App. No. 21A_____

In the Supreme Court of the United States

TALISHA VALDEZ AND JENNIFER BLACKFORD,

APPLICANTS,

v.

MICHELLE LUJAN GRISHAM AND DAVID SCRASE,

RESPONDENTS.

APPENDIX TO EMERGENCY APPLICATION FOR WRIT OF INJUNCTION
VOLUME II (Pages App. 239 to App. 442)

To the Honorable Neil M. Gorsuch
Associate Justice of the Supreme Court of the United States and Acting Circuit Justice for the Tenth Circuit

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TABLE OF CONTENTS

Order Denying Motion for Injunction Pending Appeal,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 24 ..... App. 1

Order Denying Motion for Temporary Restraining Order and Injunction,
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 18 ..... App. 6

Order Denying Motion for Stay and Injunction,
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 32 ..... App. 36

Appellants' Opening Brief,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 10 ..... App. 41

Appellants' Opposed Motion for Injunction Pending Appeal
And Stay of the District Court Proceedings,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 12 ..... App. 101

Order Requiring Response to Motion for Injunction Pending
Appeal and Stay of the District Court Proceedings,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 14 ..... App. 108

Appellees' Answer Brief,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 16 ..... App. 109

Appellees' Response to Motion for Injunction Pending
Appeal and Stay of the District Court Proceedings,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 17 ..... App. 162

Appellants' Reply Brief,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 20 ..... App. 168

Appellants' Reply In Support of Motion for Injunction
Pending Appeal and Stay of District Court Proceedings,
Valdez et al. v. Grisham et al., 21-2105
(10th Cir.), Dkt. 21..... App. 179

Plaintiffs' Class Action Complaint for Civil Rights Violations, etc..
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 1..... App. 183

Order Requiring Expedited Briefing
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 3..... App. 221

Motion to Reconsider the Court's Order of August 23, 2021,
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 4..... App. 225

Order Denying Plaintiffs' Motion for Reconsideration,
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 10..... App. 233

Defendants' Response to Motion for Temporary Restraining Order
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 13..... App. 239

Reply In Support of Motion for Temporary Restraining Order
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 14..... App. 294

Motion to Dismiss Plaintiffs' Verified Complaint
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 17..... App. 342

Notice of Interlocutory Appeal
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 19..... App. 376

Plaintiffs' Response to Motion to Dismiss
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 20..... App. 377

Motion for Stay and Injunction Pending Appeal
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 23..... App. 423

Reply In Support of Motion to Dismiss
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 26..... App. 430

Response to Motion for Stay and Injunction Pending Appeal
Valdez et al. v. Grisham et al., 1:21-cv-00783-MV-JHR
(D.N.M.) Civil Dkt. 29..... App. 440

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself and others similarly situated,

Plaintiffs,

v. **Case No. 1:21-cv-00783-MV-JHR**

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

DEFENDANTS' RESPONSE TO PLAINTIFFS' REQUEST FOR TEMPORARY RESTRAINING ORDER

Defendants Governor Michelle Lujan Grisham and Secretary David R. Scrase (collectively, "Defendants"), by and through their counsel of record, hereby provide their response to Plaintiffs' requested preliminary injunctive relief contained in their Verified Complaint for Civil Rights Violations Under 42 U.S.C.A. §1983; Violations of Rights Protected by the New Mexico Civil Rights Act; Emergency Request for a Temporary Restraining Order; Requst [sic] for Preliminary Injunction, Permanant [sic] injunctive relief and Damages [Doc. 1] (the "Complaint" or "Compl.") in accordance with this Court's August 23 Order. [Doc 3]. As grounds for their response, Defendants state as follows.

INTRODUCTION

Over a century ago, the U.S. Supreme Court declared, "[A] community has the right to protect itself against an epidemic of disease which threatens its members." *Jacobson v.*

Massachusetts, 197 U.S. 11, 31 (1905). This principle stands no less true today. In an attempt to stem the rapid resurgence of a highly contagious and potentially more lethal variant of the virus that causes COVID-19, Defendants issued a public health order requiring individuals working with New Mexico's most vulnerable populations in hospitals and congregate care settings to receive a safe and effective vaccine—one of which is now ***fully*** approved by the Food and Drug Administration—or meet a health, disability, or religious exemption. Additionally, Defendants required all vaccine-eligible individuals to show proof of vaccination or entitlement to an exemption (and a negative COVID-19 test) to attend the upcoming State Fair—one of the largest state-sponsored gatherings.

Unfortunately, not everyone agrees with the science. Those disagreements, however, do not give rise to a justiciable dispute. As Justice Cardozo eloquently observed, "The right of private judgment has never yet been so exalted above the powers and the compulsion of the agencies of government. One who is a martyr to a principle—which may turn out in the end to be a delusion or an error—does not prove by his martyrdom that he has kept within the law." *Hamilton v. Regents of Univ. of Cal.*, 293 U.S. 245, 268 (1934). Plaintiffs—a group of individuals subject to the vaccine requirements and apparently not entitled to an exemption—seek to halt Defendants' carefully calculated life-saving measures based on their (faulty and speculative) belief that the vaccines are neither safe nor necessary.[1] But such minority views are insufficient to defeat the wisdom of

[1] In so doing, Plaintiffs offensively compare the order at issue to the internment of Japanese Americans in World War II. *See* Compl. at 1. Counsel for Plaintiffs enjoys such overwrought histrionics, and with each passing lawsuit finds that the complained of prohibition is more authoritarian than the last. *See e.g.*, Plaintiffs' Motion for Preliminary Injunction [Doc 20.] at 2, *Hinkle Family Fun Ctr. v. Lujan Grisham*, No. 1:20-cv-01025-MV-KK (D.N.M. Dec. 2, 2020) ("History will not reflect anymore [sic] kindly on the government of New Mexico locking up its people and taking away their ability to earn a living nine months later, than it did when this Country locked up Japanese Americans in internment camps."); *Hernandez v. Lujan Grisham*, 494 F. Supp.

elected officials guided by the State and nation's preeminent public health experts. As the Supreme Court proclaimed,

> We are not prepared to hold that a minority, residing or remaining in any city or town where [a deadly, contagious virus] is prevalent, and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted authorities, acting in good faith for all, under the legislative sanction of the State. If such be the privilege of a minority then a like privilege would belong to each individual of the community, and the spectacle would be presented of the welfare and safety of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population.

Jacobson, 197 U.S. at 37-28. Plaintiffs give this Court no reason to reach a contrary conclusion, and their application for preliminary injunctive relief should therefore be denied.

BACKGROUND

I. The rapid and dangerous spread of COVID-19

Since its emergence last year, the novel coronavirus 2019 (Sars-CoV-2), the virus that causes COVID-19, has spread exponentially across the globe, throughout the United States, and here in New Mexico.[2] COVID-19's rapid spread is attributable to certain characteristics of the virus that causes it and the ease with which that virus is transmitted. COVID-19 is a respiratory illness that causes severe complications in some patients, including respiratory failure, organ failure, and death.[3] Like most respiratory illnesses, COVID-19 spreads easily through close person-to-person contact, and the risk of transmission increases if individuals interact with more

3d 1044, 1091 (D.N.M. 2020) (noting Plaintiffs' counsel's argument that "Governor Lujan Grisham's school reentry plan is 'appropriate[ly] . . . likened to the [sic] those of the gestapo'").

[2] *See* Declaration of Christine Ross at ¶¶ 4-5, attached at Exhibit A [hereinafter Exh. A].

[3] *See* Exh A at ¶ 7; *What Is Coronavirus?*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus (last visited Aug. 25, 2021).

people, come within six feet of one another, and spend longer periods of time together.[4] Although it has not been measured precisely, a significant portion of COVID-19 cases result in mild symptoms or no symptoms.[5] Additionally, even in cases that are symptomatic, the average time from exposure to symptom onset is five to six days, with symptoms sometimes not appearing until as long as thirteen days after infection.[6] This means that individuals who have been infected and have the potential to infect others usually do not know they are infected for at least several days (and may never know, if they remain asymptomatic).

The ease and rapidity with which COVID-19 spreads and its severe and sometimes fatal symptoms in a certain percentage of the population create a potential for mass deaths and a severely overloaded health care system. At the height of the pandemic (so far) last winter, the United States was recording on average nearly 200,000 new cases and over 4,000 COVID-related deaths *every*

[4] *How COVID-19 Spreads*, Ctr. for Disease Control and Prevention (Oct. 28, 2020), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html; *Deciding to Go Out*, Ctr. for Disease Control and Prevention (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/deciding-to-go-out.html#:~:text=COVID%2D19%20spreads%20easier%20between,People%20are%20wearing%20masks.

[5] Katie Kerwin McCrimmon, *The truth about COVID-19 and asymptomatic spread: It's common, so wear a mask and avoid large gatherings*, UC Health (Nov. 5, 2020), https://www.uchealth.org/today/the-truth-about-asymptomatic-spread-of-covid-19/.

[6] *COVID-19 Basics: Symptoms, Spread and Other Essential Information About the New Coronavirus and COVID-19*, Harvard Medical School (March 2020), https://www.health.harvard.edu/diseases-and-conditions/covid-19-basics.

day.[7] New Mexico was averaging over 2,500 new cases and over 40 deaths daily.[8] The Department of Health had to activate crisis standards of care because hospitals were literally overflowing with patients.[9] Tragically, hospitals were not the only things at capacity: so, too, were the morgues.[10] One in five New Mexicans hospitalized for COVID-19 eventually succumbed to the virus.[11]

II. The development of the COVID-19 vaccines

Thankfully, science came to the rescue. In February 2020, the U.S. Department of Health and Human Services (HHS) declared a public health emergency and instructed the U.S. Food and Drug Administration (FDA) to grant emergency use authorizations (EUAs) for medical devices

[7] *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases (last visited Aug. 20, 2021); *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths (last visited Aug. 20, 2021).

[8] *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases (follow "New Mexico" on drop down menu) (last visited Aug. 20, 2021); *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths (follow "New Mexico" on drop down menu) (last visited Aug. 20, 2021).

[9] Governor Michelle Lujan Grisham, *Executive Order 2020-083*, at 4 (Dec. 4, 2020), https://www.governor.state.nm.us/wp-content/uploads/2020/12/Executive-Order-2020-083.pdf (executive order preparing for implementation of crisis care standards); N.M. Dep't of Health, Public Health Order (Dec. 9, 2021), https://cv.nmhealth.org/wp-content/uploads/2020/12/120920-PHO_Activation-of-CSC-and-TCA.pdf (public health order activating crisis care standards).

[10] Gabrielle Burkhart, *New Mexico receives 'mortuary trailers' as COVID-19 death toll rises*, KRQE (Nov. 19, 2020), https://www.krqe.com/health/coronavirus-new-mexico/new-mexico-receives-mortuary-trailers-as-covid-19-death-toll-rises/.

[11] N.M. Dep't of Health, *New Mexico COVID-19 Hospitalization Update* (Dec. 14, 2020), https://cv.nmhealth.org/wp-content/uploads/2020/12/hospitalizations_covid19_public-report_12.14.20_final.pdf.

and interventions to combat the pandemic. *See* 85 Fed. Reg. 7316, 7316-7317; 85 Fed. Reg. 18250, 18250-18251. While an EUA generally allows a manufacturer to receive approval for a medical product using only interim clinical trial data, products that receive EUA approval still must adhere to specified safety, efficacy, and manufacturing criteria. *See* 21 U.S.C. § 360bbb-3(e)(1)(B), (A)(ii)(I)-(III). Additionally, HHS must ensure medical providers and individuals are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown"; and for individuals, of the option to refuse and the consequences of such a decision. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). Specifically with regard to the development of a COVID-19 vaccine, the FDA issued detailed guidance to manufacturers and specifically informed them that it would require a determination that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.[12]

Numerous manufacturers rose to the occasion, and three vaccines candidates quickly emerged as frontrunners: Johnson & Johnson's single-dose viral vector vaccine, and Pfizer/BioNTech and Moderna's two-dose mRNA vaccines.[13] By the time Pfizer and Moderna applied for EUA status in November 2020, each vaccine had undergone significant testing. Pfizer's application included safety, immunogenicity, and efficacy data from over 40,000 study participants in ongoing phase I, II, and III, randomized, placebo-controlled, observer-blind, clinical

[12] Exh. A at ¶¶ 30-32; U.S. Food & Drug Admin., *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* at 4 (May 2021), https://www.fda.gov/media/142749/download.

[13] *Different COVID-19 Vaccines*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html (last visited Aug. 25, 2021).

trials conducted in the U.S., Argentina, Brazil, Germany, South Africa, and Turkey.[14] Moderna's application included safety, immunogenicity, and efficacy data from over 30,000 study participants in ongoing phase I, II, and III, randomized, stratified, observer-blind, placebo-controlled clinical trials conducted at 99 locations in the United States.[15] J&J applied for EUA status in February 2021, submitting an application that included safety, immunogenicity, and efficacy data from five studies with over 70,000 participants, including two randomized, double-blind, placebo-controlled phase III trials.[16]

A team of representatives from across the FDA—including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling—reviewed the data submitted by Pfizer, Moderna and J&J, and independently assessed the risks and benefits of the vaccines. *See* U.S. Food & Drug Admin., *supra* note 14 at 1, 49-54; U.S. Food & Drug Admin., *supra* note 15 at 1, 55-60; U.S. Food & Drug Admin., *supra* note 16 at 1, 55-60. The FDA granted EUA to Pfizer and Moderna's vaccines in December 2020 and J&J's vaccine in February 2021 for individuals ages 16 and older, noting that each had met their expectations set out in the FDA's comprehensive guidance.[17] Pfizer's vaccine

[14] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 11, 2020), https://www.fda.gov/media/144416/download.

[15] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 18, 2020), https://www.fda.gov/media/144673/download.

[16] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Feb. 4, 2021), https://www.fda.gov/media/146338/download.

[17] U.S. Food & Drug Admin., *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-

has since received EUA for individuals ages 12 and older and **received *full* FDA approval for individuals ages 16 and over on August 23, 2021**.[18]

Despite the unprecedented timeline for development, the vaccines have been a resounding success. Since the three vaccines received EUA status, over 368 million doses have been administered and over 173 million Americans have been fully vaccinated. *See* Exh. A at ¶ 39 n.35 Comprehensive data collected to date demonstrates that the vaccines are safe, with serious adverse reactions remaining exceedingly rare.[19] In terms of effectiveness, initial data and evidence demonstrated that the Pfizer vaccine was 91.3% effective in preventing infections and 100% effective in preventing severe disease, Moderna's vaccine was 90% effective in preventing infections and more than 95% effective in preventing severe disease, and J&J's vaccine was 85% effective in preventing severe disease.[20] The protection provided by the vaccines has proven

covid-19-issuing-emergency-use-authorization-first-covid-19; U.S. Food & Drug Admin., F*DA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; U.S. Food & Drug Admin., *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[18] U.S. Food & Drug Admin., *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[19] Exh. A at ¶¶ 15, 39; *Selected Adverse Events Reported after COVID-19 Vaccination*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (last visited Aug. 25, 2021).

[20] Press Release, *Pfizer and BioNtech Confirm High Efficacy And No Serious Safety Concerns Through Up To Six Months Following Second Dose In Updated Topline Analysis Of Landmark Covid-19 Vaccine Study*, Pfizer (Apr. 1, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious; Press Release, *Moderna Provides Clinical and Supply Updates on COVID-19 Vaccine Program Ahead of 2nd Annual Vaccines Day* (Apr. 13, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-clinical-and-supply-updates-covid-19-vaccine; Press Release, *Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot*

relatively durable over time, with one study finding that the Pfizer and Moderna vaccines were 86% effective in preventing illness serious enough to require hospitalization 2-12 weeks after vaccination and 84% effective at 13-24 weeks. *See* Exh. A at ¶ 37. Additionally, laboratory data and real-world epidemiologic studies demonstrate that the immunity provided by vaccines is significantly more robust than natural immunity gained following infection. For instance, one recent study found that unvaccinated individuals who were previously infected had 2.34 times the odds of being reinfected than those who had been fully vaccinated. *See id.* at ¶ 28.

III. The Delta variant

Unfortunately, a new, highly infectious and possibly more deadly variant has emerged and taken the world by storm. B.1.617.2, commonly known as the "Delta" variant was first discovered in India in late 2020 and soon became the predominant strain in that country.[21] By mid-June, the CDC labeled Delta a "variant of concern."[22] Now, it is widely estimated that the Delta variant accounts for nearly all of new infections in the United States and New Mexico, and is believed to be at least twice as contagious as previous variants. *See* Exh. at ¶¶ 22 n.13, 24-25. Additionally, studies indicate that individuals infected with the Delta variant are more likely to be hospitalized than those infected with the original strain or other variants. *See id.* In terms of the variant's impact on vaccines, there is bad news and good news: while the variant is more likely to cause

Vaccine in Fight Against Global Pandemic, Johnson & Johnson (Feb. 27, 2021), https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic.

[21] Kathy Katella, *5 Things To Know About the Delta Variant*, Yale Med. (Aug. 18, 2021), https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.

[22] *See SARS-CoV-2 Variant Classifications and Definitions*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html (last visited Aug. 24, 2021).

"breakthrough" infections, the vaccines still provide strong protection against serious illness and death. *See id.* For example, one recent analysis of over 40,000 infections in Los Angeles from May to the end of July found that vaccinated individuals were nearly ***5 times less likely to become infected*** and nearly ***30 times less likely to require hospitalization***. *Id.* at ¶ 20. Accordingly, there is strong evidence that vaccinations continue to be effective.

III. New Mexico's public health emergency orders and the current state of the pandemic

Recognizing the seriousness of this virus and its ability to spread exponentially through close contacts and public spaces, the Governor declared a public health emergency under the Public Health Emergency Response Act, NMSA 1978, §§ 12-10A-1 to -19 (2003, as amended through 2015), and invoked the All Hazards Emergency Management Act, NMSA 1978, §§ 12-10-1 to -10 (1959, as amended through 2007), by directing all cabinets, departments, and agencies to comply with the directives of the declaration and the further instructions of the Department of Health.[23] Consistent with the powers provided during an emergency under the Public Health Emergency Response Act and the All Hazards Emergency Management Act, as well as the Public Health Act, NMSA 1978, §§ 24-1-1 to -40 (1973, as amended through 2019), the Secretary subsequently entered a series of public health orders ("PHOs").[24]

The PHOs initially included various measures such as limiting most public and private gatherings of any significant size and curtailing the operations of many businesses. *Id.* However,

[23] Governor Michelle Lujan Grisham, *Executive Order 2020-004* (March 11, 2020), https://www.governor.state.nm.us/wp-content/uploads/2020/03/Executive-Order-2020-004.pdf. This declaration was most recently renewed until September 15, 2021. *See* Governor Michelle Lujan Grisham, *Executive Order 2020-004* (March 11, 2020), https://www.governor.state.nm.us/wp-content/uploads/2021/08/Executive-Order-2021-049.pdf.

[24] *See generally Public Health Orders and Executive Orders*, N.M. Dep't of Health, https://cv.nmhealth.org/public-health-orders-and-executive-orders/ (last visited Aug. 24, 2021) (collecting PHOs and executive orders relating to COVID-19).

the PHOs' restrictions were largely phased out as case rates dropped dramatically with New Mexico's efficient rollout of the COVID-19 vaccines that began earlier this year.[25] Unfortunately, cases have climbed rapidly in the most recent weeks with the spread of the Delta variant. The number of new cases has risen from an average of approximately 60 cases per day in late June to nearly 900 cases per day last week—*almost a fifteenfold increase*.[26] Many hospitals are again operating over capacity to accommodate the surge of infected New Mexicans—the majority of which are unvaccinated. *See* Exh. A at ¶¶ 9-10, 28. It is unclear just how long New Mexico's hospital system can sustain such operations, with healthcare workers in short supply and reports of workers "burning out" or falling ill becoming increasingly common.[27] Indeed, crisis care standards are again likely to be implemented in the upcoming days.[28]

To stem the recent surge of cases and hopefully ease the pressures on New Mexico hospitals, the Secretary issued a PHO on August, 17, 2021, generally requiring individuals working in hospitals and certain congregate care facilities to receive their first dose of a COVID-19 vaccine

[25] *Id.*; N.M. Dep't of Health, *New Mexico COVID-19 Cases Update Statewide and County-Level Trends* at 1 (Aug. 16, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/State-Report_geotrends_08.16.21.pdf (showing cases drop significantly beginning in December and January).

[26] *COVID-19 in New Mexico*, N.M. Dep't of Health, https://cvprovider.nmhealth.org/public-dashboard.html (follow "Show Historical Statewide Date" on bottom left-hand corner; then scroll down to "Epidemic Curve") (last visited August 29, 2021).

[27] *See, e.g.*, Colleen Heild, *Stressed and exhausted, nurses are calling it quits*, Albuquerque J. (Aug. 21, 2021), https://www.abqjournal.com/2421756/stressed-and-exhausted-nurses-are-calling-it-quits.html; *see also* Exh. A at ¶¶ 12-13.

[28] *See* Chris McKee, *New Mexico's hospitals days away from 'crisis standards of care' amid COVID-19 case surge*, KRQE News (Aug. 25, 2021), https://www.krqe.com/health/coronavirus-new-mexico/new-mexicos-top-health-officials-to-address-covid-19/.

within 10 days and their second dose (for Pfizer and Moderna) within 40 days of their first dose.[29] However, such workers are not required to get a vaccine if they have a: (1) qualifying medical condition for which immunization would endanger the individual's health, (2) disability requiring reasonable accommodations, or (3) sincerely held religious belief against vaccination. *Id.* at 4. To qualify for the first and second exemptions, the individual must provide their employer with a statement from a licensed medical professional stating that the individual has a qualifying medical condition or disability that necessitates accommodation and stating the probable duration of the individual's inability to receive the vaccine or need for an accommodation. *Id.* To qualify for the religious exemption, the individual must document their request for an accommodation and provide a statement regarding the manner in which the administration of a COVID-19 vaccine conflicts with their religious observance, practice, or belief. *Id.* at 4-5. Individuals who meet an exemption must undergo weekly COVID-19 testing. *Id.* In addition to the above requirements, the PHO requires all individuals attending the New Mexico State Fair that are eligible to receive a COVID-19 vaccine (i.e., those ages 12 years and older) be fully vaccinated or meet one of the above exemptions and provide proof of a recent negative COVID-19 test result. *See id.* at 5-6.

IV. Plaintiffs' claims

Against this factual backdrop, Plaintiffs filed the instant "class action." Plaintiff Talisha Valdez is a mother of two children who entered to show their animals at the New Mexico State Fair. [Doc 1-3]. Plaintiff Jennifer Blackford is a registered nurse employed at Presbyterian Hospital

[29] N.M. Dep't of Health, *Public Health Order* 3-4 (Aug. 17, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/081721-PHO-Vaccines.pdf. This requirement also applies to employees from the Office of the Governor. *Id.* However, everyone within the Office of the Governor is vaccinated or will be fully vaccinated by the PHO's deadline. Additionally, the PHO requires school workers to either provide proof of their vaccination status or undergo weekly COVID-19 testing, *id.* at 3, but Plaintiffs do not appear to assert any claims on behalf of teachers because they are not required to receive the vaccine. *See* Compl. at 7 ¶¶ 33-34.

in Albuquerque.[30] Neither Plaintiffs nor their children have been vaccinated against COVID-19. [Docs. 1-3, 1-4]. Plaintiffs are opposed to receiving a COVID-19 vaccine, *id.*, and generally allege that the PHOs' vaccine requirements violate the Federal Food, Drug, and Cosmetic Act, their rights to due process and equal protection, Article I, § 10, and their rights under the New Mexico constitution. *See* Compl. at 9-14. In their prayer for relief, Plaintiffs request a declaratory judgment that the PHOs' vaccine requirements are unconstitutional and further request a TRO and a preliminary and permanent injunction prohibiting Defendants from enforcing the public health orders. *Id.* at 14-15. Plaintiffs also seek actual and punitive damages for their alleged injuries. *Id.* at 15.

[30] [Doc. 1-4]. Plaintiff Blackford seeks to bring claims on behalf of "all others similarly situated that work in healthcare, congregate care or the Office of the Governor for the purpose of asserting the claims alleged in this complaint on a common basis." Compl. at 6 ¶ 26. However, Plaintiffs' proposed classes will likely not satisfy Rule 23(a)'s requirement that a class representative's claims "are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). Blackford's employer is separately requiring all of its employees to be vaccinated, thus depriving Blackford of standing to challenge the PHO's vaccine requirements. *See* Colleen Heild, *Presbyterian requires vaccines for entire workforce of 13,000*, Santa Fe New Mexican (Aug. 18, 2021), https://www.abqjournal.com/2420650/presbyterian-requires-vaccines-for-entire-workforce-of-13000-ex-pnm-is-asking-all-staff-to-get-vaccinated-or-be-tested-weekly.html; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact)]. This development also deprives Plaintiff Blackford of standing to challenge the PHO or represent any class of plaintiffs. *See Bronson v. Swensen*, 500 F.3d 1099, 1109 (10th Cir. 2007) ("The principle of causation for constitutional standing requires a plaintiff's injury to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." (internal quotation marks and citations omitted)); *Abraham v. WPX Prod. Prods., LLC*, 184 F. Supp. 3d 1150, 1198 (D.N.M. 2016) ("In certifying the class, courts must find that the named plaintiff's claims are typical of the class claims, which requires a conclusion that the named plaintiff has standing.").

