

# Congress of the United States

Washington, DC 20510

February 13, 2023

Mr. Xavier Becerra  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Robert M. Califf  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Lawrence A. Tabak, D.D.S., Ph.D.  
Acting Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Secretary Becerra, Commissioner Califf, and Acting Director Tabak,

We write to express grave concern regarding a recent video in which a Pfizer employee made troubling claims about the company's research practices and interactions with the Food and Drug Administration (FDA). Project Veritas, a journalism nonprofit, filmed the video during an undercover investigation.<sup>1</sup> In the video, Project Veritas identified the employee as Dr. Jordon Triston Walker, Pfizer's Director of Research and Development, Strategic Operations - mRNA Scientific Planner. Pfizer did not dispute that Dr. Walker holds that position when responding to the video.<sup>2</sup>

Dr. Walker made two alarming claims. First, he claimed that Pfizer is considering conducting "directed evolution" research to improve the efficacy of its COVID-19 vaccine. Dr. Walker's description of directed evolution resembles gain-of-function (GOF) research, which has been the subject of much controversy—with good reason. HHS defines GOF as "*research that improves the ability of a pathogen to cause disease [and] help define the fundamental nature of human-pathogen interactions.*"<sup>3</sup> In other words, GOF research strengthens viruses so that scientists can study their effects and proactively develop countermeasures. Since 2011, such research has been the subject of intense scrutiny by scientists and ethicists.<sup>4</sup> In fact, the NIH placed a moratorium on GOF research funding from 2014 to 2017 after a series of breaches in safety protocol at the NIH and CDC.<sup>5</sup>

Multiple sources suspect that the COVID-19 pandemic began when an enhanced virus leaked from the Wuhan Institute of Virology, where GOF research was being conducted.<sup>6</sup> A few weeks ago, two scientists who previously authored UN reports on COVID-19's origins wrote an op-ed in which they stated, "*on current balance of evidence, a laboratory pathway seems the most likely cause of the pandemic.*"<sup>7</sup> In Project Veritas's video, Dr. Walker states he suspects COVID-19 originated from a lab leak, citing the

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<sup>1</sup> "Pfizer Executive: 'Mutate' COVID via 'Directed Evolution'..." [Project Veritas](#), January 25, 2023.

<sup>2</sup> "Pfizer Responds to Research Claims," [Pfizer](#), January 27, 2023.

<sup>3</sup> "Gain-of-Function Research," [Department of Health and Human Services](#), June 3, 2021.

<sup>4</sup> Talha Burki, "Ban on gain-of-function studies ends," [The Lancet](#), February 2018.

<sup>5</sup> Ibid.

<sup>6</sup> "Fact Sheet: Activity at the Wuhan Institute of Virology," [U.S. Department of State](#), January 15, 2021.

<sup>7</sup> Colin Butler, Delia Randolph, "Our view is that, on current balance of evidence, a laboratory pathway seems the most likely cause of the pandemic," [DailyMail.com](#), January 28, 2023.

virus's potency and rapid spread. Given the possibility that GOF research may have ignited the global pandemic, it is worrying that Pfizer is engaging in research that appears similar in nature.

Dr. Walker's second disturbing claim is that the relationship between major pharmaceutical companies and the FDA is a "revolving door." Below are two quotes in which Dr. Walker expounds on this conflict of interest.<sup>8</sup>

*"So, in the pharma industry, all the people who review our drugs – eventually most of them will come work for pharma companies...It's pretty good for the industry to be honest. It's bad for everybody else in America."*

The undercover interviewer then asks, "Why is it bad?" Jordan continues:

*"Because when the regulators reviewing our drugs know that once they stop regulating, they are going to work for the company, they are not going to be as hard towards the company that's going to give them a job."*

Dr. Walker's description of Pfizer's relationship with the FDA sounds like regulatory capture, in which regulators seek to advance commercial interests rather than the public's interest. If true, regulatory capture of the FDA is troubling for two primary reasons. First, it subordinates public safety to personal gain. If Dr. Walker is correct, some regulators may be sacrificing current safety standards for future employment opportunities.

Second, regulatory capture is fundamentally unfair to smaller companies without the clout to affect agency decisions. Many larger pharmaceutical firms seek to shield their products from the competition by advocating for greater regulation or special exceptions. This shielding increases prices and can limit patient access to new treatments. Dr. Walker's comments help explain why smaller pharmaceutical firms report feeling ignored by the agency. Such a system is patently unfair and is antithetical to the equal enforcement of the law.

In collaboration with the FDA and NIH, we ask that you respond to the following questions:

1. When asked if Pfizer is considering mutating COVID, Dr. Walker said, "One of the things we're exploring is like, why don't we just mutate it ourselves so we could preemptively develop new vaccines ..." Dr. Walker explains that so-called "directed-evolution" research is distinct from gain-of-function research because directed evolution involves doing "selected structure mutations to try to see if we can make [viruses] more potent."<sup>9</sup> Do subject matter experts at the FDA or NIH consider Pfizer "mutat[ing] [SARS-CoV-2] ourselves so we could preemptively develop new vaccines" to be gain-of-function research? If not, please explain the distinction.
2. The U.S. Office of Government Ethics principles states, "Employees shall act impartially and not give preferential treatment to any private organization or individual."<sup>10</sup> What steps have you taken to ensure that all FDA officials treat firms equally, regardless of size or market power?
3. What steps has the FDA taken to guard against regulatory capture and conflicts of interest among its employees?
4. Pfizer's response to the video states that it "has not conducted gain of function or directed evolution research" for its Pfizer-BioNTech COVID-19 vaccine.<sup>11</sup> Are you aware as to whether Pfizer has

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<sup>8</sup> "Pfizer Executive: 'Mutate' COVID via 'Directed Evolution'..." [Project Veritas](#), January 25, 2023.

<sup>9</sup> Ibid.

<sup>10</sup> "14 General Principles," [U.S. Government of Office Ethics](#).

<sup>11</sup> "Pfizer Responds to Research Claims," [Pfizer](#), January 27, 2023.

conducted gain-of-function or directed evolution research for its COMIRNATY® (COVID-19 Vaccine, mRNA) vaccine, which is legally distinct from its Pfizer-BioNTech COVID-19 vaccine?

Sincerely,



Michael S. Lee  
United States Senator



Chip Roy  
Member of Congress



Ted Cruz  
United States Senator



Andy Biggs  
Member of Congress



Ron Johnson  
United States Senator



W. Gregory Steube  
Member of Congress



Eric Burlison  
Member of Congress



Bill Posey  
Member of Congress



Mary Miller  
Member of Congress



Lauren Boebert  
Member of Congress



Bob Good  
Member of Congress