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July 5, 2023

Via U.S. Mail

Fraud Section
Commercial Litigation Branch
U.S. Department of Justice
175 N Street, NE
Washington, DC 20002

Re: Fraud related to the procurement of the Pfizer COVID-19 Vaccine

Dear Sir or Madam:

We write on behalf of our clients, Dr. Naomi Wolf and Daily Clout, to urge the Department of Justice to bring a claim against Pfizer, Inc., for fraud in inducing the United States government to agree to buy Pfizer's mRNA COVID vaccine.

The government declared COVID-19 a national emergency in March 2020. In April 2020, President Trump announced Operation Warp Speed ("OWS"), a joint initiative between the Department of Defense ("DOD") and the Department of Health and Human Services ("HHS"). OWS's goal, according to a government official who spoke to *Science* in May 2020, was to create a vaccine that would "prevent what looks increasingly like a second wave that could sweep come October, November."

According to the *Science* article, the key factors in the government's efforts were "safety and the potential to make hundreds of millions of doses quickly." Many people questioned this effort, with Peter Hotez of the Baylor College of Medicine saying that he did not "see a path by which you can collect enough efficacy and safety data by the end of the year."

Pfizer did not develop its mRNA shot in the United States. It partnered with BioNTEch, a biotechnology company in Germany. But, after learning that the United States government had

offered to buy virtually every dose of a successful vaccine—an offer worth billions of dollars—Pfizer began aggressively marketing its shot to the United States government.

We do not yet have access to the initial communications between Pfizer and government officials, though we have sought them through Freedom of Information Act requests, and they would be available to DOJ investigators. But we know essentially what Pfizer said: it told the United States government that its mRNA shot would prevent people from being infected with the virus that causes COVID-19 and could be developed so quickly—and with so few side effects—that it would bring a swift end to the pandemic. Thus, on July 22, 2020, Pfizer announced that United States government had placed an initial order of 100 million doses (for $1.95 billion), with the option to acquire up to 500 million additional doses (for billions more) (the "Purchase Agreement"). A copy of the agreement, dated July 21, 2020, is attached to this letter as Exhibit "A."

The Purchase Agreement reflected the material misrepresentations we believe Pfizer had made to the United States government during the procurement, including the key statement that the Pfizer shot was "aimed at preventing COVID-19 infection …." (Exhibit A, at p. 3 [Statement of Work].)

Of course, the agreement was conditioned on Pfizer getting FDA approval for its shot. That occurred after the parties signed the Purchase Agreement. Thus, Pfizer had a continuing duty to be truthful to the government when seeking FDA approval and, if it received approval, when rolling the shot out to the American public. During this critical period, from August 2020 through the fall of 2021, Pfizer made numerous material misrepresentations to DOD and HHS officials, among others (including White House officials), about the safety and efficacy of its COVID shot.

For example, when seeking emergency use authorization from the FDA in December 2020, Pfizer said its shot was "95 percent effective" in preventing COVID-19. But of the 40,000-plus people who participated in Pfizer's trial, thousands contracted COVID-19. Some of the vaccinated people even contracted COVID-19 and got seriously ill or died from it. Pfizer simply excluded those people from the data it reported to the FDA. It also manipulated the data by creating a small focus group of 170 people whose results gave Pfizer the 95 percent efficacy figure it knew the government was looking for.

Pfizer received more accounts of vaccine failure after the FDA presentation, including thousands of vaccine recipients who contracted COVID-19 in late 2020 and early 2021, as Pfizer began administering the vaccine across America. Pfizer had a contractual and common law duty to disclose this data to the government, but doing so could have cost it billions of dollars, so it withheld and manipulated the data until the government had purchased so much of Pfizer's shot—and committed to universal COVID vaccination as a national public health policy—that it was impractical for the government to cancel the Purchase Agreement.

Moreover, Pfizer's phase 3 trial was supposed to compare the vaccine group to the control group for two years to measure the true effectiveness and safety of the shot. But Pfizer eliminated most of the control group after four months by vaccinating those who had received the placebo injection. It did that to eliminate data that could undermine its vaccine rollout and

prevent Pfizer from getting the billions of dollars the United States government had committed under the Purchase Agreement.

Pfizer also withheld and manipulated data about the shot's safety. For example, by early 2021, Pfizer had received numerous reports of myo-pericarditis in people shortly after they received the COVID shot. Pfizer did not report that data to the government. It also withheld other reports of side effects during the first few months of the vaccine rollout. Indeed, Pfizer received so many reports of side effects during the vaccine rollout that it had to hire 2,400 additional people to process the paperwork. Despite receiving these tens of thousands of reports of side effects—some serious—Pfizer told the government that "no new safety signals or vaccine lack of efficacy have emerged …."

