IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ERICH SMITH, FRANK E. GARWOOD, JR., MARIBEL LORENZO and DR. DANIEL DONOFRIO Plaintiffs, vs. PRESIDENT JOSEPH R. BIDEN, JR. (in his official capacity and any successor to the Office of the President) Defendants.	The Honorable Judge Christine P. O'Hearn and The Honorable Judge Sharon A. King CIVIL ACTION NO: 1:21-cv-19457-CPO-SAK **DECLARATION OF COUNSEL IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**

BRIEF IN SUPPORT OF APPLICATION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Oral Argument Requested if opposed.

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PRELIMINARY STATEMENT

On September 9, 2021 President Joseph Biden ("the President") gave a national speech announcing that he had divided Americans into two groups for government-mandated differential treatment. The two groups, "the vaccinated" and "the unvaccinated" are, at their core, just people who made different personal healthcare decisions in the face of a novel virus, novel pharmaceuticals, a chaotic government response, and dueling information sources. The people of both groups have made the decisions they believe are right for their bodies and their lives, and both are reasonable.

The President disagrees. The President's speech scapegoated the unvaccinated, blaming them for a host of societal ills:

- He accused them of hogging healthcare resources and taking hospital beds away from others, stating "[t]he unvaccinated overcrowd our hospitals or overrun the emergency rooms and intensive care units, leaving no room for someone with a heart attack or pancreatitis or cancer." Dkt. 2-1 at pg. 1;
- He implied that the unvaccinated are a danger from which others must be protected, stating "[w]e're going to protect vaccinated workers from unvaccinated co-workers." Dkt. 2-1 at pg. 2.

- He blamed the unvaccinated for impending economic problems: "We cannot let unvaccinated do this [economic] progress — undo it." Dkt. 2-1 at pg. 5;
- He labeled the unvaccinated as "those blocking public health." Dkt. 2-1 at pg. 6;
- He stated that the unvaccinated are causing "a lot of damage." Dkt. 2-1 at pg. 2; and
- He blamed the unvaccinated group for Covid-19 still existing, stating: "This is a pandemic of the unvaccinated...caused by the fact that...we still have nearly 80 million Americans who have failed to get the shot." Dkt. 2-1 at pg. 1.

The President condoned strong negative emotions of "anger" and "frustration" from vaccinated Americans, a group in which he includes himself, toward unvaccinated Americans stating:

- "I understand your anger at those who haven't gotten vaccinated." Dkt. 2-1 at pg. 7;
- Many of us are frustrated with the nearly 80 million Americans who are still not vaccinated." Dkt. 2-1 at pg. 1; and
- Warning "We've been patient, but our patience is wearing thin. And your refusal has cost all of us." Dkt. 2-1 at pg. 3.

After blaming the unvaccinated group for societal ills and condoning negative feelings toward them, the President announced that he will coerce them into undergoing a medical procedure to become vaccinated by excluding them from two-thirds of the work force, which he claims is under his authority as President.

Never before in history has a president claimed the legal or moral authority to force American workers to submit to a medical procedure, let alone a novel and experimental medical procedure, on the threat of losing their means of income.

There is no such authority. The Mandates, on their face and as implemented, violate *at least* three Amendments to the United States Constitution: the Tenth, the Fifth, and the First. The Mandates are an unprecedented and unsupported assertion of government power into individual personal healthcare decisions.

The President claims this sweeping authority over peoples' bodies based on bureaucratic regulatory duties delegated to the executive branch by Congress. He also claims authority in the Constitution, though he has not shared where his purported constitutional authority is in the actual document. It is Plaintiffs' position that there is no such authority. However, even if there were such authority, the Mandates cannot stand because they violate the substantive due process clause of the Fifth Amendment by intruding on Plaintiffs' fundamental rights to liberty and privacy.

STATEMENT OF FACTS

A. The Mandates

Executive Order 14043 ("the Employee Mandate") requires all federal employees to undergo either one injection of a DNA viral vector pharmaceutical manufactured by Johnson and Johnson ("J&J") or two injections of mRNA pharmaceuticals manufactured by Pfizer Inc. ("Pfizer") or Moderna. Dkt. 2-20. Executive Order 14042 requires the same of any person who is even remotely connected to a federal contract or subcontract to provide services to the federal government. ("the Contractor Mandate"). Dkt. 2-22. The Contractor Mandate includes people who are *not* working on a federal contract or subcontract but who work in the same location or campus as other people who are working on such a contract.[1] Dkt. 2-23 at 11. Only "legally required" exemptions are permitted. Dkt. 2-23 at 1. People who work entirely remotely are still required to submit to injection. Dkt. 2-23 at 11. People who are immune through recovery are still required to submit to the injection. Dkt. 2-23 at 10.