DISCUSSION

I. The Court should deny Plaintiffs' request for preliminary injunctive relief

A. Standard of review for a TRO and preliminary injunction

"A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *Mrs. Fields Franchising, LLC v. MFGPC*, 941 F.3d 1221, 1232 (10th Cir. 2019) (internal quotation marks and citation omitted).[31] To obtain a TRO or preliminary injunction, the moving party must demonstrate: "(1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest." *AG of Okla. v. Tyson Foods, Inc.*, 565 F.3d 769, 776 (10th Cir. 2009) (internal quotation marks and citation omitted). "The third and fourth factors 'merge' when, like here, the government is the opposing party." *Aposhian v. Barr*, 958 F.3d 969, 978 (10th Cir. 2020). Because preliminary injunctive relief is an "extraordinary remedy, . . . the right to relief must be clear and unequivocal." *Nova Health Sys. v. Edmondson*, 460 F.3d 1295, 1298 (10th Cir. 2006). The movant *must* satisfy his or her burden for *each* one of these prerequisites. *Diné Citizens Against Ruining Our Env't*, 839 F.3d 1276, 1281-82 (10th Cir. 2016).

Furthermore, "[b]ecause the limited purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held," the Tenth Circuit specifically disfavors "(1) preliminary injunctions that alter the status quo; (2) mandatory

[31] The Court should treat Plaintiffs' request for a TRO as a request for a preliminary injunction. *See* 13 Moore's Federal Practice § 65.31 (2020) ("[W]hen a temporary restraining order is sought on notice to the adverse party, it may be treated by the court as a motion for a preliminary injunction."). Nonetheless, whether the Court treats Plaintiffs' request as one for a TRO or one for a preliminary injunction, the standard is the same. *See Firebird Structures, LCC v. United Bhd. of Carpenters & Joiners of Am., Local Union No. 1505*, 252 F. Supp. 3d 1132, 1156 (D.N.M. 2017).

preliminary injunctions; and (3) preliminary injunctions that afford the movant all the relief that it could recover at the conclusion of a full trial on the merits." *Schrier v. Univ. of Colorado et.al.*, 427 F.3d 1252, 1258-59, (10th Cir. 2005) (alterations, internal quotation marks, and citation omitted). Therefore, "any preliminary injunction fitting within one of the disfavored categories must be more closely scrutinized to assure that the exigencies of the case support the granting of a remedy that is extraordinary even in the normal course[,]" and "a party seeking such an injunction must make a strong showing both with regard to the likelihood of success on the merits and with regard to the balance of harms[.]" *O Centro Espirita Beneficente Uniao do Vegetal ("O Centro") v. Ashcroft*, 389 F.3d 973, 975 (10th Cir. 2004).

Plaintiffs' requested injunctive relief falls into the category of disfavored injunctions. Plaintiffs appear to be requesting the same injunctive relief sought in their Complaint: an injunction "[p]rohibit[ing] Defendants from enforcing the public health orders against the Plaintiffs and other putative class members that are similarly situated." *Compare* Compl. at 25 (simply asking for the Court to grant a TRO), *with* Compl. at 14-15 (listing specifics of preliminary and permanent injunctive relief sought). Plaintiffs, therefore, seek virtually all the relief they could be awarded at the end of trial on the merits.[32] *See Peterson v. Kunkel*, 492 F. Supp. 3d 1183, 2020 U.S. Dist. LEXIS 183471, at *14 (D.N.M. 2020) (Johnson, C.J.) (holding that the plaintiffs' requested preliminary injunction was disfavored because it was an exact overlay of the relief sought in their complaint). The requested preliminary injunctive relief is also disfavored because

[32] That Plaintiffs also seek monetary damages does not compel a different result. *Cf. Strickland v. Madden Sales & Serv.*, No. 19-918 MV/JFR, 2020 U.S. Dist. LEXIS 95430, at *8 (D.N.M. May 8, 2020) (Vázquez, J.) (holding that the defendant's motion for a preliminary injunction seeking enforcement of a non-compete agreement was disfavored because it sought all the relief that it could recover at the conclusion of a full trial on the merits and even though it sought monetary damages, the "primary objective" of its counterclaims was to enforce the non-compete agreement).

it would require the Court to force Defendants to affirmatively alter the PHO and the State's enforcement of it. *Cf. ETP Rio Rancho Park, LLC v. Grisham*, No. CIV 21-0092 JB/KK, 2021 U.S. Dist. LEXIS 36354, at **55, 112 (D.N.M. Feb. 26, 2021) (Browning, J.) (noting that the plaintiffs' request "to prohibit Defendants from enforcing all PHOs" required affirmative action and was therefore disfavored). Thus, this Court should closely scrutinize Plaintiffs' request for preliminary injunctive relief and require Plaintiffs to "make a strong showing both with regard to the likelihood of success on the merits and with regard to the balance of harms[.]" *O Centro*, 389 F.3d at 975.

B. Plaintiffs fail to demonstrate a strong likelihood of success on the merits of their claims

1. Food, Drug, and Cosmetics Act

Plaintiffs first claim the PHO violates the Food, Drug, and Cosmetic Act ("FDCA"). *See* Compl. at 9-10. However, such a claim entirely misconstrues the FDCA and is largely moot now. The FDCA authorizes the FDA to issue an "emergency use authorization" for a medical product, such as a vaccine, to be introduced into interstate commerce and administered to individuals in an emergency situation when the product has not yet undergone the standard review and approval process. 21 U.S.C. § 360bbb-3(a)(1), (2). Here, the FDA has granted emergency use authorizations for three COVID-19 vaccines, with each vaccine manufacturer meeting more stringent standards compared to emergency use authorization vaccines in the past. *See* Background Section II, *supra*; *Klaassen v. Trs. of Ind. Univ.*, No. 1:21-CV-238 DRL, 2021 U.S. Dist. LEXIS 133300, at **21-22 (N.D. Ind. July 18, 2021). Importantly, the FDA granted the Pfizer vaccine ***full*** approval for individuals 16 years of age and older. *See* U.S. Food & Drug Admin., *supra* note 18. Therefore, Plaintiffs claims regarding emergency use authorization are moot for anyone in that age group.

Regardless, Plaintiffs claims based on the emergency use authorization section of the FDCA fail as the FDCA does not prevent a public or private entity from requiring vaccines. The plain language of 21 U.S.C. § 360bbb-3(e) demonstrates that the section only applies to healthcare providers administering COVID-19 vaccines and to the potential vaccine recipients. The FDCA states for the emergency use of an unapproved product the Secretary of the HHS shall "*for person who carries out any activity for which the authorization is issued*, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health[.]" 21 U.S.C. § 360bbb-3(e)(1)(a) (emphasis added). Specifically, the FDCA requires the Secretary issue:

> (i) Appropriate conditions designed to ensure that *health care professionals administering the product are informed—*
>
> > (I) that the Secretary has authorized the emergency use of the product;
> > (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
> > (III) of the alternatives to the product that are available, and of their benefits and risks.
>
> (ii) Appropriate conditions designed *to ensure that individuals to whom the product is administered are informed—*
>
> > (I) that the Secretary has authorized the emergency use of the product;
> > (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> > (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(a)(i), (ii) (emphases added). Several courts, as well as the U.S. Department of Justice, have analyzed this provision and concluded that it does not apply to those

requiring vaccines but only to the individuals in the process of *receiving* a vaccine.[33] Thus, Plaintiffs are unlikely to succeed on this claim.

2. Substantive Due Process and Equal Protection

Plaintiffs next claim the PHO violates equal protection and due process. *See* Compl. at 10-12. Although the Equal Protection and Due Process clauses protect distinctly different interests, "their substantive analyses converge." *Powers v. Harris*, 379 F.3d 1208, 1215 (10th Cir. 2004). For substantive due process claims challenging legislative-type actions, such as the PHO, the Court typically applies a two-part test in which it first asks whether the action implicates a fundamental right. *See Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1182 (10th Cir. 2009). If so, the Court applies strict scrutiny; if not, the Court applies rational basis review. *Id.* Similarly, in considering equal protection claims, the Court will apply rational basis review unless the classification at issue discriminates against a suspect class. *See Curley v. Perry*, 246 F.3d 1278, 1285 (10th Cir. 2001).

a. The PHO's vaccine requirements are subject to rational basis review

i. Equal Protection

Plaintiffs summarily claim that the generally applicable vaccine requirements violate the Equal Protection Clause. *See* Compl. at 10-11. As a preliminary matter, Plaintiffs' equal protection

[33] *See id.*; *Bridges v. Hous. Methodist Hosp.*, No. H-21-1774, 2021 U.S. Dist. LEXIS 110382, at *5-6 (S.D. Tex. June 12, 2021) ("[21 U.S.C. § 360bbb-3] neither expands nor restricts the responsibilities of private employers; in fact, it does not apply at all to private employers [requiring employees be vaccinated]."); *Klaassen,* 2021 U.S. Dist. LEXIS 133300, *64-65 (interpreting 21 U.S.C. § 360bbb-3(e)(1)(A)(ii) as establishing conditions to facilitate informed consent for medical providers and the persons receiving vaccines); Dep't of Justice, *Whether Section 564 of the Food, Drug and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* at 2 (July 6, 2021), https://www.justice.gov/olc/file/1415446/download ("This language in section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements.").

claim fails because they do not allege that Defendants intentionally discriminated against them in the PHO. *See ETP Rio Rancho Park, LLC v. Grisham*, No. CIV 21-0092 JB/KK, 2021 U.S. Dist. LEXIS 23409, at *137 (D.N.M. Feb. 8, 2021) ("[I]f a statute appears facially neutral, the plaintiff must make out a 'prima facie case of discriminatory purpose.'" (quoting *Washington v. Davis*, 426 U.S. 229, 241 (1976)); *see generally* Compl. The PHO's vaccine requirements are facially neutral because they apply to all individuals working in hospitals and certain congregate care facilities, as well as all individuals attending the state fair. *Cf. ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 23409, at **138-39 (finding PHO provision neutral because it does not require only trampoline facilities to remain closed). Therefore, Plaintiffs must make out a prima facie case of discriminatory animus toward them. *Id*. Discriminatory intent "requires that the decisionmaker . . . selected or reaffirmed a particular course of action at least in part because of, not merely in spite of the law's differential treatment of a particular class of persons." *SECSYS, Ltd. Liab. Co. v. Vigil*, 666 F.3d 678, 685 (10th Cir. 2012) (internal quotation marks and citation omitted). As the Complaint contains no allegations that the PHO's restrictions are born out of animus toward unvaccinated individuals, the restrictions do not "run afoul of the Constitution." *Id.*

Assuming, *arguendo*, Plaintiffs did properly plead an equal protection claim, such a claim would be subject to rational basis review *at most*. Plaintiffs do not allege (as they cannot) that they are members of a suspect class which would give rise to any sort of heightened scrutiny. *See Save Palisade FruitLands v. Todd*, 279 F.3d 1204, 1210 (10th Cir. 2002) (stating governmental classifications are only subject to strict scrutiny if they target a suspect class such as race or national origin and intermediate scrutiny is applied to quasi-suspect classes like gender). Moreover, as described in the following section, Plaintiffs fail to demonstrate that the PHO's

vaccine requirement infringes on a fundamental right. Thus, the Court must use rational basis review when reviewing Plaintiffs' equal protection claims.

ii. Substantive Due Process

Plaintiffs substantive due process claims are similarly subject to rational basis review. There are two types of substantive due process claims: (1) claims that the government has infringed a fundamental right and (2) claims that government action deprived a person of life, liberty, or property in a manner so arbitrary it shocks the judicial conscience. *Doe v. Woodard*, 912 F.3d 1278, 1300 (10th Cir. 2019). "[Courts] apply the fundamental-rights approach when the plaintiff challenges legislative action, and the shocks-the-conscience approach when the plaintiff seeks relief for tortious executive action." *Id.* (alterations, internal quotation marks, and citation omitted). The fundamental-rights approach is applicable in this case, as the PHO is a quasi-legislative action generally applicable to thousands of New Mexicans, and it is the Department of Health's attempt to "through policy, to achieve a stated government purpose."[34] *Abdi v. Wray*, 942 F.3d 1019, 1027-28 & n.1 (10th Cir. 2019); *cf. Nicholas v. Pa. State Univ.*, 227 F.3d 133, 139 n.1 (3d Cir. 2000) ("[E]xecutive acts, such as employment decisions, typically apply to one person or to a limited

[34] Even if the "shocks conscience" standard applied in this case, Plaintiffs' claim would still fail. "Conduct that shocks the judicial conscience is deliberate government action that is arbitrary and unrestrained by the established principles of private right and distributive justice." *Woodard*, 912 F.3d at 1300. (internal quotation marks omitted). Issuing public health orders requiring certain people working with highly vulnerable populations or attending a state fair to be vaccinated or meet an exception can hardly be considered conscious-shocking. *See World Gym, Inc. v. Baker*, Civil Action No. 20-cv-11162-DJC, 2020 U.S. Dist. LEXIS 131236, at *12 (D. Mass. July 24, 2020) ("In light of the toll of the pandemic, [the plaintiffs' argument that the governor's COVID-19-related orders shock the conscious] is unconvincing. The state has a strong interest in stopping the spread of COVID-19, and accordingly, it cannot be said that the Governor's conduct amounts conscience-shocking action."); *Herrin v. Reeves*, No. 3:20cv263-MPM-RP, 2020 U.S. Dist. LEXIS 176604, at *23 (N.D. Miss. Sep. 25, 2020) ("[T]he notion that restrictions designed to save human lives are 'conscious shocking' [is] absurd and not worthy of serious discussion.").

number of persons, while legislative acts, generally laws and broad executive regulations, apply to large segments of society." (internal quotation marks and citation omitted)).

Legislative action is tested under a two-part substantive due process framework in which the Court asks first asks whether a fundamental right is implicated. *Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1182 (10th Cir. 2009). The plaintiff bears the burden of providing a "careful description of the asserted fundamental liberty interest" and demonstrating how such a right is "objectively deeply rooted in [the] Nation's history and tradition" and "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (internal quotation marks and citations omitted). Vague, conclusory, or generalized assertions will not suffice. *See ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 36354, at *119.

Plaintiffs' general allegations to a fundamental right "to live without arbitrary governmental interference," "to bodily integrity," to raise their children as they see fit," and to "engage in their chose profession" can hardly be considered to satisfy *Glucksberg*'s requirements. *See* Compl. at 11; *ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 36354, at *105-06 (holding that the plaintiffs vague and conclusory allegations to run a business did not satisfy *Glucksberg*'s "careful description" requirement because they did "not explain how the Dec. 30 PHO deprives the Plaintiffs of a fundamental right and do not address how trampoline facility operation is 'deeply rooted in Nation's history and tradition.'"). Like the plaintiffs in *ETP Rio Rancho Park*, Plaintiffs fail to explain how their "right" to work in hospitals and congregate care facilities or attend a state fair unvaccinated during a pandemic is "deeply rooted in [the n]ation's history and tradition." *Glucksberg*, 521 U.S. at 720-21. Nor could they, as federal courts have consistently applied rational basis review to assess mandatory vaccination measures. *See Klaassen*, 2021 U.S. Dist.

LEXIS 133300, at *62 (collecting cases applying rational basis review to assess mandatory vaccination measures and concluding that Indiana University's COVID-19 requirement was subject to rational basis "[g]iven over a century's worth of rulings saying there is no greater right to refuse a vaccination than what the Constitution recognizes as a significant liberty").[35] Thus, rational basis review is appropriate.

b. The PHO's vaccination requirements are rationally related to a compelling government interest in combatting the spread of COVID-19

To survive rational basis review, "the [law] need only be rationally related to a legitimate government purpose." *See Save Palisade FruitLands*, 279 F.3d at 1210. In challenging a governmental action for want of a rational basis, "the burden is upon the challenging party to negative any reasonably conceivable state of facts that could provide a rational basis for the [law]." *Bd. of Trs. v. Garrett*, 531 U.S. 356, 367 (2001) (internal quotation marks and citation omitted). "Th[e] standard is objective—if there is a reasonable justification for the challenged action, [the court] do[es] not inquire into the government actor's actual motivations." *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1216 (10th Cir. 2011). "[R]ational-basis review does not give courts the option to speculate as to whether some other scheme could have better regulated the evils in question." *Powers*, 379 F.3d at 1217. Courts "will not strike down a law as irrational simply because it may not succeed in bringing about the result it seeks to accomplish or because the statute's classifications lack razor-sharp precision. *Id.* (citations omitted). "Nor can [a court]

[35] Plaintiffs request for a TRO curiously focuses solely on the purportedly fundamental right to "engag[e] in their chosen profession." Compl. at 19-21. However, it is well established that "[t]he right to 'make a living' is not a 'fundamental right,' for either equal protection or substantive due process purposes." *Medeiros v. Vincent*, 431 F.3d 25, 32 (1st Cir. 2005); *see also Guttman v. Khalsa*, 669 F.3d 1101, 1118 (10th Cir. 2012) (holding that a right to practice in one's chosen profession is not fundamental).

overturn a statute on the basis that no empirical evidence supports the assumptions underlying the legislative choice." *Id.* Indeed, rational basis scrutiny is so deferential that courts "must independently consider whether there is any conceivable rational basis for the classification, regardless of whether the reason ultimately relied on is provided by the parties." *Teigen v. Renfrow*, 511 F.3d 1072, 1084 (10th Cir. 2007) (alterations, internal quotation marks, and citation omitted).

It cannot be disputed that Defendants have a legitimate, indeed *compelling*, interest in stemming the spread of COVID-19 and preventing more hospitalizations and deaths. *See Roman Catholic Diocese v. Cuomo*, 141 S. Ct. 63, 67 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest[.]"). The question is whether requiring individuals working at hospitals and certain congregate care facilities or attending a massive state fair to be vaccinated or meet an exception is rationally related to the State's interest? Unquestionably, it is.

Over one hundred years ago, the Supreme Court rejected a challenge to a universal smallpox vaccine mandate. In *Jacobson*, the state passed a law permitting a city to enforce vaccination of its citizens or face a $5.00 criminal penalty (about $140.00 today). 197 U.S. at 12; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). After refusing a smallpox vaccine, as required by the city of Cambridge, Jacobson was sentenced to jail until he paid the fine. *Jacobson*, 197 U.S. at 11. Jacobson sued, claiming the mandate violated his right to "bodily integrity." *Id.* at 13-14.

The Supreme Court rejected Jacobson's challenge, recognizing that a state's police power "must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety." *Id.* at 25. Thus, according to the Supreme Court, "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is beyond all question, a plain, palpable invasion of rights secured by the fundamental law." *Id.* at 31.

Cambridge's vaccine mandate withstood this test. The mandate had a real and substantial relation to stemming the spread of smallpox—despite a minority view that the vaccines were ineffective. *See id.* at 31-39. In so holding, the Court quoted the New York Court of Appeals, which stated,

> It must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox. The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease and to render it less dangerous to those who contract it. . . . The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action[.]

Id. at 34-35 (quoting *Viemeister v. White*, 179 N.Y. 235, 239-41, 72 N.E. 97 (1904). The Court also rejected Jacobson's offer of proof that the vaccine "quite often caused serious and permanent injury," stating that to allow him to avoid vaccination on this general concern "would practically strip the legislative department of its function to care for the public health and the public safety when endangered by epidemics of disease." *Id.* at 37.

Jacobson has been upheld and relied on throughout the years by courts across the country—including in challenges to COVID-19 vaccine mandates. *See, e.g.*, *Zucht v. King*, 260 U.S. 174, 176 (1922) (relying on *Jacobson* to uphold a city ordinance excluding from its public schools children not having a certificate of vaccination); *cf. Roman Catholic*, 141 S. Ct. at 71 (Gorsuch, J. concurring) ("In *Jacobson*, individuals could accept the vaccine, pay the fine, or identify a basis for exemption. The imposition on Mr. Jacobson's claimed right to bodily integrity, thus, was avoidable and relatively modest. It easily survived rational basis review, and might even have survived strict scrutiny, given the opt-outs available to certain objectors."); *America's Frontline Doctors v. Wilcox*, No. EDCV 21-1243 JGB (KKx), 2021 U.S. Dist. LEXIS 144477, at

**14-17 (C.D. Cal. July 30, 2021) (citing *Jacobson* and concluding that the plaintiffs were unlikely to succeed in their due process claim against the University of California's COVID-19 vaccination mandate).[36]

Recently, a U.S. district court relied on *Jacobson* to reject a group of students' request for a preliminary injunction against the Indiana University's requirement that all students be vaccinated against COVID-19 or meet various religious or medical exemptions. *See Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **15-17, 42-104. After carefully reviewing the current state of scientific consensus regarding the safety and effectiveness of the COVID-19 vaccines, the court noted that "the students' arguments amount to disputes over the most reliable science. But when reasonable minds can differ as to the best course of action . . . the court doesn't intervene so long as the university's process is rational in trying to achieve public health." *Id.* at *103. Ultimately, the court concluded that that Indiana University "has a rational basis to conclude that the COVID-19 vaccine is safe and efficacious for its students." *Id.* at *99.

The U.S. Court of Appeals for the Seventh Circuit denied the students' motion for an injunction pending appeal, noting that "*Jacobson*, which sustained a criminal conviction for refusing to be vaccinated, shows that plaintiffs lack [a fundamental right to attend school without being vaccinated]." *Klaassen v. Trs. of Ind. Univ.*, No. 21-2326, 2021 U.S. App. LEXIS 22785, at *2 (7th Cir. Aug. 2, 2021). The Court further observed that the case was "easier" than *Jacobson* because the university had exceptions for persons "who declare vaccination incompatible with

[36] Even Plaintiffs' counsel admits *Jacobson* "stands on solid ground without a doubt." Plaintiffs' Response to Defendant's Motion to Dismiss [Doc. 18] at 2, *N.M. Elks Ass'n v. Lujan Grisham*, No. 1:21-cv-00354-KG/LF (D.N.M. May 28, 2021) ("COVID-19 is certainly a grave concern, just like smallpox was, and the exercise of infringement into personal liberty by the government of requiring a vaccine as considered in *Jacobson* stands on solid ground without a doubt.").

their religious beliefs and persons for whom vaccination is medically contraindicated," and Indiana was not requiring every member of the public be vaccinated but instead to simply condition attendance on vaccination. *Klaassen*, 2021 U.S. App. LEXIS 22785, at **3-4. Notably, Justice Amy Coney Barrett denied the students' application for injunctive relief following the Seventh Circuit's decision, signaling the Supreme Court did not find the students' case meritorious.[37]

The instant case is identical to *Klaasen* and doomed to the same fate. Like Indiana University, Defendants side with the vast majority of the scientific community—including the CDC and the State's public health experts—in concluding that the COVID-19 vaccines are a safe and effective way to protect individuals from becoming infected or at least becoming seriously ill. *See generally* Exh. A. Relying on this general consensus, Defendants instituted a targeted vaccine mandate aimed at individuals working with the State's most vulnerable populations in hospitals and certain congregate care facilities, as well as individuals attending one of the largest events in the state. *See* N.M. Dep't of Health, *supra* note 29. Moreover, Defendants (like Indiana University) tailored the mandate to provide exemptions for individuals who have a qualifying medical condition which immunization would endanger their health or a disability or sincerely held religious belief requiring accommodation. *Compare* N.M. Dep't of Health, *supra* note 29, *with Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **15-17.

Plaintiffs' disagreement with the scientific community or speculation about theoretical long-term side effects of the vaccines does not negate Defendants' rational basis for their actions. *See Jacobson*, 197 U.S. at 34-37; *Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **103. Nor do the PHO's vaccine requirements need to "take into account for or recognize the health implications

[37] *See Docket Search*, U.S. Supreme Court, https://www.supremecourt.gov/docket/docket.aspx (search "No. 21A15"; select "Docket for 21A15") (last visited Aug. 24, 2021).

associated to [sic] individuals that have natural immunity[,]" which Plaintiffs allege is "equal to or better" than the immunity provided from vaccines. Compl. at 4 ¶¶ 13-14. As explained above, there is ample evidence that the immunity provided by vaccines is more robust and durable than natural immunity. *See generally* Background Section II, *supra*; *see also America's Frontline Doctors*, 2021 U.S. Dist. LEXIS 144477, at *17 ("The Court finds that there is clearly a rational basis for Defendants to institute the Policy requiring vaccination, *including for individuals who previously had COVID-19*." (emphasis added)). And even if Plaintiffs' allegations happened to be true, the PHO's vaccine requirements need not be narrowly tailored to exclude individuals who have been previously infected. *See Powers*, 379 F.3d at 1217 ("[W]e will not strike down a law as irrational simply because it may not succeed in bringing about the result it seeks to accomplish, or because the statute's classifications lack razor-sharp precision."). Left only with speculative arguments previously rejected by the Supreme Court, the Court must conclude Plaintiffs cannot succeed on their equal protection and substantive due process claims.

2. Procedural Due Process

Plaintiffs next claim Defendants violated Plaintiffs' right to procedural due process under the Fourteenth Amendment. *See* Compl. at 12. However, a procedural due process violation will not lie when the underlying governmental action affects a general class of persons. *See Okla. Educ. Ass'n v. Alcoholic Beverage Laws Enf't Comm'n*, 889 F.2d 929, 936 (10th Cir. 1989) ("When the legislature passes a law which affects a general class of persons, those persons have all received procedural due process—the legislative process."). Although this exception typically applies to laws passed by Congress or state legislatures, courts have applied this exception based on the nature of the action and whether it applies to a larger segment of the population rather than a limited number of individuals. *See, e.g.*, *Curlott v. Campbell*, 598 F.2d 1175, 1181 (9th Cir. 1979)

("At the outset we doubt very much that procedural due process prior to reduction of benefits is required when an agency makes a broadly applicable, legislative-type decision." (citing *Bi-Metallic Investment Co. v. State Board of Equalization*, 239 U.S. 441 (1915)). Following this principle, courts (including those within this district) have held that executive orders issued in response to the current pandemic were legislative in nature, and therefore, did not implicate procedural due process. *See, e.g.*, *Hernandez v. Lujan Grisham*, 508 F. Supp. 3d 893, 977-81 (D.N.M. 2020);[38] *ETP Rio Rancho*, 2021 U.S. Dist. LEXIS 36354, at **149-51; *Peterson*, 2020 U.S. Dist. LEXIS 183471, *25-26. Respectfully, this Court should likewise hold that Plaintiffs are not entitled to procedural due process with regard to the issuance of the PHO.

