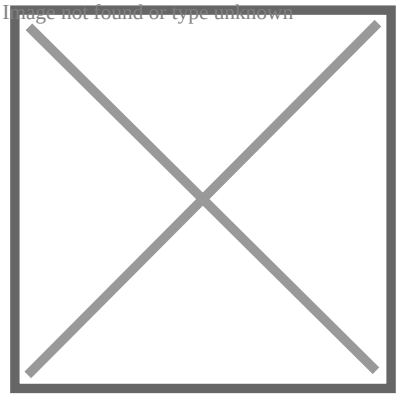

Judicial Watch: Shocking Emails Show That CDC Pressured FDA To Authorize COVID Boosters Without Clinical Trials

Description

USA: When it comes to protecting the health of American citizens, the Center for Disease Control (CDC) and the FDA are broken beyond repair. They have destroyed all trust and should be totally reconstituted and re-chartered to do what they are supposed to do, free of corruption, greed and control by Big Pharma and the biotech industry. ? TN Editor

Judicial Watch announced today it received 43 pages of heavily redacted records from the Food and Drug Administration (FDA) regarding the COVID-19 booster vaccine.

Judicial Watch obtained the records 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, (*Judicial Watch v. U.S. Department of Health and Human Services* (No. 1:22-cv-00293)).

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 …"

In a July 13, 2021, email to an individual whose name is redacted, Beatrice Kalungall, a Branch Chief in the FDA's Center for Biologics Evaluation and Research (CBER)/Office of Tissues and Advanced Therapies, provided a list of responses to questions posed about "Use of Covid-19 Vaccines in Research."

One of the questions asked was, "Are the EUA vaccines [Emergency Use Authorization Covid-19 vaccines] considered 'lawfully marketed' (21 CFR 312.2(b)) for the purposes of an IND [Investigational New Drug] exemption (though we anticipate it is likely that we would still file an IND based on other criteria)?"

Kalungall replied:

"Vaccines which are available under EUA may be considered 'lawfully marketed' if used under the scope of authorization as described in the Letter of Authorization (LOA) for each product. Note that an important consideration is the possible risk to subjects so please clearly identify the intended study population and include a discussion of the issue from your perspective."

In a separate email thread and discussion generated from the same initiating July 13, 2021, email regarding "Use of Covid-19 Vaccines in Research", Dr. Doran Fink, a top official in the Office of Vaccines Research and Review, writes:

"Providers are losing confidence in FDA/CDC to do the right thing for their patients, including that we can't give inquiring patients a straight answer about what they are allowed to do outside of an IND [Investigational New Drug]."

Dr. Krause, Deputy Director of the FDA's Office of Vaccines Research and Review, responds to Fink:

"From my brief discussion with Peter [presumably, CBER Director Peter Marks] this morning, after some calls with CDC and HHS last night, the problem is that the [redacted]. Take a deep breath before reading this next paragraph. On that call, the CDC evidently stated that they will assemble all the data they are aware of on third dosing in this setting, and send it to us in the hope that we will (very soon) authorize the third dose for immunocompromised as part of the EUA. Peter told me that CBER IOD [presumably CBER Immediate Office of the Director] will triage this—I told him I need to be cc:ed on any of these communications so we don't get blindsided, but that we also need to protect the review team."

"These FDA records further document top officials' concerns about the controversial COVID-19 booster shots," said Judicial Watch President Tom Fitton. "That it has taken months and a federal lawsuit to uncover this critical material is a scandal."

In a previous production from the February 2022 FOIA lawsuit, Judicial Watch received **112 pages** from the FDA that show top officials being pressured by companies and the Biden administration to impose timelines on approval for the booster shots "that make no sense."

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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