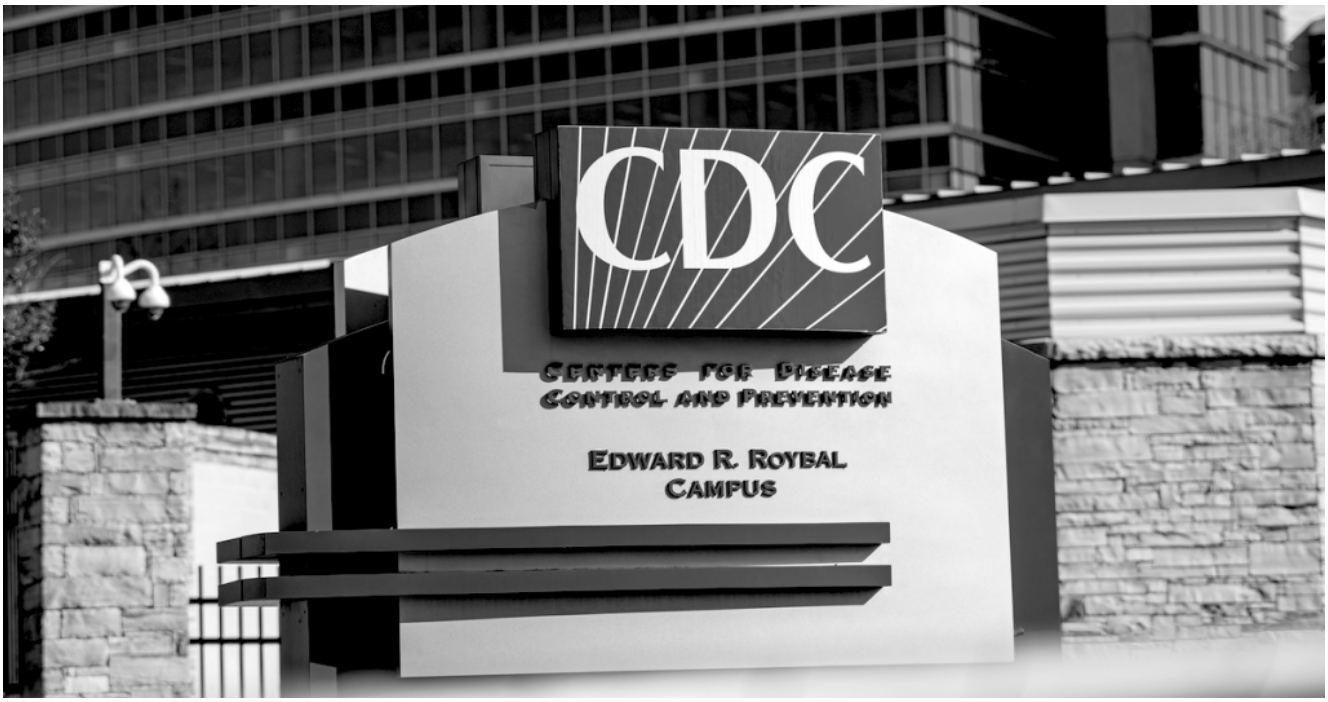
CDC Pressured Regulators to Authorize COVID-19 Boosters Without Clinical Data, Emails Show



The Centers for Disease Control and Prevention (CDC) pressured vaccine regulators to authorize COVID-19 boosters without clinical data, according to emails recently obtained by Judicial Watch.

CDC officials told U.S. Food and Drug Administration (FDA) officials in August 2021 that they wanted to authorize Moderna and Pfizer boosters for emergency use as data was showing vaccines weren't working as well as publicized. The CDC had no data to support the authorization of a third dose, nor had clinical trials been conducted to determine the safety or efficacy of giving people an additional shot.

Judicial Watch received 43 pages of heavily redacted records from the FDA on COVID-19 boosters in response to a February 2022 Freedom of Information Act lawsuit against the

Department of Health & Human Services 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.