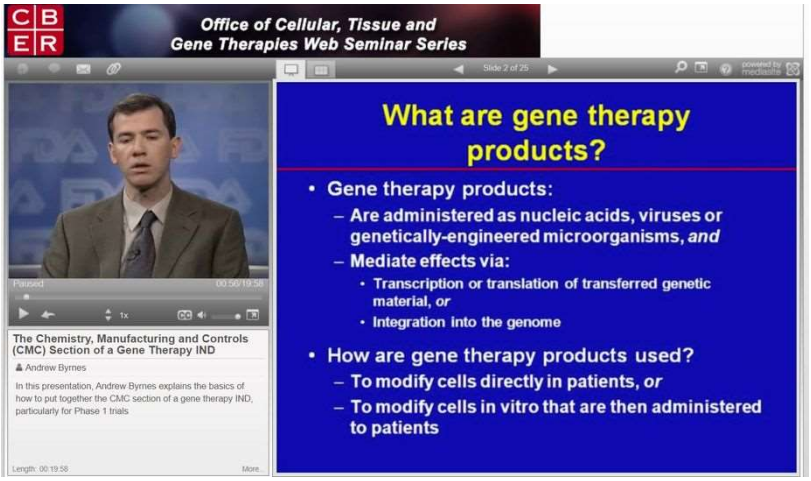
[1] Employees who are not themselves connected to a federal contract in any way, but work at the same location as employees who are connected to a federal contract must submit to injection if there is any chance they will cross paths with employees who are connected to the federal contract, even in lobbies or parking garages. Dkt. 2-23 at 10.

B. Nomenclature and the Mandated Pharmaceuticals

The stakes here are high. The federal government is attempting to coerce Plaintiffs into undergoing an irreversible medical procedure that they do not want or else lose their jobs and become ineligible for two-thirds of all American jobs. The question of *what* the mandated pharmaceuticals are, and specifically whether they are "vaccines" under relevant statutory or dictionary definitions, is a key question in ongoing litigation concerning local and university mandates. This question is key because courts are assuming that the Food and Drug Administration's labeling of these pharmaceuticals as "vaccines" compels courts to analyze mandates under rational basis due to the precedent of *Jacobson v. Massachusetts*, 1987 *U.S.* 11 (1905). However, if the pharmaceuticals are not "vaccines," then they are medical procedures and state and local government entities trying to mandate people take them must survive strict scrutiny.

These mandated pharmaceuticals do not fit the definition of any relevant statutory definition of "vaccine." They are also excluded from most dictionary definitions of "vaccine" because they are not comprised of microorganisms or pieces of microorganisms. They do, however, fit perfectly within the FDA definition of gene therapy products. The Office of Cellular, Tissue, and Gene Therapies defines gene therapy products by their composition and mechanism of action. The composition is:"nucleic

acids, viruses or genetically-engineered microorganism and the mechanism of action is to "mediate effects via: transcription or translation of the transferred genetic material..."



All three of the mandated pharmaceuticals meet both the composition and mechanism of action in this definition. The Pfizer and Moderna products are administered as synthetic RNA, which is a nucleic acid, and mediate effects by translation of that nucleic acid into a spike protein. Dkt. 2-3 at 2. Moderna's S-1 statement confirms that the FDA regulates mRNA products as gene therapy products. Dkt. 2-4 at 2. The J&J product is administered as DNA, which is a nucleic acid, and mediates effects by transcription of that DNA into mRNA and then translation of the mRNA into the spike protein. Dkt. 2-3 at 2-4. For purpose of accuracy and consistency the mandated pharmaceuticals are referred to herein as "gene therapy products" or "GTPs."[2]

[2] Though the term "gene therapy products" sometimes evokes thoughts of science fiction and conspiracy theories, federal courts are becoming familiar with handling all manner of disputes involving

C. Plaintiffs

Plaintiffs Erich Smith, Frank Garwood, and Dr. Daniel Donofrio are all federal employees and subject to the Employee Mandate. Dkt. 2 at ¶ ¶92, 93, 95. Plaintiff Maribel Lorenzo works for a private health insurance company that has federal contracts and she is subject to the Contractor Mandate. *Id.* at ¶94. The Plaintiffs do not want to take any of the GTPs for a range of personal reasons. All have been faithful employees to the government and their employers. All are now at risk of becoming unemployed and unemployable in two-thirds of existing jobs.

