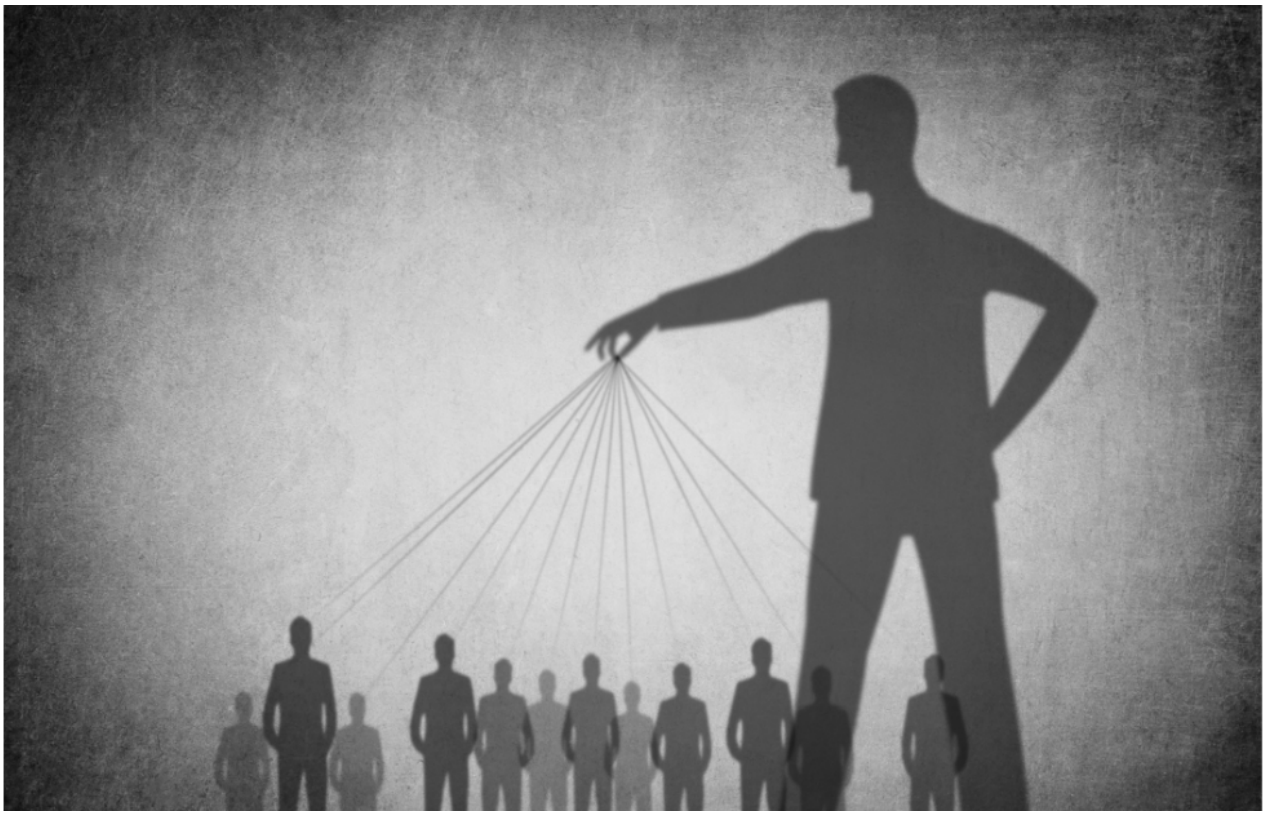
Judicial Watch Obtains Documents Showing White House Pressured FDA Officials to Authorize COVID Boosters



Judicial Watch on July 26 obtained 112 pages of documents from the U.S. Food and Drug Administration (FDA) revealing top officials at the agency were being pressured to conform to the Biden Administration's timeline for COVID-19 vaccine boosters.

The records were disclosed as part of a Freedom of Information Act (FOIA) lawsuit filed against the Department of Health and Human Services (HHS) in February after it failed to respond to a FOIA request filed on Sept. 3, 2021.

The request was for records of communications from Dr. Marion Gruber and Dr. Philip Krause, the former director and deputy director of the FDA's Office of Vaccines Research and Review.

Gruber and Krause reportedly resigned late last year after the Biden administration pushed for the general population to get COVID-19 vaccine boosters – bypassing U.S. regulatory agencies and their advisory panels – without data to support the recommendation.