In an Aug. 5 email sent by Krause to other FDA officials, he referenced a call where the CDC said it would assemble any data it had to justify a third dose in hopes they would authorize "very soon."

"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," according to the email.

Doran Fink, an official with the FDA's Center for Biologics Evaluation and Research tasked with evaluating vaccines responded:

"FYI – below is an excerpted post from this morning to an infectious diseases message board,
concerning additional doses in immunocompromised patients. I think it accurately reflects more widespread thinking that I am hearing in other forums as well (e.g., the ACIP workgroup). Providers are losing confidence in FDA/CDC to do the right thing for their patients, including that we can't give inquiring parties a straight answer about what they are allowed to do outside of IND."

Dr. Richard Nathan also copied on the email, pointed to other countries, including Israel, who had already cleared boosters and recommended putting trust in Pfizer – a billion-dollar industry that paid the largest healthcare fraud settlement in history – over U.S. health agencies.

"Israel, France, Germany, France, Russia, Hungary and the UK have announced 'booster' shots. Pfizer recommends it and I

trust their guidance over the turmoil at our federal agencies. With millions of doses of vaccine set to expire, you should do what you think is best for your patients. I can't believe you would get pushback from anyone. Keep in mind, nearly everyone in this group is six to seven months out from the second dose of the vaccine and many have significant daily exposure to the virus," Nathan wrote.

"The term booster is wrong in my opinion. We don't think of the third dose in other vaccines such as the Hepatitis B series as a booster. We should think of it as the correct dosing of an mRNA vaccine," he added.

"But it doesn't sound like they actually want to do a study. They just want to vaccinate these people – if I am reading this correctly," Krause replied. The rest of the email was redacted.

Not even two weeks later, the FDA authorized boosters for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, those in certain occupations and the immunocompromised.

The agency said that "a thorough review of the available data" concluded the group "may benefit" from a third dose.

The only data used to support the efficacy of a booster dose were from two studies conducted by French and Canadian researchers. Pfizer and Moderna hadn't completed a single clinical trial.

"As we've previously stated, other individuals who are fully vaccinated are adequately protected and do not need an additional dose of COVID-19 vaccine at this time," Dr. Janet Woodcock, the FDA's top official said.

Just weeks after making that statement, CDC director Rochelle Walensky signed onto a joint statement saying that vaccine protection was waning and that boosters "will be needed to

maximize vaccine-induced protection and prolong its durability."

Top FDA officials speak out against COVID boosters

In an opinion piece published Sept. 2021 in the Lancet, Marion Gruber and Krause, the two senior FDA vaccine officials who stepped down after being pressured to authorize boosters, said current evidence did not support giving boosters to the general population.

The scientists said the benefits of COVID vaccination outweigh the risks, but there could be risks to boosters if they are widely introduced too soon, or too frequently, "especially with vaccines that can have immune-mediated side-effects (such as myocarditis, which is more common after the second dose of some mRNA vaccines, or Guillain-Barre syndrome, which has been associated with adenovirus-vectored COVID-19 vaccines)."

"If unnecessary boosting causes significant adverse reactions, there could be implications for vaccine acceptance that go beyond COVID-19 vaccines. Thus, widespread boosting should be undertaken only if there is clear evidence that it is appropriate," the scientists wrote.

Gruber and Krause emphasized "careful and public scrutiny of evolving data will be needed to assure boosting is informed by reliable science more than politics."

"The message that boosting might soon be needed, if not justified by robust data and analysis, could adversely affect confidence in vaccines and undermine messaging about the value of primary vaccination. Public health authorities should also carefully consider the consequences for primary vaccination campaigns of endorsing boosters only for selected vaccines," they wrote.

In September 2021, Gruber and Krause announced they were leaving the FDA. They were reportedly upset that the Biden administration said adults should get a booster eight months after they received a second dose – prior to boosters undergoing review or receiving approval by the FDA.

Neither Gruber nor Krause believed there was enough data to justify offering booster shots, sources said, and both viewed the announcement, amplified by President Biden, as pressure on the FDA to quickly authorize them.