LEGAL ARGUMENT

THE MANDATES SHOULD BE ENJOINED BECAUSE THEY VIOLATE THE FIFTH AMENDMENT TO THE U.S. CONSTITUTION

A temporary injunction or restraining order should be granted when (1) the plaintiff is likely to succeed on the merits; (2) denial will result in irreparable harm to the plaintiff; (3) granting the injunction will not result in irreparable harm to the

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gene therapy products including securities fraud litigation concerning statements about gene therapy products, *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 42 (1st Cir. 2017), security class actions, *Tadros v. Celladon Corp.*, No. 15CV1458 AJB (DHB), 2016 WL 5870002, at *1 (S.D. Cal. Oct. 7, 2016), aff'd, 738 F. App'x 448 (9th Cir. 2018), wrongful death actions, *Mohr v. Targeted Genetics, Inc.*, No. 09-3170, 2009 WL 4021153, at *1 (C.D. Ill. Nov. 18, 2009), litigation concerning licensure of GTPs, *Families of Spinal Muscular* Atrophy v. Nationwide Children's Hosp., No. 16-CV-4262, 2016 WL 4987944, at *2 (N.D. Ill. Sept. 19, 2016), and patent infringement cases. *Wilson Wolf Mfg. Corp. v. Sarepta Therapeutics, Inc.*, No. CV 19-2316-RGA, 2020 WL 7771039, at *1.

defendant; and (4) granting the injunction is in the public interest. *Maldonado v. Houstoun,* 157 F.3d 179, 184 (3d Cir. 1998).

Plaintiffs fulfill each element. The Mandates violates the Due Process clause of the Fifth Amendment because they intrude on Plaintiffs' fundamental rights of liberty and privacy rights to make their own healthcare decisions and decline unwanted medical procedures.

I. STRICT SCRUTINY IS THE CORRECT LEVEL OF ANALYSIS

The right of a free and mentally competent person to decline unwanted medical procedures is well-established as essential to the ordered concept of liberty and the individual right to privacy. People have the right to decline even lifesaving medical care. This applies to taking things out of a person's body against their will. *In re A.C.,* 573 A.2d 1235 (D.C. Court of Appeals 1990) (c-section cannot be performed without consent, even to save life of baby); *Lane v. Candura*, 376 N.E.2d 1232 (Mass. App. Ct. 1978) (patient cannot be forced to undergo amputation even if they will likely die without it). It applies to putting things into a person's body against their will. *Zant v. Prevatte*, 286 S.E.2d 715 (Ga. 1982) (prisoner right to refuse food), *Erickson v. Dilgard,* 252 N.Y.S. 2d 705 (Special term 1962) (competent adult has liberty to refuse blood transfusion even if it may cause their death). It applies no matter how unreasonable or illogical the refusal. It

applies even if children will be left without a parent. *In re Osborne*, 294 A.2d 372 (D.C. Court of Appeals 1972).

The right to decline medical procedures is fundamental as it falls squarely within the right to bodily integrity under the Fifth and Fourteenth Amendments.[3] This triggers strict scrutiny. *Harris v. McRae*, 448 U.S. 297, 312 (1980) (stating that "[i]t is well settled that...if a law impinges upon a fundamental right explicitly or implicitly secured by the Constitution [it] is presumptively unconstitutional").

The right to exercise personal choice over medical decisions concerning one's body also falls within the privacy interests protected by the substantive due process clause, specifically "the individual interest in avoiding disclosure of personal matters and the interest in independence in making certain kinds of important decisions." *Doe by & through Doe* v. *Boyertown Area Sch. Dist.*, 897 F.3d 518, 527 (3d Cir. 2018)(citing *Doe v. Luzerne County*, 660 F.3d 169, 175 (3d Cir. 2011)).

Here, the Mandates condition Plaintiffs' employment, and broad employability, on surrendering their constitutional right to decline medical procedures. This violates the doctrine of

[3] The Supreme Court has noted that the due process clauses of the 5th and 14th Amendment operate in the same manner. *DeShaney v. Winnebago Cty. Dep't of Soc. Servs.*, 489 U.S. 189, 196 (1989) (stating that "[l]ike its counterpart in the Fifth Amendment, the Due Process Clause of the Fourteenth Amendment was intended to prevent government from abusing its power, or employing it as an instrument of oppression") (internal citations omitted).

unconstitutional conditions, which prohibits the government from conditioning a benefit or privilege on the surrender of a constitutional right. *Frost v. Railroad Commission of State of California,* 271 *U.S.* 583 (1926). The doctrine applies to government benefits like tax exemptions, unemployment benefits, welfare, and public employment. *Perry v. Sindermann*, 408 *U.S.* 593, 59 (1972) (internal citations omitted).

