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FDA Resignations Regarding Covid-19 Vax "Booster Shots": Top FDA Officials "Express Concern" Regarding Biden Administration's "Booster Shots"

Timelines That "Make No Sense"

By Judicial Watch
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Judicial Watch announced today it received 112 pages from the Food and Drug Administration (FDA) that show top officials being pressured by "companies and, for that matter the Administration, who try to impose timeless [sic] that make no sense."

The records were produced to Judicial Watch in response to a February 2022 Freedom of Information Act (FOIA) lawsuit against the Department of Health & Human Services (HHS) that was filed after HHS failed to respond to a September 3, 2021, FOIA request for records of communication from the former director and deputy director of the FDA's Office of Vaccines Research and Review, Dr. Marion Gruber and Dr. Philip Krause, respectively (Judicial Watch v. U.S. Department of Health and Human Services (No. 1:22-cv-00292)).

Drs. Gruber and Krause reportedly resigned during the White House's push to approve the COVID-19 vaccine "booster shots."

On September 13, 2021, Gruber and Krause were among a group of resigning doctors who agreed that, "Available evidence doesn't yet indicate a need for COVID-19 vaccine booster shots among the general population …"

The records include an August 25, 2021, email by Marion Gruber to her boss, Center for Biologics Evaluation and Research (CBER) Director Peter Marks:

Over the last couple of days, Janssen has bombarded us with emails regarding their booster dose studies.

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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 on August 27, 2012, Gruber replies to an email from Maureen Hess, a communications specialist in Center for Biologics Evaluation and Research: "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 responds, "Okay, I'll make some additional edits (but JW [likely Acting 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." After sending more emails about edits Hess made, Gruber replies, "From my perspective this is as good as it can get. Obviously, this statements [sic] puts us into a real bind but the damage is already done."

In an Aug. 20, 2021, email exchange Dr. Doran Fink, the Deputy Director of the FDA's Division of Vaccines and Related Products Applications raises questions regarding new data, that 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, Director of the Center for Biologics Evaluation and Research] 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!

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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.

Gruber states in an August 17, 2021, email "They [Dr. Doran's team] fully understand that the Acting Commissioner would like to approve this product [Pfizer Covid booster vaccine] 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 August 10, 2021 email, complains: "It sounds like Peter [likely Center for Biologics Evaluation and Research Director Peter Marks] thinks he has taken over all vaccine operations, not just the Pfizer BLA [Biologics License Application] …"

On August 23, 2021, Dr. Arnold Monto, Professor in the Department of Epidemiology of the University of Michigan School of Public Health, emails Drs. Gruber and Krause using 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 then replies 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."

On September 22, 2021, the FDA approved use of a booster dose of the Pfizer drug. According to the organization's news release, the FDA, "amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series" for people at "high risk" of "severe COVID-19."

"These FDA documents confirm a politicized approval process for the controversial Covid-19 vaccine booster shots," says 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."

Through FOIA requests and lawsuits, Judicial Watch has uncovered a substantial amount of information about COVID-19 issues:

- Recently, NIH records revealed an FBI "inquiry" into the NIH's controversial bat coronavirus grant tied to the Wuhan Institute of Virology. The records also show National Institute of Allergy and Infectious Diseases (NIAID) officials were concerned about "gain-of-function" research in China's Wuhan Institute of Virology in 2016. The Fauci agency was also concerned about EcoHealth Alliance's lack of compliance with reporting rules and use of gain-of-function research in the NIH-funded research involving bat coronaviruses in Wuhan, China.
- HHS records revealed that from 2014 to 2019, $826,277 was given to the Wuhan Institute of Virology for bat coronavirus research by the NIAID.
- NIAID records showed that it gave nine China-related grants to EcoHealth Alliance to research coronavirus emergence in bats and was the NIH's top issuer of grants to the Wuhan lab itself. The records also included an email from the vice director of the Wuhan Lab asking an NIH official for help finding disinfectants for decontamination of airtight suits and indoor surfaces.
- HHS records included an "urgent for Dr. Fauci " email chain, citing ties between the Wuhan lab and the taxpayer-funded EcoHealth Alliance. The government emails also reported that the foundation of U.S. billionaire Bill Gates worked closely with the Chinese government to pave the way for Chinese-produced medications to be sold outside China and help "raise China's voice of governance by placing representatives from China on important international counsels as high level commitment from China."
- HHS records included a grant application for research involving the coronavirus

that appears to describe "gain-of-function" research involving RNA extractions from bats, experiments on viruses, attempts to develop a chimeric virus and efforts to genetically manipulate the full-length bat SARSr-CoV WIV1 strain molecular clone.

- HHS records showed the State Department and NIAID knew immediately in January 2020 that China was withholding COVID data, which was hindering risk assessment and response by public health officials.
- University of Texas Medical Branch (UTMB) records show the former director of the Galveston National Laboratory at the University of Texas Medical Branch (UTMB), Dr. James W. Le Duc warned Chinese researchers at the Wuhan Institute of Virology of potential investigations into the COVID issue by Congress.
- HHS records regarding biodistribution studies and related data for the COVID-19 vaccines show a key component of the vaccines developed by Pfizer/BioNTech, lipid nanoparticles (LNPs), were found outside the injection site, mainly the liver, adrenal glands, spleen and ovaries of test animals, eight to 48 hours after injection.
- Records from the Federal Select Agent Program (FSAP) reveal safety lapses and violations at U.S. biosafety laboratories that conduct research on dangerous agents and toxins.
- HHS records include emails between National Institutes of Health (NIH) then-Director Francis Collins and Anthony Fauci, the director of National Institute of Allergy and Infectious Diseases (NIAID), about hydroxychloroquine and COVID-19.
- HHS records show that NIH officials tailored confidentiality forms to China's terms and that the World Health Organization (WHO) conducted an unreleased, "strictly confidential" COVID-19 epidemiological analysis in January 2020.
- Fauci emails include his approval of a press release supportive of China's response to the 2019 novel coronavirus.

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