports, publications, and any recordings or reproductions thereof.

"DOCUMENT(S)" or "RECORD(S)" mean any kind of written, graphic, or recorded matter, however produced or reproduced, of any kind or description, whether sent, received, or neither, including drafts, originals, non-identical copies, and information stored magnetically, electronically, photographically or otherwise. As used herein, the terms "DOCUMENT(S)" or "RECORD(S)" include, but are not limited to, studies, papers, books, accounts, letters, diagrams, pictures, drawings, photographs, correspondence, telegrams, cables, text messages, emails, memoranda, notes, notations, work papers, intra-office and inter-office communications, communications to, between and among employees, contracts, financial agreements, grants, proposals, transcripts, minutes, orders, reports, recordings, or other documentation of telephone or other conversations, interviews, affidavits, slides, statement summaries, opinions, indices, analyses, publications, questionnaires, answers to questionnaires, statistical records, ledgers, journals, lists, logs, tabulations, charts, graphs, maps, surveys, sound recordings, data sheets, computer printouts, tapes, discs, microfilm, and all other records kept, regardless of the title, author, or origin.

"PERSON" means individuals, entities, firms, organizations, groups, committees, regulatory agencies, governmental entities, business entities, corporations, partnerships, trusts, and estates.

"REFERS," "REFERRING TO," "REGARDS," REGARDING," "RELATES," "RELATING TO," "CONCERNS," "BEARS UPON," or "PERTAINS TO" mean containing, alluding to, responding to, commenting upon, discussing, showing, disclosing, explaining, mentioning, analyzing, constituting, comprising, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

INSTRUCTIONS

The words "and" and "or" shall be construed in the conjunctive or disjunctive, whichever is most inclusive.

The singular form shall include the plural form and vice versa.

The present tense shall include the past tense and vice versa.

In producing the records described above, you shall segregate them by reference to each of the numbered items of this FOIA request.

If you have any questions about this request, please contact Bryan Saddler by e-mail at bsaddler@empowr.us.

FEE WAIVER REQUEST

Empower Oversight agrees to pay up to $25.00 in applicable fees, but notes that it qualifies as a "representative of the news media"[14] and requests a waiver of any fees that may be associated with processing this request, in keeping with 5 U.S.C. § 552 (a)(4)(A)(iii).

Empower Oversight is a non-profit educational organization as defined under Section 501(c)(3) of the Internal Revenue Code, which helps insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities, and seeks to hold those authorities accountable to act on such reports by, among other means, publishing information concerning the same. Empower Oversight has no commercial interest in making this request.

Further, the information that Empower Oversight seeks is in the public interest because it is likely to contribute significantly to the public understanding of the operations or activities of the FDA. Specifically, the public has a significant interest in understanding how the FDA is addressing the authorization of COVID-19 vaccines and boosters and the SARS-CoV-2 pandemic.

Empower Oversight is committed to government accountability, public integrity, and transparency. In the latter regard, the information that that Empower Oversight receives that tends to explain the subject matter of this FOIA request will be disclosed publicly via its website, and copies will be shared with other news media for public dissemination.

For ease of administration and to conserve resources, we ask that documents be produced in a readily accessible electronic format. Thank you for your time and consideration. Please don't hesitate to contact me with any questions.

Cordially,

/Jason Foster/

Jason Foster
Founder & President

[14] On September 23, 2021, the Securities Exchange Commission conceded that Empower Oversight qualifies as a news media requester for purposes of fees assessed pursuant to the FOIA. "Empower Oversight Wins Appeal of Erroneous SEC Fee Decision: Must be treated as a "media requestor" in seeking ethics records of senior officials," Empower Oversight Press Release (Sep 24, 2021), https://empowr.us/empower-oversight-wins-appeal-of-erroneous-sec-fee-decision-must-be-treated-as-a-media-requestor-in-seeking-ethics-records-of-senior-officials/.