3. U.S. Const. Art. I § 10

Plaintiffs are also unlikely to succeed on their claims based on Art. I, § 10 of the Constitution. Plaintiffs incorrectly assert that the PHO constitutes a bill of attainder. *See* Compl. at 12. A bill of attainder is "a law that legislatively determines guilt and inflicts punishment upon an identifiable individual without provision of the protections of a judicial trial." *Nixon v. Administrator of Gen. Servs.*, 433 U.S. 425, 468 (1977). In deciding whether a law inflicts forbidden punishment, three inquiries must be made: "(1) whether the challenged statute falls within the historical meaning of legislative punishment; (2) whether the statute, viewed in terms of the type and severity of burdens imposed, reasonably can be said to further nonpunitive legislative purposes; and (3) whether the legislative record evinces a congressional intent to

[38] Plaintiffs' counsel was counsel in *Hernandez* and should be well aware of this holding but nonetheless chooses to reassert the same claim. This is not surprising, however, as Plaintiffs' counsel has a history of filing frivolous claims. *See, e.g.*, *Collins v. Daniels*, 916 F.3d 1302, 1320-23 (10th Cir. 2019) (upholding Rule 11 sanctions against A. Blair Dunn).

punish." *Selective Serv. Sys. v. Minn. Pub. Interest Research Grp.*, 468 U.S. 841, 852 (1984) (internal quotation marks and citation omitted).

The PHO's vaccination requirements do constitute a bill of attainder for several reasons. First, it does not list or single out individuals but applies generally to hospital workers, congregate care workers, and persons entering the State Fair. *Cf. Brady v. Tansy*, No. 93-2008, 1993 U.S. App. LEXIS 33697, at *5 (10th Cir. Dec. 21, 1993) ("Section 33-8-8 is not a bill of attainder because it does not single out Mr. Brady for treatment different from what would be imposed on anyone else found guilty of the same offense[.]" (internal quotation marks and citation omitted)). Second, they do not impose burdens based on past conduct but only individuals' *current* vaccination status. *See Consol. Edison Co. of N.Y., Inc. v. Pataki*, 292 F.3d 338, 349 (2d Cir. 2002) ("Another indispensable element of a bill of attainder is its retrospective focus: it defines past conduct as wrongdoing and then imposes punishment on that past conduct.").

Lastly, the PHO does not inflict forbidden punishment, such as the death penalty, imprisonment, or confiscation of property for unvaccinated individuals. *See Selective Serv. Sys.*, 468 U.S. at 852. Certain statutes in the past that barred groups from participation in specific employment can be impermissible legislative punishments; however, these laws only served the purpose of branding certain individuals as disloyal. *See, e.g.*, *Cummings v. Missouri,* 4 Wall. 277 (1867) (striking down a law barring clergy associated with the Confederacy during the Civil War from ministry); *Ex parte Garland,* 4 Wall. 333 (1867) (striking down a law prohibiting attorneys associated with the Confederacy from practicing law); *United States v. Brown,* 381 U.S. 437 (1965) (holding that a law barring members of the Communist Party from service as offices of labor unions was void as a bill of attainder). In contrast, the PHO's vaccination requirement serves a non-punitive purpose of preventing the spread of a deadly, contagious virus straining New

Mexico's delicate healthcare system. Nor is there any evidence the PHO was issued with intent to punish unvaccinated individuals.

Plaintiffs also appear to assert the PHO violates the Contracts Clause of Art. I, § 10. *See* Compl. at 21. "[T]he Contract Clause limits the power of the States to modify their own contracts as well as to regulate those between private parties." *U.S. Tr. Co. of N.Y. v. New Jersey*, 431 U.S. 1, 17 (1977). However, the Contracts Clause "is not an absolute one and is not to be read with literal exactness like a mathematical formula." *Home Bldg. & Loan Asso. v. Blaisdell*, 290 U.S. 398, 428 (1934). Nor does the clause "operate to obliterate the police power of the States." *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 241 (1978). Courts apply a two-step test to determine whether a state law violates the Contracts Clause. "The threshold issue is whether the state law has 'operated as a substantial impairment of a contractual relationship.'" *Sveen v. Melin*, 138 S. Ct. 1815, 1821-22, (2018) (quoting *Allied*, 438 U.S. at 244). "In answering that question, the Court has considered the extent to which the law undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights." *Id.* at 1822. When a law substantially impairs a contract, "the State, in justification, must have a significant and legitimate public purpose behind the [law], such as the remedying of a broad and general social or economic problem." *Stillman v. Teachers Ins. & Annuity Ass'n College Ret. Equities Fund*, 343 F.3d 1311, 1321 (10th Cir. 2003) (internal quotation marks and citations omitted). Specifically, the court will ask "whether the state law is drawn in an appropriate and reasonable way to advance a significant and legitimate public purpose." *Sveen*, 138 S. Ct. at 1822 (internal quotation marks and citations omitted).

As an initial matter, Plaintiffs have failed to demonstrate that the vaccine requirement substantially interferes with their contracts because they have not provided the Court any copies

of any of the purported contracts at issue.[39] Further, the PHO does not substantially impair the employee-employer contract raised by Plaintiff Blackford, as her employer, Presbyterian Healthcare Services, is requiring COVID-19 vaccinations for its entire workforce. *See* Heild, *supra* note 30; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact)]. Therefore, Plaintiff Blackford's claim fails as a matter of law.

Finally, even if the Court found that the PHO substantially impairs one of the Plaintiffs' various contracts, the vaccine requirement is an appropriate and reasonable means of advancing the State's significant and legitimate purpose. It is undeniable that Defendants have not only a legitimate but a *compelling* interest in preventing the spread of COVID-19, especially now when its hospitals are being overwhelmed by a highly contagious variant. *See Legacy Church, Inc.*, 472 F. Supp. 3d at 1022. There is also substantial evidence that vaccines are the best way to prevent the strain on New Mexico's healthcare system and protect the State's population. *See generally* Exh. A. Requiring the workers who interact with ill patients or serve persons living in close proximity is a reasonable measure to protect not only the populations within hospitals and congregate care facilities but also all employees from the risk of severe illness or death. *See id.* The PHO's vaccine requirement for all vaccine-eligible persons entering the State Fair is similarly

[39] For example, it is possible that the purported State Fair contract may have provisions allowing for the cancellation of the contract for any reason. Additionally, the State Fair contracts and employment contracts may have provisions requiring the Plaintiffs abide by all New Mexico laws and regulations, which would include the PHO. Regardless, the New Mexico State Fair is offering full refunds to participants who will not be vaccinated in time for the fair. *See 2021 Junior Livestock Refund Application*, N.M. State Fair, https://statefair.exponm.com/p/participate/competitions/livestock-shows (last visited Aug 30, 2021). Additionally, the New Mexico Youth Livestock Expo is being relocated to Roswell at a later date. *See* Jonathan Fjeld, *New Mexico Youth Livestock Expo to relocate to Roswell*, KOB4 News (Aug. 27, 2021), https://www.kob.com/albuquerque-news/new-mexico-youth-livestock-expo-to-relocate-to-roswell/6219714/.

reasonable, as it will help ensure that the thousands of people from all over the state do not contribute to a superspreading event. Therefore, Plaintiffs are unlikely to succeed on their Art. I, § 10 claims.

4. State Constitutional Claims

Finally, Plaintiffs bring a claim under the newly enacted New Mexico Civil Rights Act, NMSA 1978, §§ 41-4A-1 to -13 (2021), asserting that the PHOs violate various provisions of the New Mexico constitution. *See* Compl. at 13-14. However, sovereign immunity prohibits Plaintiffs from maintaining such claims in *federal* court. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984); *Ramirez v. Martinez*, No. 20-cv-824 MV/SMV, 2021 U.S. Dist. LEXIS 68516, at *6 (D.N.M. Apr. 7, 2021) (Vázquez, J.) ("The eleventh amendment bars a suit for damages in federal court when the action is in essence one for recovery of money from the state and the state is the real, substantial party in interest, notwithstanding that individual officials are nominal defendants."). Although the State waived sovereign immunity in passing the New Mexico Civil Rights Act, *see* § 41-4A-9, it did so only for suits brought in New Mexico *state* courts. *See* § 41-4A-3(B) (providing that a individuals "may maintain an action to establish liability and recover actual damages and equitable or injunctive relief in any *New Mexico* district court" (emphasis added)). Accordingly, Plaintiffs' state constitutional claims are barred by sovereign immunity. *See Sossamon v. Texas*, 563 U.S. 277, 285 (2011) ("[A] waiver of sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign. So, for example, a State's consent to suit in its own courts is not a waiver of its immunity from suit in federal court." (internal quotation marks and citations omitted)).

Leaving sovereign immunity aside, the Court should not consider Plaintiffs' state law claims in determining the likelihood of success on the merits in light of Plaintiffs' failure to bring

any viable federal claims. *See Merrifield v. Bd. of Cty. Comm'rs*, 654 F.3d 1073, 1085 (10th Cir. 2011) (stating that a district court may decline supplemental jurisdiction when it has "dismissed all claims over which it has original jurisdiction" (quoting 28 U.S.C. § 1367(c)(3)); *cf. Bray v. City of N.Y.*, 356 F. Supp. 2d 277, 282 (S.D.N.Y. 2004) ("This Court may not entertain the City's motion for a preliminary injunction if supplemental jurisdiction is lacking or imprudent."). Additionally, the Court should decline supplemental jurisdiction because Plaintiffs' claims raise novel and complex issues of state constitutional law that should be addressed by New Mexico courts. *See* 28 U.S.C. § 1367(c)(1); *see generally* Linda M. Vanzi, et al., *State Constitutional Litigation in New Mexico: All Shield and No Sword*, 48 N.M. L. Rev. 302, 305 (2018) (stating that the New Mexico supreme court has considered only three civil cases involving a claim under the state constitution in the past twenty years).

D. Plaintiffs fail to demonstrate any irreparable harm

Plaintiffs' failure to demonstrate a "strong" likelihood of success on the merits of their claims is determinative to their requested preliminary injunctive relief. *See Amoco Oil Co. v. Rainbow Snow*, Inc., 809 F.2d 656, 664 (10th Cir. 1987) ("As a prerequisite to the granting of a preliminary injunction, the moving party must show, *in addition to the likelihood of success on the merits*, that it will suffer irreparable injury unless the injunction issues." (emphasis added)). Equally fatal to Plaintiffs' request is their inability to demonstrate any form of irreparable harm required for their requested injunctive relief. *See Schrier*, 427 F.3d at 1267. "To constitute irreparable harm, an injury must be certain, great, actual and not theoretical." *Id.* (internal quotation marks and citations omitted). "Irreparable harm is not harm that is merely serious or substantial." *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (internal quotation marks and citation omitted). Plaintiffs have not established a likelihood of success on the merits of any of

their claims, and therefore cannot use a purported constitutional violation as the basis for any irreparable harm. *See Logan v. Pub. Emps. Ret. Ass'n*, 163 F. Supp. 3d 1007, 1030 (D.N.M. 2016) ("[A] plaintiff who cannot demonstrate a substantial likelihood of success is not entitled to a presumption of irreparable harm." (citing *Schrier*, 427 F.3d at 1266).

With regard to Plaintiff Blackford, as the Court has already noted, she cannot demonstrate *any* harm vis-à-vis the PHO because her employer has independently announced it will be requiring its entire workforce to be vaccinated. *See* Heild, *supra* note 30; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact)]. Moreover, "[a] permanent loss of employment, standing alone, does not equate to irreparable harm." *E. St. Louis Laborers' Local 100 v. Bellon Wrecking & Salvage Co.*, 414 F.3d 700, 704 (7th Cir. 2005). With regard to Plaintiff Valdez, she fails to demonstrate any irreparable harm in simply not being able to attend an annual state fair. While she may have entered into a contract for her children to exhibit animals at the fair, the State has made clear that anyone who is no longer able or interested in participating in the livestock shows will be issued a refund, *see* New Mexico State Fair, *supra* note 39, the Youth Livestock Show will be rescheduled at another venue, *see* Fjeld, *supra* note 39, and Valdez fails to explain how damages could not remedy any remainder of her injury. *See Heideman*, 348 F.3d at 1189 ("It is also well settled that simple economic loss usually does not, in and of itself, constitute irreparable harm; such losses are compensable by monetary damages."). Hence, Plaintiffs' requested preliminary injunctive relief must be denied for want of irreparable injury.

E. The balance of equities and the public interest counsel against granting injunctive relief

Even if Plaintiffs could demonstrate a strong likelihood of success or an irreparable injury, they fail to clearly demonstrate that the threatened injury outweighs the harm that preliminary injunctive relief would cause the public. It cannot be gainsaid that the State (and the public) has a

compelling interest in limiting the spread of a deadly, contagious virus. *See Legacy Church, Inc.*, 472 F. Supp. 3d at 1064 ("The public's interest in limiting the COVID-19 outbreak in the State, a compelling interest outweighs the right to gather."). Granting Plaintiffs' requested preliminary relief and allowing Plaintiffs to care for the State's most vulnerable populations or attend one of the State's largest gatherings would undoubtedly lead to more New Mexicans falling ill and dying. *See League of Indep. Fitness Facilities & Trainers, Inc. v. Whitmer*, 814 Fed. Appx. 125, 129 (6th Cir. 2020) ("Enjoining the actions of elected state officials, especially in a situation where an infectious disease can and has spread rapidly, causes irreparable harm."). New Mexico's hospitals are at or near capacity and New Mexicans continue to succumb to the virus every day. *See generally* Exh. A. Each newly announced death is not simply a statistic, but a mother, a son, a grandfather, a sister. Each one leaves a gaping hole in the lives of their loved ones, and each one deserves protection. These losses are truly irreparable, and the community's interest in preventing more is paramount. *Cf. ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 23409, at *153 (concluding that "the threatened injuries—financial injuries and possible permanent business closure—do not outweigh possible damage—increased COVID-19 spread leading to sickness, hospitalizations, and death—to the Defendants").

CONCLUSION

For the foregoing reasons, this Court should deny the Plaintiffs' request for preliminary injunctive relief.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 30, 2021, I filed the foregoing via the CM/ECF filing system, which caused all counsel of record to be served by electronic means.

Respectfully submitted,

/s/ Holly Agajanian
Holly Agajanian

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself and others similarly situated,

Plaintiffs,

v. **Case No. 1:21-cv-00783-MV-JHR**

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

DECLARATION OF CHRISTINE ROSS

I, Christine Ross, MD, MPH declare:

I. QUALIFICATIONS

1. I am over the age of eighteen. I am competent to testify as a medical expert to the facts and matters set forth herein.

2. I have been asked to provide information regarding the novel coronavirus 2019, Sars-CoV-2, ("COVID-19"), the COVID-19 vaccinations and their effectiveness, the COVID-19 Delta variant, the effect of COVID-19 on the New Mexico Health System, and the information used by the State of New Mexico to develop relevant public health orders. As the State Epidemiologist with the Department of Health, I have knowledge regarding the available scientific evidence related to COVID-19 transmission, the challenges posed by the variants of COVID-19, and COVID-19 vaccine effectiveness relied upon by the State in issuing its public health orders.

3. Attached is a true and accurate copy of my *Curriculum Vitae* for review and I further provide the following information regarding my qualifications:
    - I volunteered with the U.S. Peace Corps in Sierra Leone, and with Doctors Without Borders in Kenya and Tanzania. During this time, I worked extensively on public health issues including vaccine preventable diseases such as tetanus which was a leading cause of death among babies (neonatal tetanus) in these locations.

- I trained and worked as a physician for over 15 years primarily working in the hospital setting in northern California as an acute care hospitalist where I managed complex medical patients on the medical-surgical wards and Intensive Care Unit.
- I completed a highly competitive 2-year fellowship training program with the United States Centers for Disease Control and Prevention (CDC) in applied epidemiology.
- I worked with the CDC for over 8 years in global public health with a primary focus on the HIV pandemic in Africa. My last several years at CDC, I directed the CDC Ethiopia office which included a global immunization program with objectives of measles elimination and polio eradication both vaccine preventable diseases.
- In addition, I supported the CDC International Ebola response by deploying to Sierra Leone several times to facilitate scientific studies on the Ebola virus.
- Through my work with CDC, I collaborated with the World Health Organization and UNICEF and other multi-lateral organizations to facilitate a large immunization campaign in the country of Jordan, for Syrian refugee children in order to stop a large measles outbreak.
- I joined the NMDOH as the State Epidemiologist in October 2020 at the height of the winter surge of COVID-19 cases in the state. I came to NMDOH to use my expertise in medicine, public health, and epidemiology to help my family, fellow New Mexicans, and fellow Americans during this tragic pandemic.
- I am the Director of the Epidemiology and Response Division for the NMDOH.
- I am a member of the Medical Advisory Team for the state of New Mexico for the COVID-19 pandemic response.

II. THE SEVERITY OF COVID-19

4. Since the first case of COVID-19 was identified in China and reported to the World Health Organization in December 2019, the COVID-19 pandemic has exploded and is impacting more than 220 countries. By August 27, 2021, more than 214 million cases have been reported and over 4.4 million deaths.[1] The World Health Organization designated Region of the Americas is reporting the highest number of new cases over the past several weeks and this is driven primarily by us here in the United States.

5. As of August 29, 2021, 38.7 million cases of COVID-19 have been reported in the United States, which most likely represents a fraction of the true burden of disease in the country.[2] This is due to limitations on the number of people who seek out a laboratory test due to mild symptoms and/or do not receive a formal diagnosis.

[1] *World Health Organization Coronavirus (COVID-19) Dashboard*, https://covid19.who.int/ (last visited Aug. 29, 2021).

[2] *Vaccination and Case Trends of COVID-19 in the United States*, Ctr. for Disease Control and Prevention ("CDC") https://covid.cdc.gov/covid-data-tracker/#vaccinations-cases-trends (last visited Aug. 29, 2021) (hereafter "CDC COVID Data Tracker").

6. Tragically, more than 634,000 Americans have died from COVID-19, many of the deaths occurring prior to the development of the COVID-19 vaccines. The CDC COVID Data Tracker[3] graphs the trends of cases and deaths by age group and impact of vaccination on case and death trends. Older adults, individuals with multiple chronic conditions, and individuals residing in congregate care settings are vulnerable to this infectious disease. It is extremely striking to see the trends in mortality rates among older persons and the exponential decline after the roll-out of the COVID-19 vaccines.

7. COVID-19 is a respiratory infection caused by the SARS CoV-2 virus and it was not seen in humans prior to December 2019. It is a zoonotic disease which means the virus was originally circulating in an animal host when there was a cross-over event into a human host. Humans had no natural immunity to this novel virus. Therefore, the virus easily spread from person to person and then around the globe because of how connected we are with air, sea, and land travel.

8. COVID-19 is a major global public health threat that dramatically disrupted all sectors of society worldwide. Avoiding unabated transmission of this novel virus is necessary to minimize the significant morbidity and mortality already experienced around the globe. Mitigating disease transmission or slowing the spread and onward transmission of the virus from person to person by social distancing and avoiding large gatherings was critical early in the pandemic prior to the development of vaccines and anti-virals. Now that vaccines are available, they are not only the most effective way to protect an individual against this novel virus, but also a critical step toward ending this global pandemic.

9. Despite the implementation of mitigation measures, the healthcare delivery system continues to be severely strained and in some locations there is the potential for collapse. We have seen hospitals at the breaking point in multiple countries and also here in the United States. Currently, hospitals in multiple locations in the United States will soon no longer be able to treat COVID patients. This near collapse is due the volume of COVID-19 patients requiring hospital-level care typically needing oxygen and some requiring mechanical ventilator support due to respiratory failure from viral pneumonia and typically followed by septic shock. The impact of this large volume of patients presenting with complications of a single disease also leads to the inability for hospitals to adequately manage the other patients that seek care for things like congestive heart failure, a heart attack, a stroke, or injuries arising from an accident.

10. In New Mexico, hospitals are again experiencing significant strain due to the number of patients and are operating above capacity with staff shortages, and we have learned that patients are waiting longer for ICU beds.[4] This strain will also likely impact the quality of care hospitals can provide to critical patients.

[3] *Id.*

[4] *COVID-19 in New Mexico*, N.M. Dep't of Health, https://cvprovider.nmhealth.org/public-dashboard.html (follow "Show Historical Statewide Date" on bottom left-hand corner; then scroll down to "Current Hospitalizations") (last visited Aug. 29, 2021) ("NMDOH COVID Data Dash

11. Discussions with the New Mexico Hospital Association and healthcare delivery leaders throughout the state are underway regarding re-implementing Crisis Standards of Care. Even if there is a bed available, the limiting factors currently are inadequate numbers of staff, particularly nursing staff, related to the large volumes of patients, fatigue of the current staff, and also COVID infections among the staff.

12. Many healthcare personnel have been infected with this novel virus prior to development of the COVID-19 vaccines. To date over 500,000 healthcare workers in the United States have been infected.[5]

13. Because frontline healthcare workers are a critical asset for our health security and many face repeated high risk exposures, protecting them from infection with this novel virus has been prioritized. For these reasons, when supply was limited, healthcare and other frontline workers were the first group of Americans to receive vaccines as recommended by the Advisory Committee on Immunization Practices, the CDC, and most state governments, including New Mexico. We cannot adequately and safely manage the number of infected and sick Americans and keep our hospitals running without adequate numbers of healthy nurses and doctors and support staff.

14. Health care personnel have direct and close patient contact with persons who may be extremely vulnerable to the virus and at high risk for poor outcomes. The healthcare worker may inadvertently bring the virus into the hospital or other setting such as a long-term care facility which can prove to be a deadly situation for vulnerable patients such as those profoundly immunosuppressed or elderly residents.

15. The COVID-19 vaccines are extremely safe and highly effective and are the best tool we have to protect individuals and protect communities from this novel virus.[6]

16. Although, many COVID-19 infections result in a range of mild to moderate disease in healthy individuals, and symptoms typically resolve in a few weeks, minimizing risk of infection with this novel virus is highly recommended. No one can predict with 100% certainty who will experience mild disease and who will experience severe symptoms, although we now know the common risk factors associated with severe disease. Poor outcomes still happen in healthy individuals. Last week NMDOH reported the death of a

board"); N.M. Dep't of Health, *New Mexico COVID-19 Hospitalization Update*, (Aug. 23,2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/COVID19_hospitalizations_08.23.2021.pdf

[5] *Cases and Deaths among Healthcare Personnel,* CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#health-care-personnel (last visited Aug. 29, 2021).

[6] *Safety of COVID-19 Vaccines*, CDC, (Aug. 23, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html; *COVID-19 ACIP Vaccine Recommendations*, CDC, https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html (last visited Aug. 29, 2021).

woman in her 20's from respiratory failure secondary to viral pneumonia caused by COVID-19. She had no known underlying conditions and therefore no known conditions that would have increased her risk of severe disease or a poor outcome. A death in young person is always a tragedy and especially if it was preventable. We have no record that she received a COVID-19 vaccine.

17. There are also long-term effects of a COVID-19 infection even after an asymptomatic or mild infection. Some people do not have resolution of their symptoms in the average 7-14 day time frame, but rather they experience long-lasting symptoms for several weeks.[7] When symptoms last for more than 4 weeks this is collectively referred as "post-COVID conditions" and also referred to as "long-COVID." There are many people struggling to manage these symptoms but there is little the medical community can offer at this juncture with regards to treatment because the conditions are still so ill-defined. It is especially frustrating for families with school age children who do not have quick resolution of their symptoms.[8] Given the magnitude of the pandemic, many Americans will be affected by post-COVID conditions, and this will place tremendous burden on the individuals and the health care system for some time to come.

18. Many children with COVID-19 infection experience mild symptoms and mortality is very low compared to adults. However, when children do require hospitalization about one third require ICU level care. Children can become severely ill but most recover and survive to discharge from the hospital. There is also a rare but very serious syndrome associated with COVID-19 that primarily affects children called the "Multi-system Inflammatory Syndrome." Children can become quite ill with this post-viral inflammatory syndrome which can affect multiple organ systems.[9] It is expected that in a relatively short period of time the COVID-19 vaccines will be approved for younger age groups.

19. We are incredibly fortunate that COVID-19 is now a vaccine-preventable disease like measles, mumps, rubella, varicella, polio, tetanus, and many others.

[7] Mark W. Tendorede, MD, PhD, et.al., *Symptom Duration and Risk Factors for Delayed Return to Usual Health Among Outpatients with COVID-19 in a Multistate HealthCare Systems Network—United States, March-June 2020,* CDC Morbidity and Mortality Weekly Report (MMWR), (July 31, 2020) https://www.cdc.gov/mmwr/volumes/69/wr/mm6930e1.htm.

[8] *Post COVID Conditions: Information for Healthcare Providers*, CDC (July 9, 2021) https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html.