Similarly, during the first three months of the vaccine rollout, at least 270 pregnant women reported a vaccine injury. Inexplicably, Pfizer only followed 32 of them, a startling low figure. Even then, 28 of those 32 babies died, a shocking 87.5 percent. Pfizer did not report that data from the government. (As a general matter, Pfizer withheld and concealed data about the shot's effect on pregnant women from the government because it was so damaging to the "safe and effective" mantra).

Other examples of Pfizer's fraud abound. Our clients have spent months studying them and would be happy to share them with you.

The FDA relied on these misrepresentations and omissions when it approved the Pfizer shot for emergency use on December 11, 2020. The United States government further relied on these misrepresentations and omissions when it fulfilled its initial purchase of 50 million COVID shots and, between December 2020 and October 2021, when it purchased an additional 550 million doses of the shot. These purchases cost American taxpayers more than $5 billion. They were based on lies, statements and data that Pfizer knew were false—or, at minimum, misleading—and which Pfizer intended that the United States government rely on when entering into the Purchase Agreement and fulfilling the billions of dollars in purchases under it.

Those actions are unlawful. The False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, provides that any person who knowingly submits, or causes to submit, false claims to the government is liable for three times the government's damages plus a penalty linked to inflation. The DOJ has recovered tens of billions of dollars in such claims, which often involve health care. Although most often used against fraudulent billing practices, a False Claims Act claim can be based on fraud in the inducement. Under this theory, a contractor is liable "for each claim submitted to the Government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *United States ex rel. Bettis v. Odebrecht Contractors of Cal., Inc.*, 393 F.3d 1321, 1326 (D.C. Cir. 2005). This doctrine applies both when "a party makes promises at the time of contracting that it intends to break" and when the party's false statements "induced the government to make the initial contract or caused it to agree on particular contract terms or modifications." *United States v. DynCorp Int'l*, LLC, 253 F. Supp. 3d 89, 105 (D.D.C. 2017) (quotations and citations omitted).

The latter applies here. Put simply, Pfizer made numerous misrepresentations, and failed to disclose material facts, that induced the United States government to enter the Purchase

Agreement and to spend more than $5 billion in taxpayer money on shots that did not do what Pfizer said they would do. Pfizer defrauded the government, plain and simple. It defrauded the American public. And it knew what it was doing. At minimum, the evidence our clients have gathered shows Pfizer acted with reckless disregard for the truth when making statements about the safety and efficacy of its COVID shot to government officials between 2020 and 2022. That is enough to satisfy the False Claims Act's scienter requirement. *See id.* at 108 (noting that "knowledge for False Claims Act purposes includes deliberate ignorance or reckless disregard for the truth or falsity of information"); *see also United States ex rel. Anita Silingo v. WellPoint, Inc.*, 904 F.3d 667, 679–80 (9th Cir. 2018) (noting that this element may be alleged generally and that official corporate statements are sufficient to plead it).

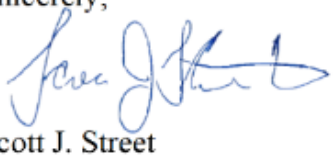
In sum, our clients have developed significant evidence that Pfizer defrauded the United States government in procuring the Purchase Agreement. It defrauded the government—and American taxpayers—of more than $5 billion in purchases under that agreement. Those actions violate the False Claims Act and give the United States a common law claim for unjust enrichment. *See United States ex rel. Shemesh v. CA, Inc.*, 89 F. Supp. 3d 67, 80-81 (D.D.C. 2015) (holding that such claims can be alleged in false claims case based on fraud in the inducement).

The COVID-19 pandemic may be over, but Americans are still dealing with the damage it caused. Forcing Pfizer to disgorge the billions of dollars it made off its fraudulent COVID shot is a key step in that recovery. It will compensate American taxpayers and send a message to companies who seek to profit, unjustly, off national emergencies.

That is why Congress passed the False Claims Act in the first place. The law dates to the Civil War (when it was called "Lincoln's Law"). It was enacted to address rampant profiteering by government contractors who defrauded the government during that national emergency. The most recent national emergency was no different. If anything, given COVID's global scope and the vast amounts of money governments were willing to spend to address it, the opportunities for fraud were greater. The government's response should match it.

Thank you for your time and attention to this matter. We look forward to working with you.

Sincerely,



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