Here, the Mandates seek to force Plaintiffs to undergo a medical procedure, specifically to be injected with a GTP, to keep their public employment. This imposes an unconstitutional condition on the exercise of Plaintiffs' fundamental right to decline medical procedures, so strict scrutiny applies.

II. THE MANDATES FAIL UNDER STRICT SCRUTINY ANALYSIS

To survive strict scrutiny, the government must demonstrate a compelling government interest and that the government action is narrowly tailored to achieve that interest. *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (stating that "the Fourteenth Amendment 'forbids the government to infringe ... 'fundamental' liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest") (quoting *Reno v. Flores*, 507 U.S. 292, 301 (1993)).

The government's asserted interests must be balanced and weighed against the seriousness of the intrusions on Plaintiffs'

liberty and privacy. *Wisconsin v. Yoder*, 406 U.S. 205, 214 (1972) (stating that with balancing, the government interest must be "of sufficient magnitude to override the interest claiming protection"). The policy also must be narrowly tailored to achieve the government's asserted interests.

A. The Government's Asserted Interests

The President asserts a few very broad state interests that are purportedly served by the Mandates. In EO 14043 (the Employee Mandate") the President set forth three interests furthered by the Mandates:

- To "halt the spread of coronavirus disease 2019";
- To "promote the health and safety of the Federal workforce and the efficiency of the civil service"; and
- To prevent the unvaccinated from "spreading COVID-19 to their co-workers and members of the public."

Dkt 2-20 at 1.

In EO 14042 (the Contractor Mandate), the President sets forth two state interests purportedly furthered by the Mandates:

- To "promote economy and efficiency in procurement by contracting with sources that provide adequate COVID-19 safeguards for their workforce"; and
- To "decrease the spread of COVID-19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites

where they are performing work for the Federal Government."

Dkt. 2-21 at 1.

The President seeks to further these state interests through coerced medical procedures because the Centers for Disease Control ("the CDC") "has determined that the best way to slow the spread of COVID-19 and to prevent infection by the Delta variant or other variants is to be vaccinated." *Id.*

Last year, the Supreme Court stated that "California undoubtedly has a compelling interest in combating the spread of COVID-19 and protecting the health of its citizens." *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1614 (2020). For purposes of this motion, it is assumed the government has this compelling interest.[4]

B. Plaintiffs' liberty and privacy rights are stronger and more compelling than the governments' interests

Weighing the government's interest against the serious intrusion on Plaintiffs' liberty and privacy rights shows that the Mandates are unconstitutional.

[4] Plaintiffs do not concede that the President has stated a compelling interest and maintain that the strength of the state's interest may be different now than it was in May 2020 at the height of the pandemic when no vaccines were available and much was unknown about the virus. This is especially true when the President himself has stated: "The path ahead, even with the Delta variant, is not nearly as bad as last winter." Dkt. 2-1 at 2.

Plaintiffs' liberty and privacy rights to decline an unwanted medical intervention are extremely strong when: 1) the mandated pharmaceutical's ability to stop infection and transmission is uncertain or unknown; 2) the pharmaceuticals are novel themselves *and* are produced and delivered *via* a novel technology; 3) being injected with the pharmaceuticals carries risk; 4) the CDC's own data shows that the vast majority of people experience symptoms of illness after taking the pharmaceuticals; 5) the pharmaceuticals are all manufactured by corporations with either extensive criminal records and product safety failures or *no* track record having never brought a product to market before; and 6) the agency tasked with overseeing the safety of the pharmaceuticals has a public image of failing in its mission due to actual high-profile failures to keep people safe.

The government's interest in coercing the medical procedure to stop the spread of a virus is less compelling when: 1) there exists a wide range of treatments for the targeted virus; 2) the virus has an objectively low mortality rate, especially among people who are pre-retirement age who are targeted by the Mandates; and 3)the federal government has navigated other viruses throughout history without these measures.

The Mandates are not narrowly tailored because: 1) there are many other methods available to slow the spread of Covid and 2) the Mandates do not account for immunity, only "vaccination."

Each of these factors is discussed in more detail below.

1. The uncertainty concerning the GTPs' efficacy and duration of protection weighs against the Mandates

Much is unknown concerning the GTPs' efficacy and duration of protection.

