

# Exhibit 358

Judicial Watch: Records Show US and UK  
'Confidentiality Agreement' Tied to Vaccine  
Adverse Events

<https://www.judicialwatch.org/us-and-uk-agreement/>

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# Judicial Watch: Records Show U.S. and UK 'Confidentiality Agreement' Tied to Vaccine Adverse Events



(Washington, DC) – Judicial Watch announced today it received **57 pages** of heavily redacted records from the U.S. Department of Health and Human Services (HHS) that show, just two days prior to FDA approval of the Pfizer-BioNTech COVID-19 vaccine, a discussion between U.S. and UK health regulators regarding the COVID shot and “anaphylaxis,” with the regulators emphasizing their “mutual confidentiality agreement.”

Judicial Watch obtained the records through a Freedom of Information Act (FOIA) **lawsuit** against HHS (*Judicial Watch v. U.S. Department of Health and Human Services* (No. 1:22-cv-00660)) after the Food and Drug Administration (FDA), which is an agency of HHS, failed to respond to an August 30, 2021, FOIA request for:

All emails sent to and from members of the Vaccines and Related Biological Products Advisory Committee regarding adverse events, deaths and/or injuries caused by investigatory vaccines for the prevention or treatment of SARS-CoV-2 and/or COVID-19 currently produced by Pfizer/BioNTech, Moderna and/or Johnson & Johnson.

The Vaccines and Related Biological Products Advisory Committee (**VRBPAC**) is the U.S. Government's central advisory body, along with Advisory Committee on Immunization Practices (**ACIP**), advising whether to approve COVID vaccines.

A lengthy, heavily redacted December 2020 **email exchange** shows U.S. and UK health officials placing a heavy emphasis on their "mutual confidentiality agreement" in a discussion regarding "anaphylactoid reactions" to the COVID vaccine.

The exchange is initiated by Jonathan Mogford, policy director of the UK's Medicines and Healthcare Products Regulatory Agency and is sent to Acting FDA Commissioner Janet Woodcock as well as Peter Marks, director of the Center for Biologics Evaluation and Research (CBER). The subject line and body of the email are fully redacted under FOIA Exemption B3 (relating to statutory prohibitions).

As background, Mogford includes information on "two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions...." Marks replies to Mogford: "It would be very helpful if our Office of Vaccines could receive additional details [redacted] from MHRA [UK Medicines and Healthcare Products Regulatory Agency] under the terms of our mutual confidentiality agreement." Mogford later replies, "... attached are [redacted] hope that's helpful in the meantime. If I can just remind - information shared under our confidentiality agreement."

Marion Gruber, head of the Office of Vaccines Research and Review (OVR), then replies to Mogford, "Thank you so much for this information. Our emails crossed. If possible, would be available for a t-con [teleconference] today?" The exchange concludes with OVR Deputy Director Phil Krause advising UK Medicines and Healthcare Products Regulatory Agency official Jamie Convisser, "Your summary is correct. I'm cc:ing Amanda Cohn at CDC who can provide the most up-to-date details about [redacted]. Obviously, [redacted], not all of this is public so please hold these details confidential." Cohn then replies to Mogford, and includes an attachment titled "Anaphylaxis CLARK Dec 19 2020 Final". She writes, "I am adding my colleagues Tom Clark and Stacey Martin, we are happy to share more information with you. Attached are slides that were presented at a public meeting on Saturday. [Redacted]."

The FDA issued its [Emergency Use Authorization](#) for the Pfizer-BioNTech COVID vaccine for individuals 16 years of age and older on December 11, 2020.

On May 14, 2021, the CDC's Dr. Amanda Cohn [emailed](#) Office of Vaccines Research and Review Director Marion Gruber and Center for Biologics Evaluation and Research Director Peter Marks with the subject line "Coadministration of COVID-19 Vaccines with Other Vaccines During Pregnancy."

Gruber writes, "I am fine with this language." Marks then responds to Cohn and her CDC colleague, Sarah Mbaeyi, "I can live with this too. Please let me know if you want to connect about the adverse event issue later today. Seems like work is still ongoing, but let me know. Thanks." Cohn replies, "We have a meeting with Rochelle [presumably CDC Director Rochelle Walensky] at 3:30 about if we should say anything or wait until we have more definitive information. I will let you know where we land. I'm not sure there is a right answer."

"It again took a lawsuit for the Biden administration to hand over, albeit heavily redacted, information regarding the safety of the COVID vaccines that the public has every right to know," said Judicial Watch President Tom Fitton. "This disturbing batch of new documents have uncovered a secret confidentiality agreement tied to COVID vaccine safety issues and emails that raise new questions about the vaccines and pregnancy."

Judicial Watch is pursuing challenges against the agency's redactions under FOIA.

In a previous production from this FOIA lawsuit, Judicial Watch received **1,081 pages** of records from HHS detailing internal discussions about myocarditis and the COVID vaccine. Other documents detailed adverse "events for which a contributory effect of the vaccine could not be excluded."

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

- HHS **records** regarding data Moderna submitted to the FDA on its mRNA COVID-19 vaccine, indicated a "statistically significant" number of rats were born with skeletal deformations after their mothers were injected with the vaccine. The documents also reveal Moderna elected not to conduct a number of standard pharmacological studies on the laboratory test animals.
- FDA records detailed **pressure** for COVID-19 vaccine booster approval and use.
- 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](#) showed 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 showed 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) revealed [safety lapses](#) and violations at U.S. biosafety laboratories that conduct research on dangerous agents and toxins.
- HHS records included [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 showed 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](#) included his approval of a press release supportive of China’s response to the 2019 novel coronavirus.

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