Gruber and Krause said "available evidence" did not yet "indicate a need for COVID-19 vaccine booster shots among the general population …"

Records obtained by Judicial Watch include an August 25, 2021, email by Gruber to her boss, Dr. Peter Marks, director of the Center for Biologics Evaluation and Research (CBER):

> *"Over the last couple of days, Janssen has bombarded us with emails regarding their booster dose studies.*
>
> *"[…] I am also very concerned that companies (such as Pfizer and Janssen) are trying to put pressure on OVRR [Office of Vaccines Research and Review] by way of PR [public relations]. We need to be given time to consider their data and cannot be pushed by these companies and, for that matter the Administration, who try to impose timeless [sic] that make no sense (e.g., Sep 20)…. It appears that at least Pfizer's data will not be aligned with this approach and the 'n' [test numbers] they have is grossly insufficient. Obviously, we have to review the data but we have taken a peak and have serious concerns.*
>
> *"Lastly, and this is my personal opinion, data we have seen so far from various companies (Pfizer, Janssen, Moderna) appear to suggest that boosters are not needed."*

In an email exchange from Aug. 27, 2021, Gruber replies to an email from Maureen Hess, a communications specialist in CBER:

> *"Well, the message appears to be 'total buy-in in the need for boosters,' this is not how I am writing the BD [likely*

> *board decision], I am trying to take a more neutral approach. This piece sounds as if we already decided to approve this supplement."*

Hess responded:

> *"Okay, I'll make some additional edits (but JW [FDA Commissioner Janet Woodcock] was included on this statement – https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html – so our edits may be rejected above us."*

"From my perspective, this is as good as it can get," Gruber later responded. "Obviously, this statements [sic] puts us into a real bind but the damage is already done."

In an email exchange from Aug. 20, 2021, Dr. Doran Fink, Deputy Director of the FDA's Division of Vaccines and Related Products Applications raisesd questions regarding new data Moderna was submitting to FDA about its COVID vaccine.

Fink told Drs. Gruber, Krause and other colleagues:

> *"I had to bite my tongue when Peter [likely Dr. Peter Marks] mentioned this morning we wouldn't be doing rushed reviews anymore so as not to ask about the booster doses that the administration promised to everyone by Sept 20!*

> *"[…] And then there is the question of the data that will support these booster doses – maybe I'm wrong, but my understanding is that Pfizer is proposing that their sBLA include the Phase 1 booster data from a grand total of 23 subjects. I'm not sure what Moderna will have, but the data Fauci presented in the press conference from NIAID studies, which was ~25 subjects per treatment arm."*

In an email dated Aug. 17, 2021, Gruber stated:

> *"They [Dr. Doran's team] fully understand that the Acting Commissioner would like to approve this product [Pfizer COVID booster shot] very soon and are trying their best to complete their review and assessment, while at the same time, maintaining our high standards and scientific and clinical integrity."*

Philip Krause, in an Aug. 10, 2021 email, said:

"It sounds like Peter [likely Marks] thinks he has taken over all vaccine operations, not just the Pfizer BLA [Biologics License Application] …"

Dr. Arnold Monto, Professor in the Department of Epidemiology of the University of Michigan School of Public Health, on Aug. 23, 2021, emailed Drs. Gruber and Krause with the subject "VRBPAC and boosters:"

> *"The Surgeon General last night made a statement that the FDA and CDC advisory committees would be reviewing. Hope that he misspoke about the VRBPAC [Vaccines and Related Biological Products Advisory Committee] Doesn't seem to be enough time to get it organized Just got asked about flu vaccination and Covid boosters being given at the same time. Gave my personal information, don't…"*

Gruber replied to Monto:

> *"We will be discussing the 'booster question' and related submissions including whether VRBPAC should be held. We do not know yet and you are right that timing will be an issue once again."*

The FDA on Sept. 22, 2021, authorized a booster dose of Pfizer's COVID vaccine for emergency use to be administered at least six months after completion of the primary series and to those at "high risk" of severe COVID-19.

“These FDA documents confirm a politicized approval process for the controversial COVID-19 vaccine booster shots,” said Judicial Watch President Tom Fitton. “It is a scandal that it took months and a federal lawsuit to these troubling facts about this unprecedented and seemingly never-ending vaccine operation.”