[9] Lindsay Kim, MD, et.al., *Hospitalization Rates and Characteristics of Children Aged <18 Years Hospitalized with Laboratory Confirmed COVID-19 —COIVD-NET, 14 States March 1-July 25, 2020*, CDC MMWR,(Aug. 14, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e3.htm; *Longitudinal study follows multisystem inflammatory syndrome in children (MIS-C)*, National Heart Lung and Blood Institute, (Feb. 16, 2021), https://www.nhlbi.nih.gov/news/2021/longitudinal-study-follows-multisystem-inflammatory-syndrome-children-mis-c.

20. The American Academy of Pediatrics, the American Academy of Family Practice, and the Infectious Diseases Society of America, recommend vaccination to protect against COVID-19 for children and adolescents aged 12 and over by using an authorized vaccine for their age unless there is a contraindication.[10] The most effective way to stop transmission to children younger than 12 years is to vaccinate eligible family members and those in the community where they live.[11]

21. The same principles hold true for protecting individuals who are not able to get vaccinated due to a contraindication such as an allergy to one of the components of the vaccine or persons who may be severely immunocompromised and not able to mount an effective immune response to the vaccine. These individuals rely on the people around them to be vaccinated in order to reduce circulation of the virus.[12]

III. THE DELTA VARIANT AND THE CURRENT SURGE OF CASES

22. We are currently experiencing a severe surge in COVID-19 infections across the United States which is fueled by the highly contagious Delta variant of the SARS-CoV-2 virus. The CDC currently estimates that the Delta variant accounts for the majority of new infections in the United States. The areas of the country currently hit hardest are those in the southern part of the United States, where vaccination coverage is relatively low compared to other parts of the United States.[13]

23. In New Mexico, we are also experiencing a surge in cases due to the Delta variant with the highest case rates (number of cases per 100,000 persons) in the southeastern part of the state and pockets of the metro region where vaccination coverage or number of

[10] *See American Academy of Pediatrics Updates Recommendations for Opening Schools in Fall 2021*, American Academy of Pediatrics, (July 19, 2021) https://www.aap.org/en/news-room/news-releases/aap/2021/american-academy-of-pediatrics-updates-recommendations-for-opening-schools-in-fall-2021/; *AAFP Celebrates Authorization of COVID-19 Vaccine for Children Ages 12 to 15*, American Academy of Family Physicians, (May 12, 2021) https://www.aafp.org/news/media-center/statements/aafp-celebrates-authorization-of-covid-19-vaccine-for-children-ages-12-to-15.html; *Special Populations: Pediatrics*, Infectious Diseases Society of America, (Aug. 16, 2021), https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/covid-19-vaccination-in-special-populations/#Pediatric.

[11] Eva Leidman, MSPH, et.al. *COVID-19 Trends Among Persons Aged 0-24 Years—United States, March 1-December 12, 2020*, CDC MMWR, (Jan. 22, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e1.htm.

[12] *COVID-19 ACIP Vaccine Recommendations*, *supra*, note 6.

[13] *Variant Proportions*, CDC, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last visited Aug. 25, 2021).

individuals fully vaccinated is lower than other parts of the state.[14] We also have pockets of low vaccination coverage across the state where large numbers of unvaccinated persons are getting sick.[15]

24. With continued transmission of the virus from person to person, the virus continually mutates, and therefore it is always changing. Many of the changes in its genome do not lead to anything meaningful or concerning but sometimes they do. The Delta variant is classified as a "variant of concern" by the CDC because it is 2-5 times as transmissible or contagious as the ancestral strains.[16] Therefore, many more people become infected by an exposure event. There is also evidence that it may cause more severe disease among unvaccinated persons.[17]

25. NMDOH conducts surveillance on "variants of concern" and we work together with our state public health lab, UNM, LANL and other labs. We were able to identify the variant in the state several months ago and it rapidly outcompeted the other variants and became the dominant strain. Currently, greater than 90% of the samples we sequence are the Delta variant.[18]

26. Unvaccinated individuals are currently at very high risk of infection and illness due to the high levels of virus circulating in our communities which is predominantly the Delta variant. One of the objectives of genomic surveillance is to also monitor for introduction of a "variant of high consequence" which could have new mutations in the viral genome that could possibly lead to more severe disease or even the ability to evade the current vaccines and anti-viral therapeutics. If we can significantly reduce the transmission of

[14] *See* NMDOH COVID Data Dashboard, *supra* note 4; *COVID-19 Variant of Concern (VOC) Case Report*, N.M. Dep't of Health, (Aug. 23, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/COVID-19-VOC-Case-Report_08.23.21.pdf (hereafter "NMDOH COVID-19 VOC Report").

[15] *See* NMDOH COVID Data Dashboard, *supra* note 4; N.M. Dep't of Health,*COVID-19 Vaccine Dashboard*, (Aug. 27, 2021), https://cvvaccine.nmhealth.org/public-dashboard.html; N.M. Dep't of Health, *COVID-19 Modeling in New Mexico*, https://cvmodeling.nmhealth.org/home/modeling-updates/; Los Alamos National Laboratory, *Modeling & Forecasting COVID-19 in NM*, (Aug. 24, 2021) https://cvmodeling.nmhealth.org/wp-content/uploads/sites/4/2021/08/LANL-COVID_ModelingResults_8.24.2021.pdf.

[16] *See SARS-CoV-2 Variant Classifications and Definitions*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.

[17] *Delta Variant: What We Know About the Science*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html (last visited Aug. 25, 2021).

[18] NMDOH COVID-19 VOC Report, *supra*, note 14.

this virus from person to person we can decrease the likelihood that these type of selective advantages will occur. The best tool we have to make this happen is through protecting as many people as possibly by vaccination.

27. The NMDOH also conducts surveillance for vaccine breakthrough cases in order to monitor for any concerning or unexpected patterns of cases by demographics, geography, vaccine lot, vaccine-type, etc. The vaccine breakthrough case rate is very low and our surveillance data is consistent with the vaccine clinical trial data that demonstrated that all three COVID-19 vaccines approved for use in the United States are highly effective at preventing infection, severe disease, and death.[19]

28. The majority of COVID-19 cases, hospitalizations, and deaths are among unvaccinated individuals in New Mexico and across the United States. We are watching the trends in vaccine breakthrough cases closely with the surge in cases related to the Delta variant. We have seen an increasing number of vaccine breakthrough infections although they tend to be mild infections. This appears to suggest a modest decline in vaccine effectiveness at preventing infection with the Delta variant, but the COVID-19 vaccines remain highly effective at preventing serious illness and death.[20]

IV. COVID-19 VACCINE APPROVAL AND EFFECTIVENESS

29. The Federal Drug Administration ("FDA") recently granted full approval for the Pfizer COVID-19 vaccine for ages 16 and up and the vaccine is available under the Emergency Use Authorization (EUA) for children ages 12 to 15.[21] The clinical trials for the younger age groups started later so the expectation by the scientific community is that the FDA approval for younger age groups will be obtained later. The Moderna and Janssen vaccines

[19] N.M. Dep't of Health, *New Mexico COVID-19 Vaccination Report*, (Aug. 23, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/Vaccination-Case-Report-2021-08-24_v3.pdf (hereafter "NMDOH COVID-19 Vaccination Report"); Jennifer B. Griffin et al., *SARS-CoV-2 Infections and Hospitalizations Among Persons Aged ≥16 Years, by Vaccination Status — Los Angeles County, California, May 1–July 25, 2021*, CDC MMWR (Aug. 24, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e5.htm?s_cid=mm7034e5_w (Analysis of over 40,000 infections in Los Angeles from May to July 2021 found that vaccinated individuals were nearly 5 times less likely to become infected and nearly 30 times less likely to require hospitalization).

[20] *See* NMDOH COVID-19 VOC Report, *supra*, note 14; NMDOH COVID-19 Vaccination Report, *supra* note 19.

[21] U.S. Food & Drug Admin. ("FDA"), *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

are currently available in the United States under an Emergency Use Authorization for people 18 and over.[22]

30. All three of the COVID-19 vaccines approved in the US, which includes the vaccine produced by Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson), were tested and found to be highly effective at protecting individuals from serious illness and death due to COVID-19 disease through rigorous randomized controlled clinical trials.[23] The safety profile of these vaccines were carefully reviewed against the risk of natural infection. Because the risks associated with natural infection are so great and far outweigh the risk of vaccination, the FDA initially used an emergency mechanism in order to allow access to the vaccines.

31. The COVID-19 vaccines are extremely unlikely to cause serious side effects that could result in long-term health problems.[24]The COVID-19 vaccines help prevent the spread of COVID-19 and are effective against the COVID-19 variants that have been detected in New Mexico.[25]

[22] FDA, *FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020) https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; U.S. Food & Drug Admin., *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (February 27, 2021) https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[23] FDA, *FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine*, (Dec. 10, 2020) https://www.fda.gov/media/144245/download; FDA, *FDA Briefing Document Moderna COVID-19 Vaccine*, (Dec. 17, 2020) https://www.fda.gov/media/144434/download; FDA, *FDA Briefing Document Jassen Ad26.COV2.S Vaccine for the Prevention of COVID-19*, (Feb. 26, 2021) https://www.fda.gov/media/146217/download; *see also Comirnaty and Pfizer-BioNTech COVID-19 Vaccine*, FDA, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine (last visited Aug. 29, 2021); *Moderna COVID-19 Vaccine*, FDA, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine (last visited Aug. 29, 2021); *Jassen COVID-19 Vaccine*, FDA, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine (last visited Aug. 29, 2021).

[24] *Safety of COVID-19 Vaccines*, *supra* note 6; *COVID-19 ACIP Vaccine Recommendations*, *supra*, note 6.

[25] *See FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine*, *supra* note 23; *FDA Briefing Document Moderna COVID-19 Vaccine*, *supra* note 23; *FDA Briefing Document Jassen Ad26.COV2.S Vaccine for the Prevention of COVID-19 supra* note 23; NMDOH COVID-19 VOC Report, *supra*, note 14; NMDOH COVID-19 Vaccination Report, *supra* note 19; *see also The Possibility of COVID-19 after Vaccination: Breakthrough Infections,* CDC, (Aug. 23, 2021) https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-

32. The FDA and the Advisory Committee on Immunization Practices (ACIP) are comprised of our nation's leading experts on the science related to vaccines, particularly immunology, infectious diseases, epidemiology, etc. The ACIP is the body that makes recommendations to the CDC.[26] The ACIP made recommendations initially for vaccination according the EUA because the risks associated with natural infection far outweighs the risks associated with vaccination.[27]

33. Natural infection appears to confer some degree of protection or immunity, but it is unknown how long this immunity lasts and how variable it may be between individuals. It is also unknown if the degree of protection varies and is dependent on whether someone experienced an asymptomatic, mild, moderate, or severe infection. There are many basic science studies currently underway to study the immune response among persons infected with this novel virus. However, the available science surrounding this novel virus recommends vaccination after natural infection.

34. We carefully study vaccine effectiveness in randomized controlled clinical trials in large numbers of people. The ACIP and CDC are recommending vaccination after natural infection to boost the immune response and protection. This is especially important for older individuals because they may have a less robust or shorter duration of protection after natural infection.[28]

effectiveness/breakthrough-cases.html; Heidi L. Moline, MD, et.al., *Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years—COVID-NET, 13 States, February-April 2021*,CDC MMWR, (Aug. 13, 2021) https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e3.htm?s_cid=mm7032e3_w.

[26] *See Vaccines and Related Biological Products Advisory Committee,* FDA, https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee (last visited Aug. 29, 2021) (stating the 15 members and the Chair are selected from among authorities knowledgeable in a range of scientific fields including immunology, molecular biology, virology; epidemiology, vaccine safety science, vaccine development including translational and clinical evaluation programs, allergy, pediatrics, and preventative medicine); Advisory Committee on Immunization Practices, *General Committee-Related Information*, CDC, https://www.cdc.gov/vaccines/acip/committee/index.html (last visited Aug. 29, 2021).

[27] *See* FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; *FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine*, *supra* note 22; *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine*, *supra* note 22.

[28] Christian Holm Hansen, PhD, et.al., *Assessment of protection against reinfection with SARS-COV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level*

35. The current data indicates reinfection with the virus that causes COVID-19 is uncommon in the 90 days after the initial infection. Similar to other human coronaviruses the probability of SARS-CoV-2 reinfection is expected to increase with time after recovery from initial infection due to waning immunity and the possibility of exposure to virus variants.[29] We have reports from several countries of reinfection with a SARS-CoV-2 variant virus including Brazil, the UK, and South Africa to date.[30] Unfortunately, the global pandemic continues, and the risk of reinfection depends on the likelihood of re-exposure to the virus. This risk is very high given the widespread transmission of the virus currently in our communities. Again, a primary issue is also the risk of reinfection with virus variants. If an individual was infected with an ancestral strain of the virus, they may not be protected against a new or emerging variant that could potentially be more deadly. The risk of reinfection from a variant would also increase the more time has passed from the original infection. For these reasons, even if an individual was previously infected, the ACIP and CDC and all state and local health departments recommend vaccination.

36. The COVID-19 virus is circulating at very high levels in the community, so it has ample opportunity to mutate and change. [31] Individuals infected early on with an ancestral strain like the alpha variant may not have strong protection against the newer strains such as the delta variant and those variants that are yet to come.

37. The vaccines are safe and effective because they target multiple proteins and prime the immune system prior to the body being exposed the virus or becoming infected. The response is robust and highly protective against multiple variants including the delta variant. Pfizer and Moderna vaccines have been found to be 86% effective in preventing illness serious enough to require hospitalization 2-12 weeks after vaccination and 84% effective at 13-24 weeks. [32] We are beginning to see more vaccine breakthrough cases

observation study, The Lancet, (March 17, 2021) https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00575-4/fulltext (concluding the study "could inform decisions on which groups should be vaccinated and advocate for vaccination of previously infected individuals because natural protection, especially among older people, cannot be relied on.").

[29] *Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19,* CDC, (March 16, 2021) https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

[30] *Id.* at notes 67-73.

[31] N.M. Dep't. of Health, *Level of Community Transmission of COVID-19 by New Mexico Counties August 10-August 23, 2021*, https://cv.nmhealth.org/wp-content/uploads/2021/08/County_Data_Report_08.24.21.pdf (last visited Aug. 29, 2021).

[32] Mark W. Tenforde, et al., *Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021*, CDC (Aug. 18, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm.

because over time immunity wanes and the highly infectious Delta variant is raging through our state and country.[33] A booster dose will most likely be recommended by the ACIP for 8 months after initial vaccination.

38. However, the immunity provided by vaccines may be more long-lasting compared to immunity gained following infection. One recent study found that unvaccinated individuals who were previously infected had 2.34 times the odds of being reinfected than those who had been fully vaccinated. [34]

39. The COVID-19 vaccines have now been administered to over 170 million Americans and these vaccines are undergoing the most intensive safety monitoring in U.S. history.[35] The same vaccines are used globally and the World Health Organization reports that hundreds of millions of vaccinations have been administered. Serious complications from vaccination are extremely rare. The risk of serious disease, long-lasting health outcomes, and death from infection with the novel SARS-CoV-2 virus far exceeds risk of vaccination.[36]

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on August 30, 2021 in Columbiana County, Ohio.

CHRISTINE ROSS, M.D.

[33] *See* NMDOH COVID-19 Vaccination Report, *supra* note 19.

[34] Alyson M. Cavanaugh, et al., *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination—Kentucky, May–June 2021*, CDC, https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w.

[35] *COVID-19 Vaccinations in the United States*, CDC, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited Aug. 23, 2021).

[36] *See Safety of COVID-19 Vaccines*, *supra* note 6.

Christine Ross, MD, MPH & TM

Summary of qualifications:
Medical officer/medical epidemiologist with over 20 years of clinical experience in both outpatient and acute care settings predominantly working with underserved and vulnerable populations. Extensive domestic and international public health and epidemiology experience working in low-resource settings with local governments, US government and non-governmental organizations.

Work Experience

10/2020 – present **State Epidemiologist, Director Epidemiology and Response Division**
NMDOH

- Serving as State Epidemiologist as lead public health expert for state of New Mexico, liaison with Centers for Disease Control and Prevention and voting member of Council of State and Territorial Epidemiologists
- Providing strategic direction, leadership and management of NMDOH Epidemiology and Response Division, office encompasses 7 bureaus (Health Emergency Management, Emergency Medical Services, Vital Records, Infectious Disease Epidemiology, Community Health and Systems Epidemiology, Injury and Behavioral Health, Environmental Health Epidemiology) and over 250 personnel.

6/2018 – 10/2020 **Director, CDC-Ethiopia and DGHT Program Director, CDC-Ethiopia**
CDC/CGH/DGHT
Federal job series: 602, temporary GS-15/step 3

Providing strategic direction, leadership, and management for CDC-Ethiopia, office of 90 personnel and operating budget of approximately 65 million USD

- Member of the US Embassy Country Team providing agency strategic leadership to the US Ambassador
- Member of the US Embassy Emergency Action Committee providing input on management decisions related to crises or security situations potentially affecting the embassy community of >1200 Americans
- Member of the Senior Interagency Team for PEPFAR
- Serving as Health Attaché for the US Embassy in Ethiopia
- Providing strategic leadership on the COVID-19 response to the government of Ethiopia and advisor to the US Ambassador on COVID-19 response as it relates to US Embassy operations
- Leading the CDC COVID-19 Incident Management Structure in Ethiopia and working directly with the GHS Program Director to oversee all CDC-supported activities and 9 million USD in supplemental funds
- Providing subject matter expertise on the epidemiology, clinical management, and surveillance of HIV, supervising the implementation of PEPFAR-supported HIV programing via 11 cooperative agreements
- Management of the CDC office, including collaborating and coordinating programmatic priorities of multiple programs including Division of Global Health Protection and Security, Global Immunization Division, Presidents Malaria Initiative, and Field Epidemiology Training Program
- Providing strategic leadership to the CDC Ethiopia Senior Management Team
- Directly supervising 6 staff in the Office of the Director and 5 senior branch chiefs (locally employed staff)

8/2017 – 6/2018 **Associate Director of HIV Care and Treatment, CDC-Ethiopia**
CDC/CGH/DGHT/HCTB
Federal job series: 602, GS-14/step 4

Expertise on PEPFAR strategy/priorities and HIV clinical and preventive services in Ethiopia

- Member of the CDC-Senior Management Team providing leadership and technical expertise on implementation and evaluation of HIV programmatic priorities for PEPFAR/CDC.

- Member of the PEPFAR-Senior Interagency Team with USAID, Peace Corps, US Department of State representatives; providing technical expertise on HIV clinical and preventive services for strategic direction development and interface with the US Embassy front office
- Member of the PEPFAR-Collaborative Team providing technical expertise on HIV clinical and preventive services and leadership on interagency technical work
- Providing technical support to the breadth of programmatic and research activities of the HCTB and implementing partners including the Ethiopia Federal Ministry of Health and the Regional Health Bureaus
- Supporting analysis of Data Quality Assessment (DQA) at 8 facilities in Addis Ababa and Oromia Region evaluating the PEPFAR testing and treatment monitoring, evaluation, and reporting indicators
- Facilitating HIV care and treatment data analysis and interpretation for the PEPFAR Oversight and Accountability Review Team (POART) reviews for report to the Office of the Global AIDS Coordinator (OGAC)
- Principle investigator on STI Etiological Study among female sex workers and family planning attendees in Addis Ababa in collaboration with Ethiopian Public Health Institute – protocol recently completed and submitted for scientific/ethical review

Technical support of broader CGH work in Ethiopia

- Providing consultation to leadership and staff from Division of Global Health Protection (DGHP), President's Malaria Initiative, Field Epidemiology Training Program (FETP), and Global Immunization Division as part of the CDC-Senior Management Team
- Providing technical expertise for concept note development with DGHP and FETP leadership on utilization of FETP officers for monitoring and analyzing HIV viral load data for epidemic control as part of Emergency Operation Center function in Amhara Region
- Member of the UN Interagency Task Force on Non-Communicable Diseases currently developing strategic framework with multiple UN agencies, WHO, World Bank, and Global Fund together with FMOH and consultation with DGHP

Management/supervisory experience

- Providing technical supervision to 10 person HCTB and technical/project officer to all CDC-Ethiopia Epidemic Control Teams with focus on Addis Ababa and Oromia Regional Health Bureaus

7/14 ─ 8/17 Medical Officer/Epidemiologist Priority Populations HIV Treatment Team
CDC/CGH/DGHT/HCTB
Federal job series: 602, GS-14/step 3
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Technical expert in global HIV care and treatment, tuberculosis, other opportunistic infections with special focus on cryptococcal disease, and key population programming:

- Served as subject matter expert to PEPFAR-supported programs on HIV care and support interventions (non-ART interventions) and treatment services; facilitated team transition from HIV care and support focus to scale-up of access to treatment services for key and priority populations. Served as liaison to HIV Prevention Branch and led development of a joint strategy document to guide provision of technical support on KP programming
- Lead CDC-headquarters HIV care and treatment technical advisor and point of contact for DGHT Ethiopia; provided technical assistance to improve access to quality treatment services for female sex workers, analyzed and interpreted treatment data and presented recommendations to OGAC; provided technical expertise to country team for the FY16 Country Operational Plan (COP) development and review
- Technical lead on cryptococcal disease and scale-up of CrAg screening in PEPFAR programs; liaison to NCEZID/ Mycotic Diseases Branch and coordinated joint projects and strategic discussions
- Lead CDC-headquarters HIV care and treatment technical advisor and point of contact for the DGHT Central America Regional program; provided guidance on decentralization of treatment services in Honduras and Panama; served as treatment technical expert for the FY16 Regional Operational Plan development and review
- Lead of the Southern Africa Unit for PPTT (includes South Africa, Swaziland, Mozambique, Malawi, Zimbabwe, Botswana, Namibia, Lesotho); managed and prioritized technical support to DGHT programs on KP and priority

populations programming, served as treatment SME on interagency assessment of KP clinical care cascade in Swaziland, identified critical gaps and provided recommendations to MOH
- Member of Interagency Collaborative for Program Improvement; participate in interagency (CDC, USAID, DOD, Peace Corps, HRSA) initiative to monitor, evaluate, and utilize PEPFAR program data
- Active member of the PEPFAR HIV Care and Treatment and Key Populations technical working groups collaborating with leads from USAID, DOD, Peace Corps, HRSA

Expertise in scientific research meeting CDC and local government scientific, human subjects and ethics standards:
- Serving as principle investigator on STI etiological survey among female sex workers and family planning attendees in Ethiopia in collaboration with CDC Division of STD Prevention Laboratory, CDC-Ethiopia and Ethiopian Public Health Institute
- Lead CDC investigator on $1.3 million implementation science study (CryptoART) of the mortality benefit associated with cryptococcal antigen screening of PLHIV with advanced immunosuppression with University of Zimbabwe; currently in close-out phase for 1300 participants at 20 study sites in Harare, Zimbabwe
- Project/technical lead of 10-person team on a $125,000 headquarter operational funded program evaluation of a package of care for PLHIV with advanced HIV disease in Lesotho, in collaboration with MOH, CDC-Lesotho, and Elizabeth Glaser Pediatric AIDS Foundation
- Co-investigator on ART outcomes study evaluating trends in prevalence of advanced HIV disease in 10 countries utilizing CDC/PEPFAR program data with multiple collaborators
- Co-investigator on multi-division/agency study on the persistence of Ebola virus in semen and other body fluids of Ebola Virus Disease survivors in Sierra Leone as part of the 2015 CDC Ebola Response

Supervisory experience:
- Acting team lead approximately 20% time; representing team at branch and team leader meetings and responding to requests by senior management and OGAC
- Primary mentor/supervisor for CDC American Association of Schools and Programs for Public Health (ASPPH) Allan Rosenfield Global Health Fellow – September 2016 until August 2017
- Supervised and mentored Headquarters Experience and Technical Assistance Fellowship (HETA) fellow from Tanzania, March to May 2015
- Senior team member, providing guidance and mentoring to 4 junior team members and branch EIS officers

CDC Ebola Response – Epidemiology Special Studies Team EOC Deployments
- Selected for two deployments as Sierra Leone in-country lead implementing a study on persistence of Ebola virus in semen of Ebola Virus Disease survivors (March 21–April 19 and May 9–May 24, 2015)
- Facilitated rapid completion of study protocol and obtained scientific approval by CDC and local Institutional Review Boards, led the implementation of the pilot study in setting of an evolving public health emergency; work completed in collaboration with the CDC's Viral Special Pathogens Branch, Division of STD Prevention, Sierra Leone MOH, and WHO
- Served as CDC technical lead on study steering committee with MOH, WHO, UNAIDS, and other community stakeholders; identified and secured pilot study site and developed implementation plan with the MOH and WHO
- Led community sensitization efforts through meetings with the National Ebola Survivor's Association
- Developed study SOPs and CRF's and training of trainers curriculum; trained study staff on the study protocol
- Co-authored rapid results manuscript published (Oct. 2015) to aid global guidance development for EVD survivors and multiple scientific publications in high impact journals followed

7/2012 ─ 6/2014 CDC Epidemic Intelligence Service Officer
CDC/NCHHSTP/DSTDP/Health Services Research and Evaluation Branch
Federal job series: 602, GS-12

- Led analysis of a large medical claims database to determine STD and HIV prenatal screening rates among Medicaid-insured population