The corporations manufacturing the GTPs do not know how long protection lasts. The "Fact Sheets for Recipients and Caregivers" for each GTP states that "the duration of protection against Covid-19 is currently unknown." Dkt. 2-5 at 4; Dkt. 2-6 at 3; Dkt. 2-7 at 3.

The government also does not know how long immunity from the GTPs lasts or their efficacy against new variants. Information is coming out in real time and government officials are even issuing conflicting information at times. For example, in April CDC Director Dr. Rochelle Walensky stated that data suggests "[v]accinated people do not carry the virus — they don't get sick." Exhibit 1 to Declaration of Dana Wefer, Esq. ("Wefer Decl."). However, a CDC spokesperson walked back the claim later that day stating "[i]t's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. *We are continuing to evaluate the evidence*." *Id.* Three months later, the CDC announced that more recent data shows vaccinated and unvaccinated people carry similar viral loads, which "suggest[s] an increased risk of transmission." Exhibit 2 to Wefer Decl. Now the CDC and FDA have recommended

booster shots for many people and CDC Director Walensky has suggested that the definition of "fully vaccinated" may change stating "[w]e have not yet changed the definition of 'fully vaccinated.' We will continue to look at this. We may need to update our definition of 'fully vaccinated' in the future." Exhibit 3 to Wefer Decl.

The fact that GTP efficacy and duration is unsettled, and may be as short as six months, weighs heavily in favor of Plaintiffs' right to decline them and against the government coercing it. The fact that people who have received the GTPs may still get and transmit Covid-19, undermines any state interest in Mandating Plaintiffs to be injected with them.

2. The experimental and novel nature of the GTPs themselves and the technology they use favor Plaintiffs' liberty to decline them

The GTPs have been given to the general population for less than a year and clinical trials are ongoing. Gene Therapy technology has never before been tested on or approved for widespread use in healthy humans. These pharmaceuticals are still investigational and Plaintiffs' right to decline novel or experimental pharmaceuticals is very strong.

3. The fact that the GTPs carry risk weighs in favor of the individual liberty to decline it

As part of informed consent, people receiving a GTP are required to be given a "Fact Sheet for Recipients and Caregivers." The Fact Sheets for the Pfizer and Moderna GTPs list several risks,

including myocarditis and pericarditis, which the CDC has stated is elevated in young men. Exhibit 4 to Wefer Decl. The Fact Sheet for the J&J GTP warns that "[b]lood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets," and Guillian Barre syndrome have occurred in some people. Dkt. 2-7 at 3-4. The fact sheets for all the GTPs state that "Serious and unexpected side effects may occur" and the "vaccine" is "still being studied in clinical trial." Dkt. 2-5 at 5; Dkt. 2-6 at 3; Dkt. 2-7 at 4.

Notably, the serious injuries of myocarditis, pericarditis, and blood clots were discovered *after* the GTPs had already been administered to people and people had suffered those injuries. The "other serious side effects [that] may occur" will be discovered by unlucky people in the same manner. There are known and unknown physical risks.

There have also been many reports of girls and women experiencing abnormal vaginal bleeding after receiving the GTPs. The NIH is researching the cause. Exhibit 5 to Wefer Decl. Currently the cause is unknown because the GTPs are experimental.

Finally, because the government is treating the GTPs as vaccines, adverse events are subject to the Vaccine Adverse Event Reporting System ("VAERS") reporting. VAERS was created by Congress in 1990 as "a national early warning system to detect

possible safety problems in U.S.-licensed vaccines."[5] The early warning system is throwing up red flags. People have reported more injuries to VAERS from the GTPs than all other injuries combined for the entire 21 year history VAERS has existed, more than 818,042 reports as of October 28, 2021, including 17,000 deaths.[6] Moreover, due to underreporting, these numbers are likely low.[7]

There is clearly *some* risk to these injections. The only other instance in which the federal government can force free people to risk the well-being of their body to further a government interest is explicitly granted to the legislative branch of government in the Constitution. Specifically, Congress has the power to raise an army and send that army to war. Other than that, there is no other authority granted to government to intrude on the liberty of a free citizen, not accused of any crime, and require them to do something with their body that carries a risk of death or permanent disability. If a federal government entity wishes to compel people to take a risk with their body the interest must be compelling enough to override the individual liberty and privacy interest to decline the risk.