- Conducted epidemiologic investigation on the prevalence of repeat syphilis and HIV co-infection among men who have sex with men in Baltimore, MD; extensive data abstraction from multiple databases, analysis and presentation of findings to stakeholders
- Provided epidemiologic support in the CDC Emergency Operations Center activation for multistate outbreak of fungal meningitis, maintaining line lists, contacted patients with risk of exposure, liaised with local health department officials
- Collaborated with North Dakota Department of Health on epidemiologic investigation of a large health care-associated hepatitis C outbreak; activities included data abstraction, patient and provider interviews, analysis and interpretation of preliminary data, and presentation of findings to stakeholders
- Provided technical expertise as part of a multi-organizational PAHO consultation in Chile with the development and testing of a tool to validate elimination of mother-to-child transmission (MTCT) of HIV and syphilis; presented findings to MOH and public health officials
- Invited to participate as member of GID mission to support the Jordanian MOH, WHO, and other UN agencies to plan, organize, and implement an emergency measles vaccination campaign targeting 600,000 Syrian refugee and Jordanian children; conducted monitoring and evaluation of campaign activities for quality assurance and contributed to development of the design and sampling frame of the post-campaign vaccination coverage survey
- Provided technical responses to >50 STD-related inquiries from clinicians, researchers, and lay people as member of DSTDP "Doctor on call" service
- Evaluated Chilean national surveillance system of congenital syphilis, presented findings at CDC's 2012 EIS Fall Course on public health surveillance
- Supervised medical students during CDC Experience Fellowship in Applied Epidemiology

9/2005 ─ 5/2012 Physician-Hospitalist, John Muir Medical Group
John Muir Medical Center, Concord, CA
Medical Director: Dr. Debbie Arce

- Supervised the medical management of patients in the intensive care unit (ICU) and medical-surgical wards in 250+bed hospital; directed medical care of 12–20 patients daily including hospital admissions, discharges, transfers and coordination of care with sub-specialists
- Extensive experience in management of medically complicated patients including those hospitalized for complications related to HIV/AIDS, other infectious diseases, and non-communicable diseases
- Led quality improvement projects evaluating patient flow between emergency department and medical/surgical wards and development of standard operating procedures for patient transition from ED to ICU admission
- Active member of the rapid response team, patient safety, and hospitalist committees

9/1997 ─ 8/1998 Doctors Without Borders (MSF) Medical Volunteer

Ugandan Country Medical Coordinator for Cholera Epidemic Intervention, Kampala, **Uganda**
- Travelled to remote regions to assess need for new cholera treatment centers, led the collection and analysis of epidemiological data from 10 existing centers in collaboration with MOH
- Trained clinic staff on diagnostic algorithm and clinical management of cholera and other highly prevalent coinfections, including malaria

Cholera Intervention Treatment Site Manager, Malindi and Kakamega, **Kenya**
- Managed and trained clinic personnel on cholera treatment and prevention
- Provided community prevention and treatment educational talks
- Performed active surveillance through outreach and investigation of suspect cases in remote villages

12/1992 ─ 8/1997 Registered Nurse

- Touro Infirmary, New Orleans, LA. Provided direct patient care for medical-surgical ward patients in all wards of the 300+ bed hospital (medical-surgical, oncology, intensive care, skilled nursing unit)
- Thom's Rehabilitation Hospital, Asheville, NC. Provided direct patient care for spinal cord injury, head trauma, and stroke patients in small specialty unit

- Akron City Hospital, Akron, OH. Provided direct patient care for step-down ICU and telemetry patients in 500+ bed hospital

6/1993 ─ 5/1994 United States Peace Corps Health Volunteer - Sierra Leone

- Completed 3-month Peace Corps course training on Sierra Leone culture and Krio language
- Led the development of a maternal-child health aide training program aimed at decreasing maternal and neonatal mortality in rural areas in collaboration with UNICEF
- Led the development of a curriculum for safer birthing techniques and prenatal and maternal health including vaccine-preventable diseases (neonatal tetanus) and malaria

Education

1998-2002	Louisiana State University School of Medicine	Doctor of Medicine
1995-1997	Tulane University SPHTM	Master of Public Health and Tropical Medicine
1995-1997	Tulane University	Post-baccalaureate Pre-medical Program
1987-1991	University of Akron School of Nursing	Bachelor of Science in Nursing

Post-graduate Training

2012-2014	US CDC Epidemic Intelligence Service (EIS) Fellowship Division of STD Prevention, Health Services Research and Evaluation, Atlanta, GA
2003-2005	Family Medicine Residency, UCSF affiliate, Contra Costa County FM Residency, Martinez, CA
2002-2003	Family Medicine Internship, UCLA affiliate, Ventura County FM Residency, Ventura, CA

Additional training

Foreign Affairs Counter Threat Training (FACT). Glynco, GA (2017)
FEMA training course: Preparing Healthcare Workers to Work in Ebola Treatment Units in Africa. Anniston, AL (2015)
Principles of STD/HIV Research course (certificate), University of Washington Center for AIDS and STD. Seattle, Washington (2013)

Licensure/Certification

Diplomate of the American Board of Family Medicine, board certified 2005, recertified 2012
Physician & Surgeon License; New Mexico currently active; Georgia and California – currently inactive

Medical Residency International Experiences

2/04-3/04 Himalayan Health Exchange, northern region, India

- Supervised medical students in outpatient temporary clinics, provided basic clinical services including minor procedures to isolated communities on 6-week mission

5/03-6/03 Surgical Relief Project, Tegucigalpa, Honduras

- Surgical-assistant to plastic surgeon for repair of facial deformities
- Provided basic clinical services to indigent populations on 4 week mission

Other Skills

Spanish basic speaking, writing and comprehension
Krio (lingua franca of Sierra Leone) limited speaking and comprehension

Medical Volunteer Work

9/15-12/16 Sexually Transmitted Diseases Drop-in Clinic, Fulton County Dept. of Health and Wellness

Membership in Professional Societies

Epidemic Intelligence Service Association

American Academy of Family Practitioners
Doctors Without Borders Association

Publications – Peer Reviewed

Bingham T, Chang G, Parekh B, Patel H, Sleeman K, Benech I, Selenic D, Duong Y, Justman J, Saito S, + 20 co-authors, **Ross C**, Kancheya N, Voetsch A. Can "Undetectable equals Untransmittable (U=U)" be applied in resource-limited settings: Results of the Population-based HIV Impact Assessment surveys in eleven African countries, 2015-2018. *MMWR Full Report, Publication Pending.*

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Deen G, Knust B, Broutet N, Sessay F, Formenty P, **Ross C.** et al. Ebola RNA Persistence in Semen of Ebola Virus Disease Survivors–Preliminary Report. *N Engl J Med 2015; published online Oct 14.* http://www.nejm.org/doi/full/10.1056/NEJMoa1511410

Ross C, Tao G, Hoover, K. Screening for Human Immunodeficiency Virus and Other Sexually Transmitted Diseases among U.S. Women with Prenatal Care. *Obstetrics and Gynecology. 2015 May; 125(5):1211-6.*

Cooley L**,** Pearl M, Flynn C, **Ross C,** et al. Low Viral Suppression and High HIV Diagnosis Rate among Men Who Have Sex With Men With Syphilis — Baltimore, Maryland. *Sexually Transmitted Diseases. 2015 April; 42(4); 226-231.*

Cooley L, **Ross C,** Hart-Cooper G, Oster A, Pearl M, et al. Repeat Syphilis Infection and HIV Coinfection Among Men Who Have Sex With Men — Maryland, 2010-2011. *MMWR Morb Mortal Wkly Rep.* 2013; 62(32); 649-650.

Abstracts and Presentations

Woldehanna, D, Tedla Y, Eskinder B Abayneh S, **Ross C.** Bridging the gap in viral load testing coverage and suppression among patients on anti-retroviral therapy. Accepted as poster presentation, 23rd IAS Conference, July 2020.

Eshetu F, Abdella S, Ayalew Aklilu, Haile A, Beletel W, Melaku Z, Habte D, Deressa T, Ahmed J, Altaye Feleke, Kaydos-Daniels S, **Ross C**, Moges B, Kifle T, Tollera G, Abate E, HIV case-based surveillance team. Building a sustainable HIV case surveillance and response system for reaching Epidemic control: lessons learned from Ethiopia. Accepted as oral poster presentation, 23rd IAS Conference, July 2020.

Makadzange A, Boyd K, Machekano R, Hlupeni A, Chagumaira T, **Ross C** et al. Sensitivity and Specificity of Point-of-Cryptococcal Antigen Testing on Fingerprick and Urine Specimens among Asymptomatic HIV-infected Individuals with CD4≤100 cells/uL. Accepted as poster presentation at *International Conference on AIDS and STIs in Africa*; 2017 December, Abidjan, Cote d'Ivoire.

Makadzange A, Hlupeni A, Boyd K, Chagumaira T, **Ross C**, et al. High Prevalence of CNS Dissemination among People with Asymptomatic Cryptococcal Antigenemia. Poster presentation at *Conference on Retroviruses and Opportunistic Infections;* 2017 March, Seattle, WA.

Ross C, Vallabhaneni S, Govender N, ICAP. Satellite symposium on Current Topics on Advanced HIV disease and Viral Load Scale-up. Oral presentation at the *2015 International Conference on AIDS and STDs in Africa)*; 2015 December, Harare, Zimbabwe.

Ross C, Tao G, Hoover K. Prenatal Screening for Chlamydia and Gonorrhea and the Association with Papanicolaou Testing Among Medicaid-insured Women — United States, 2009–2010. Oral presentation at *STD Prevention Conference;* 2014 June, Atlanta, GA.

Ross C, Tao G, Hoover K. Prenatal HIV Testing Coverage of Medicaid-insured Women — United States, 2009–2010. Poster presentation at *Conference on Retroviruses and Opportunistic Infections;* 2014 March, Boston, MA.

Cooley L, Pearl M, Flynn C, Hart-Cooper G, **Ross C**, Burnett P, Olthoff G, Chaulk P, Morgan J, Oster A. Low Viral Suppression and High HIV Diagnosis Rate Among MSM with Syphilis — Baltimore, Maryland, 2010–2011. Poster presentation at *Conference on Retroviruses and Opportunistic Infections;* 2014 March, Boston, MA.

Ross C, Hoover K, Kamb M. Sexually Transmitted Diseases in Pregnancy: an Update. Webinar presentation for *American Public Health Association*; 2013 September; Atlanta, GA.

Ross C, Cooley L. Epi-aid: Repeat Syphilis Infection and HIV Coinfection among Men Who Have Sex with Men — Maryland, 2010-2011. Oral presentation at *The Division of STD Prevention Learning Hour*; 2013 August; Atlanta, GA.

Hoover K, Alonso M. **Ross, C**, Kamb, M. Piloting Methods for Validation of Elimination of MTCT of HIV and Syphilis in St. Lucia and Chile. *International Society of Sexually Transmitted Diseases Research*; 2013 July, Vienna, Austria.

Ross C, Hoover K, San Martin A, Tao G, Alonso M, Aguila R, Kamb M. Validating Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis — Chile, 2012. Oral presentation at 62nd *Annual Epidemic Intelligence Service Conference*; 2013 April, Atlanta, GA.

Calles D, Collier A, Suryaprasad F, Xu F, Kolwaite A, Ko S, Allison R, Lee-Kwan S, **Ross C**, Weninger S. Healthcare-associated Hepatitis C in a Skilled-care Facility — North Dakota, 2014. *63rd Annual Epidemic Intelligence Service Conference*; 2014 April, Atlanta, GA.

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Ross C, Schechtman A. Ask the Doctor: The ABC's of Hepatitis for the Traveler. *South American Explorer*. Summer edition 2001.

Schechtman A, **Ross C**. Ask the Doctor: Don't Get Hooked by the Hookworm. *South American Explorer*. Fall edition 2001.

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

TALISHA VALDEZ, on behalf of herself
and others similarly situated, and
JENNIFER BLACKFORD on behalf of herself
And others similarly situated,

Plaintiffs,

Civil Action. 1:21-cv-00783-MV-JHR

v.

MICHELLE LUJAN GRISHAM,
Officially and Individually, Acting Under the Color of Law,
and
DAVID SCRASE,
Officially and Individually, Acting Under the Color of Law,

Defendants.

REPLY TO DEFENDANTS' RESPONSE TO PLAINTIFFS' REQUEST FOR TEMPORARY RESTRAINGING ORDER

COMES NOW Plaintiffs and hereby provide this Honorable Court their Reply to the Defendants Response to Plaintiff's Request for Temporary Restraining Order and states as follows in support thereof.

ARGUMENT

It is neither histrionic nor hyperbolicity in a country founded upon resisting an overbearing head of state (the King of England then) who gave zero regard to an individual's freedom to choose for themselves what was best for their lives and imposing taxation without representation; for private citizens to criticize a head of state unilaterally using executive power to institute policies that trample individual civil liberties to invade the citizens' bodily integrity to strip them of their chosen profession, deprive them of their property and to punish

their children for exercising the freedom upon their own analysis and investigation to choose what is best for their children. In fact, such a list of offenses begins to resemble the grievances in the Declaration of Independence when it states:

> We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness. That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed, That whenever any Form of Government becomes destructive of these ends, it is the Right of the People to alter or to abolish it, and to institute new Government, laying its foundation on such principles and organizing its powers in such form, as to them shall seem most likely to effect their Safety and Happiness. Prudence, indeed, will dictate that Governments long established should not be changed for light and transient causes; and accordingly all experience hath shown, that mankind are more disposed to suffer, while evils are sufferable, than to right themselves by abolishing the forms to which they are accustomed. But when a long train of abuses and usurpations, pursuing invariably the same Object evinces a design to reduce them under absolute Despotism, it is their right, it is their duty, to throw off such Government, and to provide new Guards for their future security.--Such has been the patient sufferance of these Colonies; and such is now the necessity which constrains them to alter their former Systems of Government. The history of the present King of Great Britain is a history of repeated injuries and usurpations, all having in direct object the establishment of an absolute Tyranny over these States. To prove this, let Facts be submitted to a candid world.

U.S.C.A. § DECLARATION OF INDEPENDENCE.

Nor is it offensive or overwrought to address such usurpations by a head of state behaving in such a fashion comparing them to similar dark point in our history when civil liberties were trampled upon in the name of public safety. As the Supreme Court has observed: [t]he Constitution was adopted in a period of grave emergency. Its grants of power to the federal government and its limitations of the power of the States were determined in the light of emergency, and they are not altered by emergency." *Home Building & Loan Ass'n. v. Blaisdell*, 290 U.S. 398, 425, 54 S.Ct. 231, 78 L.Ed. 413 (1934). After all, this head of state justifies using her technocratic selective science to mandate vaccination in the name of

fighting a war on Covid displaying when she does an absolutely offensive disregard for the civil rights of the unvaccinated to make their own decision about what the put in their bodies trusting the science they think is best and their own doctors to decide for themselves what is best for them. What this court should find offensive is not that the comparison was made to *Korematsu*, but rather but that the actions of this government to trample civil rights in the name of public health could give rise to such comparison. It is clear that this Governor's actions are premised upon a rallying cry of crisis for public health to declare war on a disease, demanding the hypocritical surrender of civil rights as it fits their agenda in favor of the collective good.

This is particularly troubling coming from a governor from the Democratic Party that has long professed to be the better champion for civil rights fighting for the bodily integrity of women, marriage rights for the LGBTQ community and for racial equality. Yet despite the stanch advocacy for such social justice in our jurisprudence like *Roe v. Wade*, 410 U.S. 113 (1973) or *Obergefell v. Hodges*, 576 U.S. 644 (2015), here these Democratic Defendants would rather villainize healthcare workers and punish children for citizens exercising those same liberties. To be honest, it is hard to stomach the stench of hypocrisy on full display in the instant Response from a governor that on one hand signs an abortion bill into law in the midst of the pandemic that provides than an abortion may be performed up to the delivery of that child thereby ending a life stating **"[a]nyone who seeks to violate bodily integrity, or to criminalize womanhood, is in the business of dehumanization. New Mexico is not in that business — not any more. Our state statutes now reflect this inviolable recognition**

of humanity and dignity"[1] but, then on the other hand tells nurses and mothers that they must allow that same bodily integrity to be violated in order to continue to earn a livelihood in their chosen profession or for their children to participate in activities to which great time and precious resources have already been devoted.

Yet, here in this litigation, Defendants continue their campaign to villainize those that disagree with their science behind injecting experimental vaccines (all of which are still authorized under an "Emergency Use Authorization," *see* Exhibit 4, despite the attempted misdirection to claim that the Pfizer vaccine is fully approved and no longer needs emergency authorization) by attempting to label Plaintiffs, or other like them and their legal counsel heretical for even having a difference of opinion as to the state's selected science even though there is documented considerable difference of scientific opinion. *See* Exhibit 5. This type of attack on those that disagree with the dogma of the state's selected science is what earns them the well deserved gestapo comparison.

But, this case is not really about the science. Plaintiffs are not asking this Court to decide whose science is better. Plaintiffs seek to have this Court consider the law and apply the Constitutions as it is the proper role of the Court. Plaintiffs have properly alleged sufficient plausible facts alleging that the actions of the Defendants infringement upon the long recognized fundamental liberty interest in engaging in ones chosen profession and to ask this Court to evaluate under strict scrutiny whether or not the PHO at issue is narrowly tailored. Moreover, Plaintiffs ask this Court to enjoin the Defendants from taking an action that clearly violates the Constitutions' prohibitions of New Mexico impairing the obligation of preexisting

[1] https://apnews.com/article/legislature-michelle-lujan-grisham-statutes-legislation-us-supreme-court-e233ebe60f2af544ca9d59287a634315

contracts for employment or to exhibit livestock at the New Mexico State Fair. *See* U.S. Const. art. I, § 10, cl. 1[2] and N.M. Const. art. II, § 19[3]. Facially, it is hard to imagine that pleading filed in this matter does not satisfy the requirement for interim relief of a likelihood of success on the merits and irreparable harm in the loss of constitutional freedoms.

I. Engaging in One's Chosen Profession is a Long Recognized Fundamental Liberty Interest

Defendants entire argument in their Response misses the boat because they have failed to recognize the undeniable jurisprudence that supports that the government acting through the Defendants here has acted to deprive Plaintiff Blackford and other similarly situated of the ability to engage in their chosen profession. And frankly, the brief of Defendants thereafter never recovers to explain to this Court why their actions are likely to survive strict scrutiny that would make Plaintiff Blackford unlikely to succeed on the merits, meaning simply that the preliminary injunction should issue on that point alone which Defendants should be deemed to have waived any argument to the contrary. Here Plaintiff Blackford has plausibly alleged and verified that she has protected property interest to engage in her chosen profession and that if the government's PHO mandate is enforced she is prohibited from working as nurse in New Mexico as long as the order is in effect and she is unvaccinated. It is important to note that her employer has implemented a policy in order to comply with the PHO mandate that has now resulted in her being placed on leave without pay at least for the next 4 months.

Plaintiff Blackford has identified a liberty interest warranting due process of law,

[2] **No State shall** enter into any Treaty, Alliance, or Confederation; grant Letters of Marque and Reprisal; coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts; **pass any** Bill of Attainder, ex post facto Law, or **Law impairing the Obligation of Contracts**, or grant any Title of Nobility. (emphasis added)

[3] **No** ex post facto law, bill of attainder nor **law impairing the obligation of contracts shall be enacted by the legislature.** (emphasis added)

Defendants disagree because otherwise their actions most certainly run afoul of the Due Process Clause's protections by depriving Plaintiff in the manner they did of their ability to earn a livelihood in the occupation of their choosing.[4] For example, the United States Supreme Court in *Barry v. Barchi* has opined as to the constitutionally protected property interest in engaging in one's chosen profession of horse racing, stating "Plaintiffs have a liberty interest in pursuing their profession of horse racing and are entitled to due process of law if they are to be lawfully denied an opportunity to do so." *Barry v. Barchi*, 443 U.S. 55, 64, 99 S.Ct. 2642, 61 L.Ed.2d 365 (1979).

Thus, the right of citizens to support themselves by engaging in a chosen occupation is deeply rooted in our nation's legal and cultural history and has long been recognized as a component of the liberties protected by the Fourteenth Amendment. Over a century ago, the Supreme Court recognized that "[i]t requires no argument to show that the right to work for a living in the common occupations of the community is of the very essence of the personal freedom and opportunity that it was the purpose of the [Fourteenth] Amendment to secure." *Truax v. Raich*, 239 U.S. 33, 41, 36 S.Ct. 7, 60 L.Ed. 131 (1915) (holding that a state anti-alien labor statute violated both equal protection and due process). Later, in striking down a law banning the teaching of foreign languages in school, the Supreme Court observed that the Fourteenth Amendment guaranteed the right, *inter alia*, "to engage in any of the common occupations of life ...." *Meyer v. Nebraska*, 262 U.S. 390, 399, 43 S.Ct. 625, 67 L.Ed. 1042 (1923). Despite later jurisprudence following the *Lochner* era, *Lochner v. New York*, 198 U.S. 45, 25 S.Ct. 539, 49 L.Ed. 937 (1905), de-emphasizing economic substantive due process, our Supreme Court has

[4] "The right to work, I had assumed, was the most precious liberty that man possesses. Man has indeed as much right to work as he has to live, to be free, to own property. The American ideal was stated by Emerson · in his essay on Politics, 'A man has a right to be employed, to be trusted, to be loved, to be revered.' It does many men little good to stay alive and free and propertied, if they cannot work. To work means to eat. It also means to live. For many it would be better to work in jail, than to sit idle on the curb. The great values of freedom are in the opportunities afforded man to press to new horizons, to pit his strength against the forces of nature, to match skills with his fellow man." *Barsky v. Board of Regents of University of State of New York*, 347 U.S. 442, 472 (1954) (Douglas, J, dissenting).

never repudiated the recognition that a citizen has the right to work for a living and pursue his or her chosen occupation.

The Third Circuit has recognized "[t]he right to hold specific private employment and to follow a chosen profession free from unreasonable governmental interference comes within both the 'liberty' and the 'property' concepts of the Fifth and Fourteenth Amendments." *Piecknick v. Comm. of Pa.*, 36 F.3d 1250, 1259 (3d. Cir. 1994) (citing *Greene v. McElroy*, 360 U.S. 474, 492, 79 S.Ct. 1400, 3 L.Ed.2d 1377 (1959); *Truax*, 239 U.S. at 41, 36 S.Ct. 7). However,

> [t]he Constitution only protects this liberty from state actions that threaten to deprive persons of the right to pursue their chosen occupation. State actions that exclude a person from one particular job are not actionable in suits ... brought directly under the due process clause. It is the liberty to pursue a calling or occupation, and not the right to a specific job, that is secured by the Fourteenth Amendment.

Id. (internal citations and quotation marks omitted). Thus, Defendants here are flat wrong, Plaintiff Blackford and the many others similarly situated most certainly have a right to engage in their chosen professions of nursing, other healthcare employees, congregate caregivers or detention officers. There is no question, then, that the Fourteenth Amendment recognizes a liberty interest in citizens—the Plaintiffs here—to pursue their chosen occupation. The dispositive question is not whether such a right exists, but rather, the level of infringement upon the right that may be tolerated.

II. Defendants Impairment of Contracts is Beyond Question a Violation Both the United States Constitution and the Constitution of New Mexico

The United States Constitution is unequivocal in Art. I Section 10 that a State may not enact impair the obligation of existing contracts. Defendants' multipage discussion regarding bills of attainder is a complete red herring, referencing an inapplicable part of that clause of the Constitution. Furthermore, the New Mexico Constitution in Article II Section 19, from its Bill of Rights, further emphasizes the notion set forth by the United States Constitution and clearly states

"[n]o ex post facto law, bill of attainder nor law impairing the obligation of contracts shall be enacted by the legislature." Plaintiffs have plausibly and sufficiently alleged that they have existing contracts, employment for Plaintiff Blackford and to exhibit livestock at the New Mexico State Fair for Plaintiff Valdez, which are impaired by the enactment of the PHO by the Defendants here on behalf of the state of New Mexico acting under the color of law of a delegation from the New Mexico Legislature.

First with regard to the claims of Plaintiff Valdez, the Defendant's brief fails to address that Plaintiff Valdez has alleged a contract with the State itself. Plaintiff has alleged the contract was with Expo New Mexico a state agency. Plaintiff Valdez has alleged not only the contractual relationship but also that she and her children are completely deprived of the benefit of the contract by disallowing their attendance to the fair to compete which is unequivocally a substantial impairment satisfying the test from *Energy Reserves Group v. Kansas Power & Light Co.*, 459 U.S. 400, 411–12, 103 S.Ct. 697, 74 L.Ed.2d 569 (1983). Moreover, because the contract is with the state as a contracting party the Court does not properly defer to the legislative judgement of Defendants here as to the necessity and reasonableness of a particular measure. And here this is important junior livestock exhibitors are in large outdoor or indoor areas, where social distancing and masking reasonably meet the State's stated objectives in combatting the disease. In truth, this one size fits all approach that fully removed the ability of these children to participate at all (as punishment for not being previously vaccinated) is not reasonable.

Likewise, as to Plaintiff Blackford's employment contract, she is now on administrative leave without pay so that her employer can remain complaint with the Defendants' PHO. She is receiving none of the benefits of her contract which is beyond question a substantial impairment resulting from the Defendants' PHO. Moreover, this concept that the unvaccinated are contributing

in a great amount to the spread of the Delta Variant has been widely debunked with the vaccinated carrying identical if not greater viral loads. Nor does the science that is observed on a global level support the notion that the unvaccinated are at a greater risk for hospitalization. The Plaintiffs respectfully direct the Court's attention to the studies from Israel and Great Britain observed in Exhibit 2. There has been no showing that the State's previous restrictions for testing, masking and social distancing where not appropriate and reasonable enough to satisfy the government's legitimate public purpose. Especially, given that the potential side effects recognized by the FDA of the vaccines are a serious but yet unknow concern. *See* Exhibit 6 page 6.

III. This Court has Supplemental Jurisdiction at Its Discretion.

Here this Court has supplemental jurisdiction or pendant jurisdiction just as it would under the New Mexico Tort Claims Act. Judge Browning has clearly articulated this law as he is prone to do stating:

> Although a statutory basis is necessary for federal courts to exercise jurisdiction over a controversy, "it is well established—in certain classes of cases—that, once a court has original jurisdiction over some claims in the action, it may exercise supplemental jurisdiction over additional claims that are part of the same case or controversy." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. at 552, 125 S.Ct. 2611. The term "supplemental jurisdiction" is now used to refer collectively to the common-law doctrines of ancillary jurisdiction,[9] pendent jurisdiction,[10] and pendant-party jurisdiction.[11] 28 U.S.C. § 1367, *statutorily codifying Owen Equip. & Erection Co. v. Kroger*, 437 U.S. 365, 98 S.Ct. 2396, 57 L.Ed.2d 274 (1978) (outlining the doctrine of ancillary jurisdiction), *and United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 86 S.Ct. 1130, 16 L.Ed.2d 218 (1966) (outlining the doctrine of pendent jurisdiction), *and invalidating Finley v. United States*, 490 U.S. 545, 109 S.Ct. 2003, 104 L.Ed.2d 593 (1989) (rejecting the doctrine of pendent-party jurisdiction). Federal courts may exercise pendent jurisdiction over state law claims when "state and federal claims ... derive from a common nucleus of operative fact." *United Mine Workers v. Gibbs*, 383 U.S. at 725, 86 S.Ct. 1130. Supplemental jurisdiction gives federal courts the flexibility to hear a cause of action after the introduction of third parties whose insertion into the litigation lacks support of any independent grounds for federal jurisdiction, when those parties share a common interest in the outcome of the litigation and are logical participants in it. *See Owen Equip. & Erection Co. v. Kroger*, 437 U.S. at 375 n. 18, 98 S.Ct. 2396.

> In 1988, the Honorable William H. Rehnquist, then-Chief Justice of the United States, created the Federal Courts *1307 Study Committee to analyze the federal court system and to recommend reforms. *See James v. Chavez*, No. CIV 09–0540 JB/CG, 2011 WL 6013547, at *5 (D.N.M. Nov. 21, 2011)(Browning, J.) (citing 16 James W. Moore et al., *Moore's Federal Practice* § 106.04[5] (Matthew Bender 3d ed.)). In response to the Committee's findings regarding pendent, ancillary, and pendent-party jurisdiction, Congress codified the doctrines when it passed the Judicial Improvements Act of 1990:
>
> [I]n any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. Such supplemental jurisdiction shall include claims that involve the joinder or intervention of additional parties.
>
> 28 U.S.C. § 1367(a). In enacting 28 U.S.C. § 1367, Congress conferred upon federal district courts "supplemental forms of jurisdiction ... [that] enable them to take full advantage of the rules on claim and party joinder to deal economically—in single rather than multiple litigation—with matters arising from the same transaction or occurrence." Report of the Federal Courts Study Committee, Part II.2.B.2.b. (April 2, 1990), reprinted in 22 Conn. L.Rev. 733, 787 (1990).

Saenz v. Lovington Mun. Sch. Dist., 105 F. Supp. 3d 1271, 1306–07 (D.N.M. 2015). Here the four factors from the statute that Tenth Circuit has relied on for the district courts exercise of discretion in these case weighs in favor of the Court keeping those claims. *See Estate of Harshman v. Jackson Hole Mountain Resort Corp.*, 379 F.3d 1161, 1165 (10th Cir.2004)(citing *City of Chi. v. Int'l Coll. of Surgeons*, 522 U.S. 156, 173, 118 S.Ct. 523, 139 L.Ed.2d 525 (1997)). Yes, this is a novel case as the statute was recently passed, however, the state law claims do not predominate over the federal claims, the Court has not dismissed those federal claims and there are no exceptional circumstances or compelling reasons for declining jurisdiction. Just like certain claims under the New Mexico Tort Claims Act the Legislature has waived immunity here under the New Mexico Civil Rights Act. At this juncture, the Court should exercise it discretion not to dismiss these claims.

CONCLUSION

Here, Plaintiffs have demonstrated in this Reply and in the Complaint and Request for TRO (ECF Doc. No. 1) the likelihood of success on the merits and the irreparable harms of loss of constitutional freedoms warranting injunctive relief. Likewise, Plaintiffs incorporate the Complaint for their argument regarding the balancing of equities and the public interest in protecting constitutional freedoms here as further supporting the injunctive relief requested. This Court should grant the Plaintiffs the injunctive relief they seek.

Respectfully submitted this 1st day of September 2021.

WESTERN AGRICULTURE, RESOURCE AND BUSINESS ADVOCATES, LLP

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CERTIFICATE OF SERVICE

I hereby certify that on September 1, 2021, I filed the foregoing via the CM/ECF filing system and caused a copy to be served upon counsel for Defendants via email.

/s/ A. Blair Dunn
A. Blair Dunn, Esq.

EXHIBIT 4

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[8]

[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals or comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide a two-dose regimen for individuals aged 12 through 15 years, or

to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[11] to emergency response stakeholders[12] as directed by the U.S.

[9] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA.

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[11] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[12] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[13] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[13] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and

under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[14]

[14] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that

processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise).

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

MERCOLA
Take Control of Your Health

EXHIBIT 5

60% of Those Older Than 50 Who Die From COVID Are Double Vaxxed

Analysis by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE -

- As of August 15, 2021, 68% of COVID patients admitted to hospital in the U.K. who were over the age of 50 had received one or two doses of COVID injections. By mid-August, 59% of serious cases in Israel were also among those who had received two COVID injections, mirroring U.K. data
- Only in the 50 and younger category were a majority, 74%, of British COVID patients unvaccinated. Those claiming we're in a pandemic of the unvaccinated fail to differentiate between age groups
- The same applies to COVID deaths in the U.K. Unvaccinated make up the majority of deaths only in the under-50 age group. In the over-50 group, the clear majority, 70%, are either partially or fully "vaccinated"
- We cannot rely on U.S. data to get a clear idea of how the COVID shots are working, as the CDC has chosen to only track breakthrough cases that result in hospitalization and/or death
- Reanalysis of Pfizer's, Moderna's and Janssen's COVID trial data using the proper endpoint show the shots are hurting the health of the population, and if mass vaccination continues we face "a looming vaccine-induced public health catastrophe"
- A new study shows that vaccinated individuals are up to 13 times more likely to get infected with the new Delta variant than unvaccinated individuals who have had a natural COVID infection

The oft-repeated refrain right now is that we're in a "pandemic of the unvaccinated," meaning those who have not received the COVID jab make up the bulk of those hospitalized and dying from the Delta variant. For example, August 20, 2021, England's chief medical officer professor Chris Whitty tweeted:[1,2]

> *"Four weeks working on a COVID ward makes stark the reality that the majority of our hospitalized COVID patients are unvaccinated and regret delaying. Some are very sick including young adults. Please don't delay your vaccine."*

Curiously, if you take the time to actually look at the data, you'll find that this blanket statement is rather deceptive. Here's a graphic published in the Evening Standard, sourced from Public Health England:[3]

As you can see, as of August 15, 2021, 58% of COVID patients admitted to hospital who were over the age of 50 had actually received two doses of COVID injections and 10% had received one dose. So, partially or fully "vaccinated" individuals made up 68% of hospitalizations.

Only in the 50 and younger category were a majority, 74%, of hospitalizations among the unvaccinated. Whitty, however, completely neglected to differentiate between the age groups. The same applies to deaths. Unvaccinated only make up the majority of COVID deaths in the under-50 age group. In the over-50 group, the clear majority, 70%, are either partially or fully "vaccinated."

It's also unclear whether hospitals in the U.K. (and elsewhere) are still designating anyone who is admitted and tests positive with a PCR test as a "COVID patient." If so, people with broken bones or any number of other health problems who have no symptoms of COVID-19 at all might be unfairly lumped into the "unvaccinated COVID patient" total.

Israeli Data Show COVID Jab Is Failing in Over-50s

In Israel, where vaccine uptake has been very high due to restrictions on freedom for those who don't comply,[4] data show those who have received the COVID jab are 6.72

times more likely to get infected than people with natural immunity.[5,6,7]

The fully "vaccinated" also made up the bulk of serious cases and COVID-related deaths in July 2021, as illustrated in the graphs below.[8] The red is unvaccinated, yellow refers to partially "vaccinated" and green fully "vaccinated" with two doses. By mid-August, 59% of serious cases were among those who had received two COVID injections,[9] mirroring the data coming out of the U.K.

In an August 16, 2021, Science article,[10] Israeli Minister of Health Nitzan Horowitz is quoted saying the nation has entered a "critical time" in the race against the pandemic. Horowitz allegedly was given a third booster shot August 13, 2021, the day they began offering a third dose to people over the age of 50.

From Public Health England's data, it seems clear that the COVID shots are failing to protect people over the age of 50 in the U.K. as well, so it's probably only a matter of time before booster shots are rolled out there too. And, provided the COVID injections are the same irrespective of country, there's every reason to assume the same trends will emerge in other countries, including the U.S.

This is precisely what Ran Balicer, chief innovation officer at Clalit Health Services, Israel's largest health maintenance organization (HMO), told Science: "If it can happen here, it can probably happen everywhere."[11]

Israeli Data Considered the Best Around

The data coming out of Israel is considered by many to be the best we have, and can give us a glimpse of what to expect elsewhere. As explained by Science magazine:[12]

> *"Israel is being closely watched now because it was one of the first countries out of the gate with vaccinations in December 2020 and quickly achieved a degree of population coverage that was the envy of other nations — for a time.*
>
> *The nation of 9.3 million also has a robust public health infrastructure and a population wholly enrolled in HMOs that track them closely, allowing it to*

produce high-quality, real-world data on how well vaccines are working.

'I watch [Israeli data] very, very closely because it is some of the absolutely best data coming out anywhere in the world,' says David O'Connor, a viral sequencing expert at the University of Wisconsin, Madison.

'Israel is the model,' agrees Eric Topol, a physician-scientist at Scripps Research. 'It's pure mRNA vaccines. It's out there early. It's got a very high level population [uptake]. It's a working experimental lab for us to learn from.'

Israel's HMOs … track demographics, comorbidities, and a trove of coronavirus metrics on infections, illnesses, and deaths. 'We have rich individual-level data that allows us to provide real-world evidence in near–real time,' Balicer says …

Now, the effects of waning immunity may be beginning to show in Israelis vaccinated in early winter; a preprint[13] published last month … found that protection from COVID-19 infection during June and July dropped in proportion to the length of time since an individual was vaccinated.People vaccinated in January had a 2.26 times greater risk for a breakthrough infection than those vaccinated in April."

Where Will It End?

According to Science magazine, breakthrough cases are now multiplying at breakneck speed. "There are so many breakthrough infections that they dominate and most of the hospitalized patients are actually vaccinated," Uri Shalit, a bioinformatician at the Israel Institute of Technology told Science.[14]

Nearly 1 million Israelis over the age of 50 have now received a third booster of Pfizer's mRNA shot. Time will tell whether this will worsen the rate of breakthrough cases or tame it.

Dvir Aran, a biomedical data scientist at the Israel Institute of Technology doesn't seem very hopeful, telling Science the surge is already so steep, "even if you get two-thirds of

those 60-plus [boosted], it's just gonna give us another week, maybe two weeks until our hospitals are flooded" again.[15]

The obvious question is, what then?! Will the answer be a fourth injection before the year is over? Will we be looking at quarterly injections? Monthly injections? Biweekly? Weekly? Where and when does it end? It is fairly easy to predict that this can only end very badly.

US Tracks Only Fraction of Breakthrough Infections

Unfortunately, we cannot rely on U.S. data to get a clear idea of how the COVID shots are working, as the U.S. Centers for Disease Control and Prevention has chosen not to track all breakthrough cases. As reported by ProPublica,[16] May 1, 2021, the CDC stopped tracking and reporting all breakthrough cases, opting to log only those that result in hospitalization and/or death.

As noted in the article, this irrational decision has "left the nation with a muddled understanding of COVID-19's impact on the vaccinated." It also prevents us from understanding how variants are spreading and whether those who have received the jab can still develop so-called "long-haul syndrome."

Individual states are also setting their own criteria for how they collect data on breakthrough cases, and this patchwork muddies the waters even further. Despite these limitations, what little data we do have is starting to mirror that of Israel and the U.K.

August 18, 2021, the CDC released three reports,[17,18,19] which show the protection you get from the COVID shot is rapidly waning.

> *"Among nursing home residents, one of the studies showed vaccine effectiveness dropped from 74.7% in the spring to just 53.1% by midsummer,"*ProPublica writes.[20] *"Similarly, another report found that the overall effectiveness among vaccinated New York adults dropped from 91.7% to just under 80% between May and July.*

The new findings prompted the Biden administration to announce on Wednesday that people who got a Moderna or Pfizer vaccine will be offered a booster shot eight months after their second dose. The program is scheduled to begin the week of Sept. 20 but needs approval from the Food and Drug Administration and a CDC advisory committee.

This latest development is seen by some as another example of shifting public health messaging and backpedaling that has accompanied every phase of the pandemic for 19 months through two administrations. A little more than a month ago, the CDC and the FDA released a joint statement saying that those who have been fully vaccinated 'do not need a booster shot at this time' …

The CDC tracked all breakthrough cases until the end of April, then abruptly stopped without making a formal announcement. A reference to the policy switch appeared on the agency's website in May about halfway down the homepage.

'I was shocked,' said Dr. Leana Wen, a physician and visiting professor of health policy and management at George Washington University. 'I have yet to hear a coherent explanation of why they stopped tracking this information' …

Sen. Edward Markey, D-Mass., became alarmed after the Provincetown outbreak and wrote to CDC director Dr. Rochelle Walensky on July 22, questioning the decision to limit investigation of breakthrough cases. He asked what type of data was being compiled and how it would be shared publicly[21] *... Markey asked the agency to respond by Aug. 12. So far the senator has received no reply …"*

Vaxxed Are Up to 13 Times More Likely to Get Delta Variant

While the U.S. is lax about recording breakthrough infections, researchers in Israel have some breaking news: They have been keeping track, and their studies[22] show that vaccinated individuals are up to 13 times more likely to get the Delta variant of COVID-19 than those who were not vaccinated, but had recovered from a COVID infection.

As explained by ScienceMag:[23] The study "found in two analyses that people who were vaccinated in January and February were, in June, July and the first half of August, six to 13 times more likely to get infected than unvaccinated people who were previously infected with the coronavirus. In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was 27 times higher among the vaccinated, and the risk of hospitalization eight times higher."

The study also said that, while vaccinated persons who also had natural infection did appear to have additional protection against the Delta variant, the vaccinated were still at a greater risk for COVID-19-related-hospitalizations compared to those without the vaccine, but who were previously infected. Vaccinees who hadn't had a natural infection also had a 5.96-fold increased risk for breakthrough infection and a 7.13-fold increased risk for symptomatic disease.

One thing to note here is that the wording of this is important: The study does not say that getting a vaccine helps protect you if you've had a natural infection; rather, it says that natural protection helps boost the vaccine. Either way, even if you do have natural infection in combination with the vaccination, vaccinees are still at an increased risk for a breakthrough infection.

"This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity," the study authors concluded.

Fully Vaxxed Speak Out

Back America, in an August 24, 2021, article,[24] The Defender cites data from seven states (California, Colorado, Massachusetts, Oregon, Utah, Vermont and Virginia) that keep more detailed records than most. In six of these states, breakthrough infections accounted for 18% to 28% of all new COVID diagnoses in the past several weeks, as well as 12% to 24% of all COVID-related hospitalizations.

In Los Angeles, breakthrough cases have risen from 5% in April and 13% in July to a current of 30%. Fully vaxxed celebrities and elected officials have now started speaking out after getting COVID. As reported by The Defender: [25]

> *"Melissa Joan Hart, the former 'Sabrina the Teenage Witch' star is 'really mad' she has a breakthrough case. Hart shared on Instagram Aug. 19 … 'I got COVID. I am vaccinated. And I got COVID. And it's bad. It's weighing on my chest, it's hard to breathe' …*
>
> *Celebrity Hilary Duff, **revealed** she had COVID on Instagram Aug. 20. Duff said she was experiencing a bad headache, brain fog, sinus pressure and a loss of taste and smell despite being vaccinated …*
>
> *Slipknot singer Corey Taylor, 47, was devastated after testing positive for COVID and was forced to call off his upcoming appearance at a Michigan pop culture convention this weekend, Rolling Stone reported. 'I wish I had better news,' said Taylor in a recorded video message last week on Facebook. 'I woke up today and tested positive and I'm very, very sick' …*
>
> *Rev. Jesse Jackson, and his wife, Jacqueline, remained under doctors' observation Monday*[August 23, 2021] *at a Chicago hospital after getting COVID … Jackson, a Chicago civil rights leader, was fully vaccinated and received his first dose in January during a publicized event where he urged others to receive the vaccine as soon as possible …*
>
> *Three U.S. senators — John Hickenlooper (D-Colo.), Angus King (I-Maine) and Roger Wicker (R-Miss.) — announced Aug. 19 they tested positive for COVID despite being fully vaccinated, CBS News reported …*
>
> *The news came days after **Texas Gov. Greg Abbott**, who also was fully vaccinated, tested positive for COVID. Illinois state Sen. Dan McConchie announced Aug. 21 he had a 'breakthrough' case of COVID."*

CDC Has Also Hidden Breakthrough Cases in Other Ways

The CDC also cooked the books on COVID breakthrough cases in other ways. Originally, the CDC recommended labs use a CT of 40[26] when testing for SARS-CoV-2 infection. This, despite using a CT above 35 was known to create a false positive rate of 97%.[27] By using an exaggerated CT, healthy people were deemed stricken with COVID-19.

In May 2021, the CDC lowered the CT from 40 to 28 or lower — but only when doing PCR testing on individuals who have received the COVID jab.[28] Unvaccinated were still tested using a CT of 40. The end result is obvious: "Vaccinated" individuals became far less likely to test positive for SARS-CoV-2 infection while unvaccinated were still exceedingly getting false positives. As noted by Off-Guardian:[29]

> *"This is a policy designed to continuously inflate one number, and systematically minimize the other. What is that if not an obvious and deliberate act of deception?"*

How the CDC Invented the 'Pandemic of Unvaxxed' Narrative

The CDC also played fast and loose with the data when it invented the "pandemic of the unvaccinated" narrative[30] that we're now being indoctrinated with. In a July 16, 2021, White House press briefing,[31] CDC director Dr. Rochelle Walensky claimed "over 97% of people who are entering the hospital right now are unvaccinated."

> **“Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe. ~ Dr. Bart Classen, Trends in Internal Medicine”**

As it turns out, that statistic is based on hospitalization data from January through June 2021, when the majority of Americans had not yet gotten the COVID jab. January 1, 2021, only 0.5% of the U.S. population had received a COVID shot. By mid-April, an estimated 31% had received one or more shots,[32] and as of June 30, just 46.9% were "fully vaccinated."[33]

COVID Shots 'Proven to Cause More Harm Than Good'

While the official narrative is that the COVID shots may be "less than perfect" but are still better than the alternative (i.e., getting the infection when you're unvaccinated), Dr. Bart Classen published a study[34] in the August 2021 issue of Trends in Internal Medicine, disputing this claim.

The study,[35] "U.S. COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, 'All Cause Severe Morbidity,'" details a core problem with Pfizer's, Moderna's and Janssen's (Johnson & Johnson) trials.

All three employ a surrogate primary endpoint for health, namely "severe infections with COVID-19." This, Classen says, "has been proven dangerously misleading," and many fields of medicine have stopped using disease-specific endpoints in clinical trials and have adopted "all-cause mortality and morbidity" instead.

The reason for this is because if a person dies from the treatment or is severely injured by it, even if the treatment helped block the progression of the disease they're being treated for, the end result is still a negative one.

To offer an extreme example of what you can do with a disease-specific endpoint, you could make the claim that shooting people in the head is a cure for cancer, because no one who got the treatment — who got shot in the head — died from cancer.

When reanalyzing the clinical trial data from these COVID shots using "all-cause severe morbidity" as the primary endpoint, the data reveal they actually cause far more harm than good.

The proper endpoint was calculated by adding together all severe events reported in the trials, not just COVID-19 but also all other serious adverse events. By doing this, severe COVID-19 infection gets the same weight as other adverse events of equivalent severity. According to Classen:[36]

> *"Results prove that none of the vaccines provide a health benefit and all pivotal trials show a statistically significant increase in 'all cause severe morbidity' in the vaccinated group compared to the placebo group.*
>
> *The Moderna immunized group suffered 3,042 more severe events than the control group. The Pfizer data was grossly incomplete but data provided showed the vaccination group suffered 90 more severe events than the control group, when only including 'unsolicited' adverse events.*
>
> *The Janssen immunized group suffered 264 more severe events than the control group. These findings contrast the manufacturers' inappropriate surrogate endpoints:*
>
> *Janssen claims that their vaccine prevents 6 cases of severe COVID-19 requiring medical attention out of 19,630 immunized; Pfizer claims their vaccine prevents 8 cases of severe COVID-19 out of 21,720 immunized; Moderna claims its vaccine prevents 30 cases of severe COVID-19 out of 15,210 immunized.*
>
> *Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe."*

To make the above numbers more clear and obvious, here are the prevention stats in percentages:

- Pfizer 0.00036%
- Moderna 0.00125%

- Janssen 0.00030%

Where Do We Go From Here?

If you've already gotten one or two shots, there's nothing you can do about that. It seems pretty obvious, though, if you objectively analyze the data, that your best bet is to say no to any and all future boosters, as each additional shot can magnify the damage and increase your risk of serious side effects.

If you develop symptoms of SARS-CoV-2 infection, there are several treatment protocols available that have been shown to be effective. Options include the Zelenko protocol,[37] the MATH+ protocols[38] and nebulized hydrogen peroxide, as detailed in Dr. David Brownstein's case paper[39] and Dr. Thomas Levy's free e-book, "**Rapid Virus Recovery**."

Whichever treatment protocol you use, make sure you begin treatment as soon as possible, ideally at first onset of symptoms. Also, realize that if you've gotten one or more COVID shots, your risk of severe infection may actually be greater, not lesser, than had you not gotten the injections. This appears particularly true if you're over the age of 50. So, do not delay treatment if you develop symptoms.

Sources and References

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- [13] medRxiv July 31, 2021 DOI: 10.1101/2021.07.29.21261317 (PDF)
- [16, 20] ProPublica August 20, 2021
- [17] CDC MMWR August 18, 2021; 70 New COVID Cases and Hospitalizations Among Adults by Vaccination Status
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- [19] CDC MMWR August 18, 2021; 70 Effectiveness of Pfizer and Moderna Vaccines Among Nursing Home Residents
- [21] Ed Markey Press Release July 22, 2021
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- [23] ScienceMag August 26, 2021
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- [26] FDA.gov CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions, July 13, 2020 (PDF) Page 35
- [27] Clinical Infectious Diseases September 28, 2020; ciaa1491
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- [31] WH.gov Press Briefing July 16, 2021
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- [39] Science, Public Health Policy and The Law July 2020; 1: 4-22 (PDF)

EXHIBIT 6

Our STN: BL 125742/0 **BLA APPROVAL**

BioNTech Manufacturing GmbH August 23, 2021
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at (b) (4) The final formulated product will be manufactured, filled, labeled and packaged at Pfizer (b) (4) . The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at (b) (4)

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at (b) (4) , the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer (b) (4) , it is defined as the date of the (b) (4) Following the final sterile filtration, (b) (4) , no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion: December 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself and others similarly situated,

Plaintiffs,

v. **Case No. 1:21-cv-00783-MV-JHR**

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

MOTION TO DISMISS PLAINTIFFS' VERIFIED COMPLAINT

Defendants Governor Michelle Lujan Grisham and Secretary David R. Scrase (collectively, "Defendants"), by and through their counsel of record, hereby submit their motion to dismiss Plaintiffs' Verified Complaint for Civil Rights Violations Under 42 U.S.C.A. §1983; Violations of Rights Protected by the New Mexico Civil Rights Act; Emergency Request for a Temporary Restraining Order; Requst [sic] for Preliminary Injunction, Permanant [sic] injunctive relief and Damages [Doc. 1] (the "Complaint" or "Compl.") pursuant to Federal Rule of Civil Procedure 12(b)(6). As grounds for this motion, Defendants state as follows.

INTRODUCTION

Over a century ago, the U.S. Supreme Court declared, "[A] community has the right to protect itself against an epidemic of disease which threatens its members." *Jacobson v. Massachusetts*, 197 U.S. 11, 31 (1905). This principle stands no less true today. In an attempt to

stem the rapid resurgence of a highly contagious and potentially more lethal variant of the virus that causes COVID-19, Defendants issued a public health order requiring individuals working with New Mexico's most vulnerable populations in hospitals and congregate care settings to receive a safe and effective vaccine—one of which is now ***fully*** approved by the Food and Drug Administration—or meet a health, disability, or religious exemption. Additionally, Defendants required all vaccine-eligible individuals to show proof of vaccination or entitlement to an exemption (and a negative COVID-19 test) to attend the upcoming State Fair—one of the largest state-sponsored gatherings.