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[5] https://vaers.hhs.gov/about.html

[6] https://www.openvaers.com/

[7] Department of Health and Human Services, *Guide to interpreting VAERS data*, (undated) available at https://vaers.hhs.gov/data/dataguide.html (last accessed September 7, 2021) (stating that "'Underreporting' is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events")

Here, it is not. Moreover, the urgency of the individual liberty to avoid this risk is heightened because individuals have no recourse against the product manufacturers or the government if they are injured. This is because the manufacturers have been granted legal immunity for harm caused by their product[8] and the government has sovereign immunity.

4. The fact that the GTPs are likely to make individuals ill in the short term weighs in favor of Plaintiffs' liberty to decline them

According to data provided by the CDC, most people experience short-term symptoms of illness after the injections including headache, fatigue, fever, muscle ache and chills. 82.8% of the participants between the ages of 18 and 55 in Pfizer's clinical trials experienced at least one of these symptoms, 81.9% of the Moderna and 61.5% of the J&J participants in that age range. Dkt. 2-8 at 3; Dkt. 2-9 at 2; Dkt. 2-10 at 1.

The fact that an individual is more likely than not to experience symptoms of illness after the procedure favors the individual right to decline the procedure. It is impossible that the Constitution forbids the government from forcing an ill person to take something that will make them well, but permits the government to force someone who is well to take something that

[8]HHS, PREP Act Immunity from Liability for COVID-19 Vaccinators, (last reviewed April 2021) available at https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pages/PREP-Act-Immunity-from-Liability-for-COVID-19-Vaccinators.aspx

will likely make them ill. That would be a logical and moral absurdity.

5. The fact that the GTPs are manufactured by corporations with either extensive criminal records or no track record at all weighs in favor of the individual right to decline the pharmaceuticals

Of the three corporations manufacturing the GTPs, two (Pfizer and J&J) have extensive track records of criminality, fraud, and product safety issues. The third, Moderna, has no track record at all, having never brought a product to market.

Pfizer, J&J, and their subsidiaries have pled guilty to felony and misdemeanor criminal violations of an astonishing range of statutes including the Food, Drug and Cosmetics Act, the False Claims Act, and the Foreign Corrupt Practices Act. A jury also found that Pfizer violated the Racketeering Influenced and Corrupt Organizations Act. Wefer. Decl. Exhibit 6. Pfizer's underlying criminal and unethical actions include (but are not limited to): feloniously misbranding drugs with intent to defraud or mislead, illegally promoting drugs, submitting false claims to the government, paying kickbacks to doctors, withholding evidence about faulty medical products, falsifying records to cover up unsafe manufacturing practices, and testing an experimental drug on children in Nigeria. Dkt 2-11, 2-12, 2-13, 2-14. In addition to criminality, Pfizer has been the subject of many high-profile drug safety scandals, most famously Bextra and Celebrex, which were both recalled due to safety issues.

J&J and its' subsidiaries' records of criminality and deception may exceed Pfizer's. Highlights include: causing children's medicine contaminated with metal to enter commerce and attempting to cover up the contamination without informing the public, obstructing justice and "corruptly persuading others" to shred evidential documents, numerous instances of illegally marketing drugs, submitting false claims to the government, and paying kickbacks to doctors, pharmacists, and nursing homes. Dkt. 2-15, 2-16, 2-17, 2-18, 2-19. J&J has also been the subject of several high profile drug safety scandals, the most recent involving billions of dollars in civil awards to plaintiffs alleging that J&J knew its baby powder might be contaminated with cancer-causing asbestos and covered it up.[9]

The shocking backgrounds of these corporations weighs in favor of the individual liberty to decline being injected with products they manufacture.

6. The fact that the federal agency tasked with ensuring pharmaceutical safety is plagued by scandals and failures directly related to the agency's ability to protect the public from unsafe pharmaceuticals favors the individual liberty to decline the GTPs.

Whistleblowers, industry experts, and even U.S. Senators have been warning the public for more than a decade that the FDA is not

[9]Roni Caryn Rabin and Tiffany Hsu, *Johnson & Johnson Feared Baby Powder's Possible Asbestos Link for Years*, New York Times (December 14, 2018) available at https://www.nytimes.com/2018/12/14/business/baby-powder-asbestos-johnson-johnson.html

working properly. High profile drug recalls, high profile class action lawsuits, and commercials that begin "Have you or a loved one taken [FDA-approved pharmaceutical]?" reflect this reality in everyday life.