Unfortunately, not everyone agrees with the science. Those disagreements, however, do not give rise to a justiciable dispute. As Justice Cardozo eloquently observed, "The right of private judgment has never yet been so exalted above the powers and the compulsion of the agencies of government. One who is a martyr to a principle—which may turn out in the end to be a delusion or an error—does not prove by his martyrdom that he has kept within the law." *Hamilton v. Regents of Univ. of Cal.*, 293 U.S. 245, 268 (1934). Plaintiffs—a group of individuals subject to the vaccine requirements and apparently not entitled to an exemption—seek to halt Defendants' carefully calculated life-saving measures based on their (faulty and speculative) belief that the vaccines are neither safe nor necessary.[1] But such minority views are insufficient to defeat the wisdom of

[1] In so doing, Plaintiffs offensively compare the targeted vaccine mandates to the internment of Japanese Americans in World War II. *See* Compl. at 1. Counsel for Plaintiffs enjoys such overwrought histrionics, and with each passing lawsuit finds that the complained of prohibition is more authoritarian than the last. *See e.g.*, Plaintiffs' Motion for Preliminary Injunction [Doc 20.] at 2, *Hinkle Family Fun Ctr. v. Lujan Grisham*, No. 1:20-cv-01025-MV-KK (D.N.M. Dec. 2, 2020) ("History will not reflect anymore [sic] kindly on the government of New Mexico locking up its people and taking away their ability to earn a living nine months later, than it did when this Country locked up Japanese Americans in internment camps."); *Hernandez v. Lujan Grisham*, 494 F. Supp. 3d 1044, 1091 (D.N.M. 2020) (noting Plaintiffs' counsel's argument that "Governor Lujan Grisham's school reentry plan is 'appropriate[ly] . . . likened to the [sic] those of the gestapo'").

elected officials guided by the State and nation's preeminent public health experts. As the Supreme Court proclaimed,

> We are not prepared to hold that a minority, residing or remaining in any city or town where [a deadly, contagious virus] is prevalent, and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted authorities, acting in good faith for all, under the legislative sanction of the State. If such be the privilege of a minority then a like privilege would belong to each individual of the community, and the spectacle would be presented of the welfare and safety of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population.

Jacobson, 197 U.S. at 37-28. Plaintiffs give this Court no reason to reach a contrary conclusion, and their complaint should therefore be dismissed.

BACKGROUND

I. The rapid and dangerous spread of COVID-19

Since its emergence last year, the novel coronavirus 2019 (Sars-CoV-2), the virus that causes COVID-19, has spread exponentially across the globe, throughout the United States, and here in New Mexico.[2] COVID-19's rapid spread is attributable to certain characteristics of the virus that causes it and the ease with which that virus is transmitted. COVID-19 is a respiratory illness that causes severe complications in some patients, including respiratory failure, organ failure, and death.[3] Like most respiratory illnesses, COVID-19 spreads easily through close person-to-person contact, and the risk of transmission increases if individuals interact with more

[2] *See Cases in the U.S.*, Ctr. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last visited Aug. 31, 2021); *WHO Coronavirus Disease (COVID-19) Dashboard*, World Health Organization, https://covid19.who.int/ (last visited Aug. 31, 2021); *2019 Novel Coronavirus Disease (COVID-19)*, N.M. Dep't of Health, https://cv.nmhealth.org/ (last visited Aug. 31, 2021).

[3] *What Is Coronavirus?*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus (last visited Aug. 25, 2021).

people, come within six feet of one another, and spend longer periods of time together.[4] Although it has not been measured precisely, a significant portion of COVID-19 cases result in mild symptoms or no symptoms.[5] Additionally, even in cases that are symptomatic, the average time from exposure to symptom onset is five to six days, with symptoms sometimes not appearing until as long as thirteen days after infection.[6] This means that individuals who have been infected and have the potential to infect others usually do not know they are infected for at least several days (and may never know, if they remain asymptomatic).

The ease and rapidity with which COVID-19 spreads and its severe and potentially fatal symptoms create a potential for mass deaths and a severely overloaded health care system. Indeed, at the height of the pandemic (so far) last winter, New Mexico was averaging over 2,500 new cases and over 40 deaths daily.[7] The situation was so dire that the Department of Health activated crisis

[4] *How COVID-19 Spreads*, Ctr. for Disease Control and Prevention (Oct. 28, 2020), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html; *Deciding to Go Out*, Ctr. for Disease Control and Prevention (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/deciding-to-go-out.html#:~:text=COVID%2D19%20spreads%20easier%20between,People%20are%20wearing%20masks.

[5] Katie Kerwin McCrimmon, *The truth about COVID-19 and asymptomatic spread: It's common, so wear a mask and avoid large gatherings*, UC Health (Nov. 5, 2020), https://www.uchealth.org/today/the-truth-about-asymptomatic-spread-of-covid-19/.

[6] *COVID-19 Basics: Symptoms, Spread and Other Essential Information About the New Coronavirus and COVID-19*, Harvard Medical School (March 2020), https://www.health.harvard.edu/diseases-and-conditions/covid-19-basics.

[7] *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases (follow "New Mexico" on drop down menu) (last visited Aug. 20, 2021); *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths (follow "New Mexico" on drop down menu) (last visited Aug. 20, 2021).

standards of care to accommodate the masses of patients inundating the hospitals.[8] Tragically, hospitals were not the only things at capacity: so, too, were the morgues.[9] One in five New Mexicans hospitalized for COVID-19 eventually succumbed to the virus.[10]

II. The development of the COVID-19 vaccines

Thankfully, science came to the rescue. In February 2020, the U.S. Department of Health and Human Services (HHS) declared a public health emergency and instructed the U.S. Food and Drug Administration (FDA) to grant emergency use authorizations (EUAs) for medical devices and interventions to combat the pandemic. *See* 85 Fed. Reg. 7316, 7316-7317; 85 Fed. Reg. 18250, 18250-18251. While an EUA generally allows a manufacturer to receive approval for a medical product using only interim clinical trial data, products that receive EUA approval still must adhere to specified safety, efficacy, and manufacturing criteria. *See* 21 U.S.C. § 360bbb-3(e)(1)(B), (A)(ii)(I)-(III). Additionally, HHS must ensure medical providers and individuals are informed of the product's EUA status, the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown"; and for individuals, of the option to refuse and the consequences of such a decision. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III). Specifically with regard to the development of a COVID-19 vaccine, the FDA issued detailed

[8] Governor Michelle Lujan Grisham, *Executive Order 2020-083*, at 4 (Dec. 4, 2020), https://www.governor.state.nm.us/wp-content/uploads/2020/12/Executive-Order-2020-083.pdf (executive order preparing for implementation of crisis care standards); N.M. Dep't of Health, Public Health Order (Dec. 9, 2021), https://cv.nmhealth.org/wp-content/uploads/2020/12/120920-PHO_Activation-of-CSC-and-TCA.pdf (public health order activating crisis care standards).

[9] Gabrielle Burkhart, *New Mexico receives 'mortuary trailers' as COVID-19 death toll rises*, KRQE (Nov. 19, 2020), https://www.krqe.com/health/coronavirus-new-mexico/new-mexico-receives-mortuary-trailers-as-covid-19-death-toll-rises/.

[10] N.M. Dep't of Health, *New Mexico COVID-19 Hospitalization Update* (Dec. 14, 2020), https://cv.nmhealth.org/wp-content/uploads/2020/12/hospitalizations_covid19_public-report_12.14.20_final.pdf.

guidance to manufacturers and specifically informed them that it would require a determination that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.[11]

Numerous manufacturers rose to the occasion, and three vaccines candidates quickly emerged as frontrunners: Johnson & Johnson's single-dose viral vector vaccine, and Pfizer/BioNTech and Moderna's two-dose mRNA vaccines.[12] By the time Pfizer and Moderna applied for EUA status in November 2020, each vaccine had undergone significant testing. Pfizer's application included safety, immunogenicity, and efficacy data from over 40,000 study participants in ongoing phase I, II, and III, randomized, placebo-controlled, observer-blind, clinical trials conducted in the U.S., Argentina, Brazil, Germany, South Africa, and Turkey.[13] Moderna's application included safety, immunogenicity, and efficacy data from over 30,000 study participants in ongoing phase I, II, and III, randomized, stratified, observer-blind, placebo-controlled clinical trials conducted at 99 locations in the United States.[14] J&J applied for EUA status in February 2021, submitting an application that included safety, immunogenicity, and

[11] U.S. Food & Drug Admin., *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* at 4 (May 2021), https://www.fda.gov/media/142749/download.

[12] *Different COVID-19 Vaccines*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html (last visited Aug. 25, 2021).

[13] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 11, 2020), https://www.fda.gov/media/144416/download.

[14] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 18, 2020), https://www.fda.gov/media/144673/download.

efficacy data from five studies with over 70,000 participants, including two randomized, double-blind, placebo-controlled phase III trials.[15]

A team of representatives from across the FDA—including experts in clinical review, toxicology, biostatistics, products, production facilities, pharmacovigilance, data integrity, bioresearch monitoring, and labeling—reviewed the data submitted by Pfizer, Moderna and J&J, and independently assessed the risks and benefits of the vaccines. *See* U.S. Food & Drug Admin., *supra* note 13 at 1, 49-54; U.S. Food & Drug Admin., *supra* note 14 at 1, 55-60; U.S. Food & Drug Admin., *supra* note 15 at 1, 55-60. The FDA granted EUA to Pfizer and Moderna's vaccines in December 2020 and J&J's vaccine in February 2021 for individuals ages 16 and older, noting that each had met their expectations set out in the FDA's comprehensive guidance.[16] Pfizer's vaccine has since received EUA for individuals ages 12 and older and **received *full* FDA approval for individuals ages 16 and over on August 23, 2021**.[17]

Despite the unprecedented timeline for development, the vaccines have been a resounding success. Since the three vaccines received EUA status, over 368 million doses have been

[15] *See generally* U.S. Food & Drug Admin., *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Feb. 4, 2021), https://www.fda.gov/media/146338/download.

[16] U.S. Food & Drug Admin., *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; U.S. Food & Drug Admin., F*DA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; U.S. Food & Drug Admin., *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[17] U.S. Food & Drug Admin., *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

administered and over 173 million Americans have been fully vaccinated.[18] Comprehensive data collected to date demonstrates that the vaccines are safe, with serious adverse reactions remaining exceedingly rare.[19] In terms of effectiveness, initial data and evidence demonstrated that the Pfizer vaccine was 91.3% effective in preventing infections and 100% effective in preventing severe disease, Moderna's vaccine was 90% effective in preventing infections and more than 95% effective in preventing severe disease, and J&J's vaccine was 85% effective in preventing severe disease.[20] The protection provided by the vaccines has proven relatively durable over time, with one study finding that the Pfizer and Moderna vaccines were 86% effective in preventing illness serious enough to require hospitalization 2-12 weeks after vaccination and 84% effective at 13-24 weeks.[21] Additionally, laboratory data and real-world epidemiologic studies demonstrate that the

[18] *COVID-19 Vaccinations in the United States*, Ctr. for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited Aug. 30, 2021).

[19] *Selected Adverse Events Reported after COVID-19 Vaccination*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (last visited Aug. 30, 2021).

[20] Press Release, *Pfizer and BioNtech Confirm High Efficacy And No Serious Safety Concerns Through Up To Six Months Following Second Dose In Updated Topline Analysis Of Landmark Covid-19 Vaccine Study*, Pfizer (Apr. 1, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious; Press Release, *Moderna Provides Clinical and Supply Updates on COVID-19 Vaccine Program Ahead of 2nd Annual Vaccines Day* (Apr. 13, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-clinical-and-supply-updates-covid-19-vaccine; Press Release, *Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic*, Johnson & Johnson (Feb. 27, 2021), https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-against-global-pandemic.

[21] Mark W. Tenforde, et al., *Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021*, Ctr. for Disease Control and Prevention (Aug. 18, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm.

immunity provided by vaccines is significantly more robust than natural immunity gained following infection. For instance, one recent study found that unvaccinated individuals who were previously infected had 2.34 times the odds of being reinfected than those who had been fully vaccinated. *See id.* at ¶ 28.

III. The Delta variant

Unfortunately, a new, highly infectious and possibly more deadly variant has emerged and taken the world by storm. B.1.617.2, commonly known as the "Delta" variant was first discovered in India in late 2020 and soon became the predominant strain in that country.[22] By mid-June, the CDC labeled Delta a "variant of concern."[23] Now, it is widely estimated that the Delta variant accounts for nearly all of new infections in the United States and New Mexico, and is believed to be at least twice as contagious as previous variants.[24] Additionally, studies indicate that individuals infected with the Delta variant are more likely to be hospitalized than those infected with the original strain or other variants. *See id.* In terms of the variant's impact on vaccines, there is bad news and good news: while the variant is more likely to cause "breakthrough" infections, the vaccines still provide strong protection against serious illness and death. *See id.* For example, one recent analysis of over 40,000 infections in Los Angeles from May to the end of July found that vaccinated individuals were nearly ***5 times less likely to become infected*** and nearly ***30 times less***

[22] Kathy Katella, *5 Things To Know About the Delta Variant*, Yale Med. (Aug. 18, 2021), https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.

[23] *See SARS-CoV-2 Variant Classifications and Definitions*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html (last visited Aug. 24, 2021).

[24] *Delta Variant: What We Know About the Science*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html (last visited Aug. 30, 2021).

likely to require hospitalization. *Id.* at ¶ 20. Accordingly, there is strong evidence that vaccinations continue to be effective.

III. New Mexico's public health emergency orders and the current state of the pandemic

Recognizing the seriousness of this virus and its ability to spread exponentially through close contacts and public spaces, the Governor declared a public health emergency under the Public Health Emergency Response Act, NMSA 1978, §§ 12-10A-1 to -19 (2003, as amended through 2015), and invoked the All Hazards Emergency Management Act, NMSA 1978, §§ 12-10-1 to -10 (1959, as amended through 2007), by directing all cabinets, departments, and agencies to comply with the directives of the declaration and the further instructions of the Department of Health.[25] Consistent with the powers provided during an emergency under the Public Health Emergency Response Act and the All Hazards Emergency Management Act, as well as the Public Health Act, NMSA 1978, §§ 24-1-1 to -40 (1973, as amended through 2019), the Secretary subsequently entered a series of public health orders ("PHOs").[26]

The PHOs initially included various measures such as limiting most public and private gatherings of any significant size and curtailing the operations of many businesses. *Id.* However, the PHOs' restrictions were largely phased out as case rates dropped dramatically with New

[25] Governor Michelle Lujan Grisham, *Executive Order 2020-004* (March 11, 2020), https://www.governor.state.nm.us/wp-content/uploads/2020/03/Executive-Order-2020-004.pdf. This declaration was most recently renewed until September 15, 2021. *See* Governor Michelle Lujan Grisham, *Executive Order 2020-004* (March 11, 2020), https://www.governor.state.nm.us/wp-content/uploads/2021/08/Executive-Order-2021-049.pdf.

[26] *See generally Public Health Orders and Executive Orders*, N.M. Dep't of Health, https://cv.nmhealth.org/public-health-orders-and-executive-orders/ (last visited Aug. 24, 2021) (collecting PHOs and executive orders relating to COVID-19).

Mexico's efficient rollout of the COVID-19 vaccines that began earlier this year.[27] Unfortunately, cases have climbed rapidly in the most recent weeks with the spread of the Delta variant. The number of new cases has risen from an average of approximately 60 cases per day in late June to nearly 900 cases per day last week—*almost a fifteenfold increase*.[28] Many hospitals are again operating over capacity to accommodate the surge of infected New Mexicans—the majority of which are unvaccinated.[29] It is unclear just how long New Mexico's hospital system can sustain such operations, with healthcare workers in short supply and reports of workers "burning out" or falling ill becoming increasingly common.[30] Indeed, crisis care standards are again likely to be implemented in the upcoming days.[31]

To stem the recent surge of cases and hopefully ease the pressures on New Mexico hospitals, the Secretary issued a PHO on August, 17, 2021, generally requiring individuals working

[27] *Id.*; N.M. Dep't of Health, *New Mexico COVID-19 Cases Update Statewide and County-Level Trends* at 1 (Aug. 16, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/State-Report_geotrends_08.16.21.pdf (showing cases drop significantly beginning in December and January).

[28] *COVID-19 in New Mexico*, N.M. Dep't of Health, https://cvprovider.nmhealth.org/public-dashboard.html (follow "Show Historical Statewide Date" on bottom left-hand corner; then scroll down to "Epidemic Curve") (last visited Sept. 2, 2021).

[29] *See* Dan McKay, *Some NM hospitals 'well beyond capacity'*, Albuquerque J. (Aug. 19, 2021), https://www.abqjournal.com/2421024/some-nm-hospitals-well-beyond-capacity.html; Maggie Krajewski, *In last 4 weeks, 89.6% of COVID-19 hospitalizations and 93.3% deaths are among unvaccinated New Mexicans*, KOAT 7 News (Sept 1, 2021), https://www.koat.com/article/covid-hospitalizations-deaths-breakthrough-vaccinated-unvaccinated/37455811.

[30] *See, e.g.*, Colleen Heild, *Stressed and exhausted, nurses are calling it quits*, Albuquerque J. (Aug. 21, 2021), https://www.abqjournal.com/2421756/stressed-and-exhausted-nurses-are-calling-it-quits.html.

[31] *See* Chris McKee, *New Mexico's hospitals days away from 'crisis standards of care' amid COVID-19 case surge*, KRQE News (Aug. 25, 2021), https://www.krqe.com/health/coronavirus-new-mexico/new-mexicos-top-health-officials-to-address-covid-19/.

in hospitals and certain congregate care facilities to receive their first dose of a COVID-19 vaccine within 10 days and their second dose (for Pfizer and Moderna) within 40 days of their first dose.[32] However, such workers are not required to get a vaccine if they have a: (1) qualifying medical condition for which immunization would endanger the individual's health, (2) disability requiring reasonable accommodations, or (3) sincerely held religious belief against vaccination. *Id.* at 4. To qualify for the first and second exemptions, the individual must provide their employer with a statement from a licensed medical professional stating that the individual has a qualifying medical condition or disability that necessitates accommodation and stating the probable duration of the individual's inability to receive the vaccine or need for an accommodation. *Id.* To qualify for the religious exemption, the individual must document their request for an accommodation and provide a statement regarding the manner in which the administration of a COVID-19 vaccine conflicts with their religious observance, practice, or belief. *Id.* at 4-5. Individuals who meet an exemption must undergo weekly COVID-19 testing. *Id.* In addition to the above requirements, the PHO requires all individuals attending the New Mexico State Fair that are eligible to receive a COVID-19 vaccine (i.e., those ages 12 years and older) be fully vaccinated or meet one of the above exemptions and provide proof of a recent negative COVID-19 test result. *See id.* at 5-6.

[32] N.M. Dep't of Health, *Public Health Order* 3-4 (Aug. 17, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/08/081721-PHO-Vaccines.pdf. This requirement also applies to employees from the Office of the Governor. *Id.* However, everyone within the Office of the Governor is vaccinated or will be fully vaccinated by the PHO's deadline. Additionally, the PHO requires school workers to either provide proof of their vaccination status or undergo weekly COVID-19 testing, *id.* at 3, but Plaintiffs do not appear to assert any claims on behalf of teachers because they are not required to receive the vaccine. *See* Compl. at 7 ¶¶ 33-34.

IV. Plaintiffs' claims

Against this factual backdrop, Plaintiffs filed the instant "class action." Plaintiff Talisha Valdez is a mother of two children who entered to show their animals at the New Mexico State Fair. [Doc 1-3]. Plaintiff Jennifer Blackford is a registered nurse employed at Presbyterian Hospital in Albuquerque.[33] Neither Plaintiffs nor their children have been vaccinated against COVID-19. [Docs. 1-3, 1-4]. Plaintiffs are opposed to receiving a COVID-19 vaccine, *id.*, and generally allege that the PHOs' vaccine requirements violate the Federal Food, Drug, and Cosmetic Act, their rights to due process and equal protection, Article I, § 10, and their rights under the New Mexico constitution. *See* Compl. at 9-14. In their prayer for relief, Plaintiffs request a declaratory judgment that the PHOs' vaccine requirements are unconstitutional and further request a TRO and a preliminary and permanent injunction prohibiting Defendants from enforcing the public health orders. *Id.* at 14-15. Plaintiffs also seek actual and punitive damages for their alleged injuries. *Id.* at 15.

[33] [Doc. 1-4]. Plaintiff Blackford seeks to bring claims on behalf of "all others similarly situated that work in healthcare, congregate care or the Office of the Governor for the purpose of asserting the claims alleged in this complaint on a common basis." Compl. at 6 ¶ 26. However, Plaintiffs' proposed classes will likely not satisfy Rule 23(a)'s requirement that a class representative's claims "are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). Blackford's employer is separately requiring all of its employees to be vaccinated, thus depriving Blackford of standing to challenge the PHO's vaccine requirements. *See* Colleen Heild, *Presbyterian requires vaccines for entire workforce of 13,000*, Santa Fe New Mexican (Aug. 18, 2021), https://www.abqjournal.com/2420650/presbyterian-requires-vaccines-for-entire-workforce-of-13000-ex-pnm-is-asking-all-staff-to-get-vaccinated-or-be-tested-weekly.html; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact)]. This development also deprives Plaintiff Blackford of standing to challenge the PHO or represent any class of plaintiffs. *See Bronson v. Swensen*, 500 F.3d 1099, 1109 (10th Cir. 2007) ("The principle of causation for constitutional standing requires a plaintiff's injury to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." (internal quotation marks and citations omitted)); *Abraham v. WPX Prod. Prods., LLC*, 184 F. Supp. 3d 1150, 1198 (D.N.M. 2016) ("In certifying the class, courts must find that the named plaintiff's claims are typical of the class claims, which requires a conclusion that the named plaintiff has standing.").

DISCUSSION

I. Standard of review for a motion to dismiss under Rule 12(b)(6)

The Court must dismiss a complaint under Rule 12(b)(6) if it fails "to state a claim upon which relief can be granted." "[T]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation marks and citation omitted). Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*; *see also Mocek v. City of Albuquerque*, 813 F.3d 912, 921 (10th Cir. 2015) (stating that in reviewing a 12(b)(6) motion, courts should "disregard conclusory statements and look only to whether the remaining, factual allegations plausibly suggest the defendant is liable"). Rather, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombley*, 550 U.S. 544, 555 (2007). "Determining whether a complaint states a plausible claim for relief" is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense" to decide whether any well-pleaded facts have shown any entitlement to relief by "permit[ting] the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679.

When examining a complaint under Rule 12(b)(6), the Court must determine "the sufficiency of the allegations within the four corners of the complaint after taking those allegations as true." *Mobley v. McCormick*, 40 F.3d 337, 340 (10th Cir. 1994). In doing so, the Court should "consider the complaint as a whole, along with the documents incorporated by reference into the

complaint." *Nakkhumpun v. Taylor*, 782 F.3d 1142, 1146 (10th Cir. 2015). Moreover, if "a complaint does not reference or attach a document, but the complaint refers to the document, and the document is central to the plaintiff's claim, the defendant may submit an "indisputably authentic copy to the court to be considered on a motion to dismiss.'" *Harjo v. City of Albuquerque*, 307 F. Supp. 3d 1163, 1185 (D.N.M. 2018) (Browning, J.) (quoting *GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1384 (10th Cir. 1997)).

The Court may also properly consider facts for which it may take judicial notice, such as those facts which are a matter of public record (like government publications) and scientific facts accepted in the scientific community. *Id.* at 1185; *Simon v. Taylor*, 252 F. Supp. 3d 1196, 1240 (D.N.M. 2017) (observing that "[t]he federal courts have long taken judicial notice of scientific facts established and accepted in the appropriate scientific community"); *Legacy Church, Inc. v. Kunkel*, 472 F. Supp. 3d 926, 1066-67 (D.N.M. 2020) (collecting cases and noting that "[c]ourts presiding over similar cases have taken judicial notice of Public Health Orders and scientific consensus regarding the coronavirus"); *cf. Gent v. CUNA Mut. Ins. Soc.*, 611 F.3d 79, 84 & n.5 (1st Cir. 2010) (taking judicial notice of CDC guidance and facts related to Lyme disease, which "are not subject to reasonable dispute").

A. The Food, Drug, and Cosmetics Act does not prohibit Defendants from implementing vaccine mandates

Plaintiffs first claim the PHO violates the Food, Drug, and Cosmetic Act ("FDCA"). *See* Compl. at 9-10. However, such a claim entirely misconstrues the FDCA and is largely moot now. The FDCA authorizes the FDA to issue an "emergency use authorization" for a medical product, such as a vaccine, to be introduced into interstate commerce and administered to individuals in an emergency situation when the product has not yet undergone the standard review and approval process. 21 U.S.C. § 360bbb-3(a)(1), (2). Here, the FDA has granted emergency use authorizations

for three COVID-19 vaccines, with each vaccine manufacturer meeting more stringent standards compared to emergency use authorization vaccines in the past. *See* Background Section II, *supra*; *Klaassen v. Trs. of Ind. Univ.*, No. 1:21-CV-238 DRL, 2021 U.S. Dist. LEXIS 133300, at **21-22 (N.D. Ind. July 18, 2021). Importantly, the FDA granted the Pfizer vaccine ***full*** approval for individuals 16 years of age and older. *See* U.S. Food & Drug Admin., *supra* note 17.[34] Therefore, Plaintiffs claims regarding emergency use authorization are moot for anyone in that age group.