In 2007, Senator Chuck Grassley testified before the House Oversight Committee concerning what he had learned in his oversight of the FDA while Chairman of the Senate Finance Committee. His testimony details ineptitude and perversion of purpose. He identified four "systemic" problems with the FDA:

> First, scientific dissent is discouraged, quashed, and sometimes muzzled inside the Food and Drug Administration. Second, the FDA's relationship with drug makers is too cozy. The FDA worries about smoothing things over with industry much more than it should with its regulatory responsibilities. Third, inside the FDA there's widespread fear of retaliation for speaking up about problems. And fourth, the public safety would be better served if the agency was more transparent and forthcoming about drug safety and drug risks.

Exhibit 7 to Wefer Decl.

The corruption of the pharmaceutical industry and failures of the FDA are so notorious that the Edmund J. Safra Center for Ethics at Harvard University sponsored a fellowship for Dr. David W. Light that specifically focused on researching "the historical roots of institutional corruption in the development of prescription drugs and its consequences." Exhibit 8 to Wefer Decl. In his year there, Dr. Light wrote prolifically on various topics concerning corruption in the pharmaceutical sector, including the FDA. In one

article titled "Risky Drugs: Why The FDA Cannot Be Trusted," Dr. Light argued that financial conflicts of interest have had a corrupting influence on the FDA:

> since the [pharmaceutical] industry started making large contributions to the FDA for reviewing its drugs, as it makes large contributions to Congressmen who have promoted this substitution for publicly funded regulation, the FDA has sped up the review process with the result that drugs approved are significantly more likely to cause serious harm, hospitalizations, and deaths. New FDA policies are likely to increase the epidemic of harms.

Exhibit 9 to Wefer Decl. Dr. Light closes the article with advice to readers that "[e]xperienced, independent physicians recommend not to take a new drug approved by the FDA until it is out for 7 years, unless you have to, so that evidence can accumulate about its real harms and benefits." *Id.*

Many people have personally been hurt by FDA failures, including Plaintiff Maribel Lorenzo. Dkt. at ¶94. Enough information has percolated to the surface of public awareness through personal experience and publically available information that it is reasonable for people to distrust the federal agency's ability to keep people safe from harmful pharmaceuticals. People have the liberty to distrust the FDA in their minds and should not be coerced to submit their bodies against their will on the word of the very federal agency they distrust.

7. The Mandates' failure to account for natural immunity shows that the Mandates are not narrowly tailored

People who recover from Covid-19 develop robust and broad immunity that protects them from reinfection. Exhibit 11 to Wefer Decl. A study funded by the National Institute of Health and National Cancer Institute and published in the journal Science found that "more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection." Exhibit 10 to Wefer Decl. Another study published in Science found that the naturally immune produce an array of antibodies that are resistant to every Sars-Cov2 variant in circulation at the time the study was published, including delta.[10]

It is strange that the concept of natural immunity is totally absent from both the Employee Mandate and the Contractor Mandate. In fact, the words "immune" and "immunity" *do not appear once* in either Mandate or in the President's speech announcing the Mandates. The fact that people who become sick from a virus and subsequently recover develop natural immunity is well-established. Indeed, in 1997, this very district acknowledged, under a section the Judge titled "*Basic Principles of Virology*" that

> When a higher organism such as an animal or human is exposed to a virus and its cells become viral hosts, the animal or human develops a natural immunity. This immune response operates at two levels: first, at the

[10] Lingshu Wangu, *Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants* Science, Vol. 373 Issue 6556 (August 13, 2021) available at https://science.sciencemag.org/content/373/6556/eabh1766

> initial stage of the infection before the virus has invaded the host and second, after the virus has invaded. When the virus stimulates certain specialized cells, these cells produce antibodies which prevent future infection.

Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp., 984 F. Supp. 239, 243 (D.N.J. 1997). The fact that natural immunity is totally absent from the President's Mandates is notable and shows that the Mandates are not narrowly tailored because they are overinclusive.

8. The wide range of treatments available for Covid-19 undermines the government's interests and shows that the Mandates are not narrowly tailored

Most people who contract Covid-19 require no treatment and are given no treatment. For people who need treatment, there are no fewer than eight FDA authorized treatments available.[11] The availability of multiple treatments undermines the government's interest in mandating a prophylactic pharmaceutical of questionable efficacy.

9. Covid-19's low infection fatality rate even without treatment, weighs in favor of Plaintiffs' liberty and privacy rights to decline the medical procedure

To balance the state and individual interests, it is not necessary to know the exact infection mortality rate of Covid.

[11] FDA, Emergency Use Authorization (listing authorized therapeutics under Drug and Biological Therapeutic Products, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#Coviddrugs (last accessed September 7, 2021)

Viruses have a range of mortality rates ranging from 100% fatal (rabies)[12] to essentially zero. Smallpox had a mortality rate of up to 30%.[13] The government's interest in stemming the spread of viruses through coerced medical procedures is logically more compelling with more fatal viruses and less compelling with less fatal viruses.

The CDC has not released an estimated infection fatality rate for Covid-19 or, if it has, it's very hard to find. However, the World Health Organization Bulletin, a peer reviewed journal, published a study that found that "the infection fatality rate of COVID-19...ranged from 0.00% to 0.31% (median 0.05%)" for people under 70. Exhibit 12 to Wefer Decl. Even if these numbers are not exact, it is clear Sars-Cov2 is on the low end of virus mortality, which weighs in favor of Plaintiffs' right to decline the GTPs.

The President's Mandates are unprecedented in the history of the United States. For such extreme government action, the government interest must be compelling enough to justify it. Here it is not. Covid has a very low mortality rate among working age people, the people who are impacted by the Mandates. If the government can compel people to undergo a novel experimental

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[12] Pieracci EG, Pearson CM, Wallace RM, et al. Vital Signs: Trends in Human Rabies Deaths and Exposures — United States, 1938–2018. MMWR Morb Mortal Wkly Rep 2019;68:524–528, *available at* https://www.cdc.gov/mmwr/volumes/68/wr/mm6823e1.htm.

[13] CDC, *What is Smallpox?* (last reviewed June 7, 2016) available at https://www.cdc.gov/smallpox/about/index.html

medical procedure to prevent the spread of a virus that 99.7% percent of people under 70 survive, then the government holds the power to coerce people to undergo novel medical procedures for nearly any disease that exists, or is yet to emerge, that carries even a small risk of mortality to others. This power is not granted to the federal government in the Constitution. However, the liberty to decline such coerced medical procedures is protected by the substantive due process clause of the Fifth Amendment.

10. The fact that the government has navigated similar viruses without mandating medical procedures and medical surveillance undermines the government's interests and shows the Mandate is not narrowly tailored

There is ample precedent for protecting the federal workforce from respiratory viruses and other disease with measures that do not violate the Constitution. In the 233 years since the Constitution was ratified many viral diseases, new and old, have swept the country and the federal government has navigated all of those without ever coercing the federal workforce to be injected with a novel and experimental pharmaceutical. The President's Mandates are not narrowly tailored because history proves they are not necessary. Moreover, the President's own words undermine the need for these Mandates. He stated: "The path ahead, even with the Delta variant, is not nearly as bad as last winter."

III. GRANTING THE INJUNCTION WILL PRESERVE THE STATUS QUO, PREVENT IRREPARABLE HARM TO PLAINTIFFS, WILL NOT RESULT IN IRREPARABLE HARM TO THE PRESIDENT, AND WILL SERVE THE PUBLIC GOOD

An injunction would simply preserve the status quo while the constitutionality of these mandates is considered by the federal courts.

The Mandates require Plaintiffs to undergo an irreversible medical procedure that carries risk or lose their jobs and become effectively disqualified from two-thirds of American jobs. Either road constitutes irreparable harm.

If Plaintiffs submit to the government coercion, what is done to their bodies cannot be undone. If the Mandate is later found to be unconstitutional, there is no adequate remedy at law for the harm done.

Moreover, if they are injured by the pharmaceuticals, which do carry risk, any route of monetary recovery leads to actors that are immunized from liability.

If they are forced out from their jobs and excluded from two-thirds of the workforce, they are essentially being forced into an underclass based purely on the fact that they made a different personal healthcare decision than what the federal government wants them to make. These Mandates create two classes of people based on medical status and then regulate the disfavored class into an underclass for which it is difficult to earn a livelihood.

Allowing this caste system to go into effect would constitute irreparable harm, not just to Plaintiffs, but to the country. The public interest is served in preserving the status quo. *See Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir. 1994)(noting that "[a]s a practical matter, if a plaintiff demonstrates both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interest will favor the plaintiff").

There is no irreparable harm to Defendant in striking down the Mandates because "the Government does not have an interest in the enforcement of an unconstitutional law." *New York Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013) Moreover, there are many alternative and constitutional methods that the government has at its disposal to achieve its interest of stopping the spread of Covid.

CONCLUSION

For the foregoing reasons, it is respectfully requested that the Court enter an order enjoining EO 14042 and EO 14043.

Respectfully submitted,

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