Regardless, Plaintiffs claims based on the emergency use authorization section of the FDCA fail as the FDCA does not prevent a public or private entity from requiring vaccines. The plain language of 21 U.S.C. § 360bbb-3(e) demonstrates that the section only applies to healthcare providers administering COVID-19 vaccines and to the potential vaccine recipients. The FDCA states for the emergency use of an unapproved product the Secretary of the HHS shall "*for person who carries out any activity for which the authorization is issued*, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health[.]" 21 U.S.C. § 360bbb-3(e)(1)(a) (emphasis added). Specifically, the FDCA requires the Secretary issue:

> (i) Appropriate conditions designed to ensure that *health care professionals administering the product are informed—*
>
> > (I) that the Secretary has authorized the emergency use of the product;
> > (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

[34] Strangely, Plaintiffs dispute that the Pfizer vaccine was not fully approved by citing to a letter *confirming that the FDA approved Pfizer's biologics license application*. *See* Reply to Defendants' Response to Plaintiffs' Request for Temporary Restrainging [sic] Order [Doc. 14] ("Reply"), at 4 (citing Exhibit 4); *see also* [Doc 14-1 at 2 (stating that "[o]n August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older")]; *see generally* 42 U.S.C. § 262 (biologics license provisions).

> (III) of the alternatives to the product that are available, and of their benefits and risks.
>
> (ii) Appropriate conditions designed *to ensure that individuals to whom the product is administered are informed—*
>
> (I) that the Secretary has authorized the emergency use of the product;
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(a)(i), (ii) (emphases added).

Several courts have held that the plain language of this provision indicates that it does not apply to those requiring vaccines but only to the individuals in the process of *receiving* a vaccine. *See Bridges v. Hous. Methodist Hosp.*, No. H-21-1774, 2021 U.S. Dist. LEXIS 110382, at *5-6 (S.D. Tex. June 12, 2021) ("[21 U.S.C. § 360bbb-3] neither expands nor restricts the responsibilities of private employers; in fact, it does not apply at all to private employers [requiring employees be vaccinated]."); *Klaassen,* 2021 U.S. Dist. LEXIS 133300, *64-65 (interpreting 21 U.S.C. § 360bbb-3(e)(1)(A)(ii) as establishing conditions to facilitate informed consent for medical providers and the persons receiving vaccines). Indeed, even the Department of Justice issued a thorough memorandum opinion concluding that the "language in section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements."[35] Thus, Plaintiffs' claim clearly fails as a matter of law.

[35] Dep't of Justice, *Whether Section 564 of the Food, Drug and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* at 2 (July 6, 2021), https://www.justice.gov/olc/file/1415446/download. The Court should give deference to the Department of Justice's thorough analysis. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) ("[A]n agency's interpretation may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency and

B. The vaccine requirements do not violate equal protection or substantive due process because they are rationally related to a *compelling* government interest

Plaintiffs next claim the PHO violates equal protection and due process. *See* Compl. at 10-12. Although the Equal Protection and Due Process clauses protect distinctly different interests, "their substantive analyses converge." *Powers v. Harris*, 379 F.3d 1208, 1215 (10th Cir. 2004). For substantive due process claims challenging legislative-type actions, such as the PHO, the Court typically applies a two-part test in which it first asks whether the action implicates a fundamental right. *See Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1182 (10th Cir. 2009). If so, the Court applies strict scrutiny; if not, the Court applies rational basis review. *Id.* Similarly, in considering equal protection claims, the Court will apply rational basis review unless the classification at issue discriminates against a suspect class. *See Curley v. Perry*, 246 F.3d 1278, 1285 (10th Cir. 2001).

1. The vaccine requirements are subject to rational basis review because they do not discriminate against a suspect class or infringe upon a fundamental right

i. Equal Protection

Plaintiffs summarily claim that the generally applicable vaccine requirements violate the Equal Protection Clause. *See* Compl. at 10-11. As a preliminary matter, Plaintiffs' equal protection claim fails because they do not allege that Defendants intentionally discriminated against them in the PHO. *See ETP Rio Rancho Park, LLC v. Grisham*, No. CIV 21-0092 JB/KK, 2021 U.S. Dist. LEXIS 23409, at *137 (D.N.M. Feb. 8, 2021) ("[I]f a statute appears facially neutral, the plaintiff must make out a 'prima facie case of discriminatory purpose.'" (quoting *Washington v. Davis*, 426 U.S. 229, 241 (1976)); *see generally* Compl. The PHO's vaccine requirements are facially neutral because they apply to all individuals working in hospitals and certain congregate care facilities, as

given the value of uniformity in its administrative and judicial understandings of what a national law requires." (internal quotation marks and citations omitted)).

well as all individuals attending the state fair. *Cf. ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 23409, at **138-39 (finding PHO provision neutral because it does not require only trampoline facilities to remain closed). Therefore, Plaintiffs must make out a prima facie case of discriminatory animus toward them. *Id*. Discriminatory intent "requires that the decisionmaker . . . selected or reaffirmed a particular course of action at least in part because of, not merely in spite of the law's differential treatment of a particular class of persons." *SECSYS, Ltd. Liab. Co. v. Vigil*, 666 F.3d 678, 685 (10th Cir. 2012) (internal quotation marks and citation omitted). As the Complaint contains no allegations that the PHO's restrictions are born out of animus toward unvaccinated individuals, the restrictions do not "run afoul of the Constitution." *Id.*

Assuming, *arguendo*, Plaintiffs did properly plead an equal protection claim, such a claim would be subject to rational basis review *at most*. Plaintiffs do not allege (as they cannot) that they are members of a suspect class which would give rise to any sort of heightened scrutiny. *See Save Palisade FruitLands v. Todd*, 279 F.3d 1204, 1210 (10th Cir. 2002) (stating that governmental classifications are only subject to strict scrutiny if they target a suspect class such as race or national origin and intermediate scrutiny is applied to quasi-suspect classes like gender). Moreover, as described in the following section, Plaintiffs fail to demonstrate that the PHO's vaccine requirement infringes on a fundamental right. Thus, the Court must use rational basis review when reviewing Plaintiffs' equal protection claims.

ii. Substantive Due Process

Plaintiffs substantive due process claims are similarly subject to rational basis review. There are two types of substantive due process claims: (1) claims that the government has infringed a fundamental right and (2) claims that government action deprived a person of life, liberty, or property in a manner so arbitrary it shocks the judicial conscience. *Doe v. Woodard*, 912 F.3d

1278, 1300 (10th Cir. 2019). "[Courts] apply the fundamental-rights approach when the plaintiff challenges legislative action, and the shocks-the-conscience approach when the plaintiff seeks relief for tortious executive action." *Id.* (alterations, internal quotation marks, and citation omitted). The fundamental-rights approach is applicable in this case, as the PHO is a quasi-legislative action generally applicable to thousands of New Mexicans, and it is the Department of Health's attempt to "through policy, to achieve a stated government purpose."[36] *Abdi v. Wray*, 942 F.3d 1019, 1027-28 & n.1 (10th Cir. 2019); *cf. Nicholas v. Pa. State Univ.*, 227 F.3d 133, 139 n.1 (3d Cir. 2000) ("[E]xecutive acts, such as employment decisions, typically apply to one person or to a limited number of persons, while legislative acts, generally laws and broad executive regulations, apply to large segments of society." (internal quotation marks and citation omitted)).

Legislative action is tested under a two-part substantive due process framework in which the Court asks first asks whether a fundamental right is implicated. *Dias v. City & Cty. of Denver*, 567 F.3d 1169, 1182 (10th Cir. 2009). The plaintiff bears the burden of providing a "careful description of the asserted fundamental liberty interest" and demonstrating how such a right is "objectively deeply rooted in [the] Nation's history and tradition" and "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed."

[36] Even if the "shocks conscience" standard applied in this case, Plaintiffs' claim would still fail. "Conduct that shocks the judicial conscience is deliberate government action that is arbitrary and unrestrained by the established principles of private right and distributive justice." *Woodard*, 912 F.3d at 1300. (internal quotation marks omitted). Issuing public health orders requiring certain people working with highly vulnerable populations or attending a state fair to be vaccinated or meet an exception can hardly be considered conscious-shocking. *See World Gym, Inc. v. Baker*, Civil Action No. 20-cv-11162-DJC, 2020 U.S. Dist. LEXIS 131236, at *12 (D. Mass. July 24, 2020) ("In light of the toll of the pandemic, [the plaintiffs' argument that the governor's COVID-19-related orders shock the conscious] is unconvincing. The state has a strong interest in stopping the spread of COVID-19, and accordingly, it cannot be said that the Governor's conduct amounts conscience-shocking action."); *Herrin v. Reeves*, No. 3:20cv263-MPM-RP, 2020 U.S. Dist. LEXIS 176604, at *23 (N.D. Miss. Sep. 25, 2020) ("[T]he notion that restrictions designed to save human lives are 'conscious shocking' [is] absurd and not worthy of serious discussion.").

Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997) (internal quotation marks and citations omitted). Vague, conclusory, or generalized assertions will not suffice. *See ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 36354, at *119.

Plaintiffs' general allegations to a fundamental right "to live without arbitrary governmental interference," "to bodily integrity," to raise their children as they see fit," and to "engage in their chose profession" can hardly be considered to satisfy *Glucksberg*'s requirements. *See* Compl. at 11; *ETP Rio Rancho Park*, 2021 U.S. Dist. LEXIS 36354, at *105-06 (holding that the plaintiffs vague and conclusory allegations to run a business did not satisfy *Glucksberg*'s "careful description" requirement because they did "not explain how the Dec. 30 PHO deprives the Plaintiffs of a fundamental right and do not address how trampoline facility operation is 'deeply rooted in Nation's history and tradition.'"). Like the plaintiffs in *ETP Rio Rancho Park*, Plaintiffs fail to explain how their "right" to work in hospitals and congregate care facilities or attend a state fair unvaccinated during a pandemic is "deeply rooted in [the n]ation's history and tradition." *Glucksberg*, 521 U.S. at 720-21. Nor could they, as federal courts have consistently applied rational basis review to assess mandatory vaccination measures or laws impacting an individual's decision practice a chosen profession. *See Klaassen*, 2021 U.S. Dist. LEXIS 133300, at *62 (collecting cases applying rational basis review to assess mandatory vaccination measures and concluding that Indiana University's COVID-19 requirement was subject to rational basis "[g]iven over a century's worth of rulings saying there is no greater right to refuse a vaccination than what the Constitution recognizes as a significant liberty"); *Medeiros v. Vincent*, 431 F.3d 25, 32 (1st Cir. 2005) ("The right to 'make a living' is not a 'fundamental right,' for either equal protection or substantive due process purposes."); *see also Guttman v. Khalsa*, 669 F.3d 1101, 1118 (10th

Cir. 2012) (holding that a right to practice in one's chosen profession is not fundamental). Thus, rational basis review is appropriate.

2. The vaccination requirements are rationally related to a compelling government interest in combatting the spread of COVID-19 and mitigating hospitalizations and deaths

To survive rational basis review, "the [law] need only be rationally related to a legitimate government purpose." *See Save Palisade FruitLands*, 279 F.3d at 1210. In challenging a governmental action for want of a rational basis, "the burden is upon the challenging party to negative any reasonably conceivable state of facts that could provide a rational basis for the [law]." *Bd. of Trs. v. Garrett*, 531 U.S. 356, 367 (2001) (internal quotation marks and citation omitted). "Th[e] standard is objective—if there is a reasonable justification for the challenged action, [the court] do[es] not inquire into the government actor's actual motivations." *Kan. Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1216 (10th Cir. 2011). "[R]ational-basis review does not give courts the option to speculate as to whether some other scheme could have better regulated the evils in question." *Powers*, 379 F.3d at 1217. Courts "will not strike down a law as irrational simply because it may not succeed in bringing about the result it seeks to accomplish or because the statute's classifications lack razor-sharp precision. *Id.* (citations omitted). "Nor can [a court] overturn a statute on the basis that no empirical evidence supports the assumptions underlying the legislative choice." *Id.* Indeed, rational basis scrutiny is so deferential that courts "must independently consider whether there is any conceivable rational basis for the classification, regardless of whether the reason ultimately relied on is provided by the parties." *Teigen v. Renfrow*, 511 F.3d 1072, 1084 (10th Cir. 2007) (alterations, internal quotation marks, and citation omitted).

It cannot be disputed that Defendants have a legitimate, indeed *compelling*, interest in stemming the spread of COVID-19 and preventing more hospitalizations and deaths. *See Roman*

Catholic Diocese v. Cuomo, 141 S. Ct. 63, 67 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest[.]"). The question is whether requiring individuals working at hospitals and certain congregate care facilities or attending a massive state fair to be vaccinated or meet an exception is rationally related to the State's interest? Unquestionably, it is.

Over one hundred years ago, the Supreme Court rejected a similar challenge to a universal smallpox vaccine mandate. In *Jacobson*, the state passed a law permitting a city to enforce vaccination of its citizens or face a $5.00 criminal penalty (about $140.00 today). 197 U.S. at 12; *Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring). After refusing a smallpox vaccine, as required by the city of Cambridge, Jacobson was sentenced to jail until he paid the fine. *Jacobson*, 197 U.S. at 11. Jacobson sued, claiming the mandate violated his right to "bodily integrity." *Id.* at 13-14.

The Supreme Court rejected Jacobson's challenge, recognizing that a state's police power "must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety." *Id.* at 25. Thus, according to the Supreme Court, "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is beyond all question, a plain, palpable invasion of rights secured by the fundamental law." *Id.* at 31. Cambridge's vaccine mandate withstood this test. The mandate had a real and substantial relation to stemming the spread of smallpox—despite a minority view that the vaccines were ineffective. *See id.* at 31-39. In so holding, the Court quoted the New York Court of Appeals, which stated,

> It must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox. The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease and to render it less dangerous to those who contract it. . . . The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the

> common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action[.]

Id. at 34-35 (quoting *Viemeister v. White*, 179 N.Y. 235, 239-41, 72 N.E. 97 (1904). The Court also rejected Jacobson's offer of proof that the vaccine "quite often caused serious and permanent injury," stating that to allow him to avoid vaccination on this general concern "would practically strip the legislative department of its function to care for the public health and the public safety when endangered by epidemics of disease." *Id.* at 37.

Jacobson has been upheld and relied on throughout the years by courts across the country—including in challenges to COVID-19 vaccine mandates. *See, e.g.*, *Zucht v. King*, 260 U.S. 174, 176 (1922) (relying on *Jacobson* to uphold a city ordinance excluding from its public schools children not having a certificate of vaccination); *cf. Roman Catholic*, 141 S. Ct. at 71 (Gorsuch, J. concurring) ("In *Jacobson*, individuals could accept the vaccine, pay the fine, or identify a basis for exemption. The imposition on Mr. Jacobson's claimed right to bodily integrity, thus, was avoidable and relatively modest. It easily survived rational basis review, and might even have survived strict scrutiny, given the opt-outs available to certain objectors."); *America's Frontline Doctors v. Wilcox*, No. EDCV 21-1243 JGB (KKx), 2021 U.S. Dist. LEXIS 144477, at **14-17 (C.D. Cal. July 30, 2021) (citing *Jacobson* and concluding that the plaintiffs were unlikely to succeed in their due process claim against the University of California's COVID-19 vaccination mandate).[37]

[37] Even Plaintiffs' counsel admits *Jacobson* "stands on solid ground without a doubt." Plaintiffs' Response to Defendant's Motion to Dismiss [Doc. 18] at 2, *N.M. Elks Ass'n v. Lujan Grisham*, No. 1:21-cv-00354-KG/LF (D.N.M. May 28, 2021) ("COVID-19 is certainly a grave concern, just like smallpox was, and the exercise of infringement into personal liberty by the government of requiring a vaccine as considered in *Jacobson* stands on solid ground without a doubt.").

Recently, a U.S. district court relied on *Jacobson* to reject a group of students' request for a preliminary injunction against the Indiana University's requirement that all students be vaccinated against COVID-19 or meet various religious or medical exemptions. *See Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **15-17, 42-104. After carefully reviewing the current state of scientific consensus regarding the safety and effectiveness of the COVID-19 vaccines, the court noted that "the students' arguments amount to disputes over the most reliable science. But when reasonable minds can differ as to the best course of action . . . the court doesn't intervene so long as the university's process is rational in trying to achieve public health." *Id.* at *103. Ultimately, the court concluded that that Indiana University "has a rational basis to conclude that the COVID-19 vaccine is safe and efficacious for its students." *Id.* at *99.

The U.S. Court of Appeals for the Seventh Circuit denied the students' motion for an injunction pending appeal, noting that "*Jacobson*, which sustained a criminal conviction for refusing to be vaccinated, shows that plaintiffs lack [a fundamental right to attend school without being vaccinated]." *Klaassen v. Trs. of Ind. Univ.*, No. 21-2326, 2021 U.S. App. LEXIS 22785, at *2 (7th Cir. Aug. 2, 2021). The Court further observed that the case was "easier" than *Jacobson* because the university had exceptions for persons "who declare vaccination incompatible with their religious beliefs and persons for whom vaccination is medically contraindicated," and Indiana was not requiring every member of the public be vaccinated but instead to simply condition attendance on vaccination. *Klaassen*, 2021 U.S. App. LEXIS 22785, at **3-4. Notably, Justice Amy Coney Barrett denied the students' application for injunctive relief following the Seventh Circuit's decision, signaling the Supreme Court did not find the students' case meritorious.[38]

[38] *See Docket Search*, U.S. Supreme Court, https://www.supremecourt.gov/docket/docket.aspx (search "No. 21A15"; select "Docket for 21A15") (last visited Aug. 24, 2021).

The instant case is nearly identical to *Klaasen* and doomed to the same fate. Like Indiana University, Defendants side with the vast majority of the scientific community—including the CDC and the State's public health experts—in concluding that the COVID-19 vaccines are a safe and effective way to protect individuals from becoming infected or at least becoming seriously ill. *See generally* Background Section II, *supra*. Relying on this general consensus, Defendants instituted a targeted vaccine mandate aimed at individuals working with the State's most vulnerable populations in hospitals and certain congregate care facilities, as well as individuals attending one of the largest events in the state in an attempt to mitigate the mass hospitalizations caused by the highly contagious Delta variant. *See* N.M. Dep't of Health, *supra* note 32. Moreover, Defendants (like Indiana University) tailored the mandate to provide exemptions for individuals who have a qualifying medical condition which immunization would endanger their health or a disability or sincerely held religious belief requiring accommodation. *Compare* N.M. Dep't of Health, *supra* note 32, *with Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **15-17.

Plaintiffs' disagreement with the scientific community or speculation about theoretical long-term side effects of the vaccines does not negate Defendants' rational basis for their actions. *See Jacobson*, 197 U.S. at 34-37; *Klaassen*, 2021 U.S. Dist. LEXIS 133300, at **103. Nor do the PHO's vaccine requirements need to "take into account for or recognize the health implications associated to [sic] individuals that have natural immunity[,]" which Plaintiffs allege is "equal to or better" than the immunity provided from vaccines. Compl. at 4 ¶¶ 13-14. As explained above, there is ample evidence that the immunity provided by vaccines is more robust and durable than natural immunity. *See generally* Background Section II, *supra*; *see also America's Frontline Doctors*, 2021 U.S. Dist. LEXIS 144477, at *17 ("The Court finds that there is clearly a rational basis for Defendants to institute the Policy requiring vaccination, *including for individuals who*

previously had COVID-19." (emphasis added)). And even if Plaintiffs' allegations happened to be true, the PHO's vaccine requirements need not be narrowly tailored to exclude individuals who have been previously infected. *See Powers*, 379 F.3d at 1217 ("[W]e will not strike down a law as irrational simply because it may not succeed in bringing about the result it seeks to accomplish, or because the statute's classifications lack razor-sharp precision."). Left only with speculative arguments previously rejected by the Supreme Court, the Court must dismiss Plaintiffs' equal protection and substantive due process claims.

C. The promulgation of the PHO does not implicate procedural due process because it is quasi-legislative

Plaintiffs next claim Defendants violated Plaintiffs' right to procedural due process under the Fourteenth Amendment. *See* Compl. at 12. However, a procedural due process violation will not lie when the underlying governmental action affects a general class of persons. *See Okla. Educ. Ass'n v. Alcoholic Beverage Laws Enf't Comm'n*, 889 F.2d 929, 936 (10th Cir. 1989) ("When the legislature passes a law which affects a general class of persons, those persons have all received procedural due process—the legislative process."). Although this exception typically applies to laws passed by Congress or state legislatures, courts have applied it based on the nature of the action and whether it applies to a larger segment of the population rather than a limited number of individuals. *See, e.g.*, *Curlott v. Campbell*, 598 F.2d 1175, 1181 (9th Cir. 1979) ("At the outset we doubt very much that procedural due process prior to reduction of benefits is required when an agency makes a broadly applicable, legislative-type decision." (citing *Bi-Metallic Investment Co. v. State Board of Equalization*, 239 U.S. 441 (1915)). Following this principle, courts (including those within this district) have held that executive orders issued in response to the current pandemic were legislative in nature, and therefore, did not implicate procedural due process. *See, e.g.*,

Hernandez v. Lujan Grisham, 508 F. Supp. 3d 893, 977-81 (D.N.M. 2020);[39] *ETP Rio Rancho*, 2021 U.S. Dist. LEXIS 36354, at **149-51; *Peterson*, 2020 U.S. Dist. LEXIS 183471, *25-26. Respectfully, this Court should likewise hold that Plaintiffs are not entitled to procedural due process with regard to the issuance of the PHO.

D. The vaccine requirements do not violate the contracts clause

Plaintiffs also assert that the vaccine requirements violate the contracts clause of Art. I, § 10 of the U.S. Constitution, which provides, in relevant part, that "[n]o state shall . . . pass any . . . law impairing the obligation of contracts[.]"[40] *See* Compl. at 21. "[T]he Contract Clause limits the power of the States to modify their own contracts as well as to regulate those between private parties." *U.S. Tr. Co. of N.Y. v. New Jersey*, 431 U.S. 1, 17 (1977). However, the Contracts Clause "is not an absolute one and is not to be read with literal exactness like a mathematical formula." *Home Bldg. & Loan Asso. v. Blaisdell*, 290 U.S. 398, 428 (1934). Nor does the clause "operate to obliterate the police power of the States." *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 241 (1978). Courts apply a two-step test to determine whether a state law violates the Contracts Clause. "The threshold issue is whether the state law has 'operated as a substantial impairment of a contractual relationship.'" *Sveen v. Melin*, 138 S. Ct. 1815, 1821-22, (2018) (quoting *Allied*, 438 U.S. at 244). "In answering that question, the Court has considered the extent to which the law

[39] Plaintiffs' counsel was counsel in *Hernandez* and should be well aware of this holding but nonetheless chooses to reassert the same claim. This is not surprising, however, as Plaintiffs' counsel has a history of filing frivolous claims. *See, e.g.*, *Collins v. Daniels*, 916 F.3d 1302, 1320-23 (10th Cir. 2019) (upholding Rule 11 sanctions against A. Blair Dunn).

[40] While the Complaint also alleged the PHO constitutes a bill of attainder, *see* Compl. at 12, Plaintiffs have since abandoned that claim and acknowledged that the bill of attainder clause is inapplicable. *See* Reply at 7.

undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights." *Id.* at 1822.

When a law substantially impairs a contract, "the State, in justification, must have a significant and legitimate public purpose behind the [law], such as the remedying of a broad and general social or economic problem." *Stillman v. Teachers Ins. & Annuity Ass'n College Ret. Equities Fund*, 343 F.3d 1311, 1321 (10th Cir. 2003) (internal quotation marks and citations omitted). Specifically, courts will ask "whether the state law is drawn in an appropriate and reasonable way to advance a significant and legitimate public purpose." *Sveen*, 138 S. Ct. at 1822 (internal quotation marks and citations omitted). However, the courts will "refuse to second-guess the [government']s determinations that [the measures] are the most appropriate ways of dealing with the problem." *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 506 (1987); *see also United States Tr. Co. v. New Jersey*, 431 U.S. 1, 22-23 (1977) ("As is customary in reviewing economic and social regulation, however, courts properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.").

As an initial matter, Plaintiffs have failed to demonstrate that the vaccine requirement substantially interferes with their contracts because they have not provided the Court any copies of any of the purported contracts at issue. Nor have they said who their contract is with and what it is for. For example, it is possible that Plaintiff Valdez's purported State Fair contract may have provisions allowing for the cancellation of the contract for any reason. Additionally, the contract may have provisions requiring the Plaintiffs abide by all New Mexico laws and regulations, which would include the PHO. Regardless, the New Mexico State Fair is cancelling the junior livestock

show and offering full refunds.[41] Additionally, the New Mexico Youth Livestock Expo is being relocated to Roswell at a later date.[42] Further, the PHO does not substantially impair the employee-employer contract raised by Plaintiff Blackford, as her employer, Presbyterian Healthcare Services, is requiring COVID-19 vaccinations for its entire workforce. *See* Heild, *supra* note 33; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact)].

Finally, even if the Court found that the PHO substantially impairs one of Plaintiffs' various contracts, the vaccine requirement is an appropriate and reasonable means of advancing the State's significant and legitimate purpose. It is undeniable that Defendants have not only a legitimate but a *compelling* interest in preventing the spread of COVID-19, especially now when its hospitals are being overwhelmed by a highly contagious variant. *See Legacy Church, Inc.*, 472 F. Supp. 3d at 1022. There is also substantial evidence that vaccines are an effective in preventing the strain on New Mexico's healthcare system and protect the State's population. *See generally* Background Section II, *supra*. Requiring the workers who interact with ill patients or serve persons living in close proximity is a reasonable measure to protect not only the populations within hospitals and congregate care facilities but also all employees from the risk of severe illness or death. *See id.* The PHO's vaccine requirement for all vaccine-eligible persons entering the State Fair is similarly reasonable, as it will help ensure that the thousands of people from all over the state do not contribute to a superspreading event.

[41] *See 2021 Junior Livestock Refund Application*, N.M. State Fair, https://statefair.exponm.com/p/participate/competitions/livestock-shows (last visited Sept. 2, 2021).

[42] Jonathan Fjeld, *New Mexico Youth Livestock Expo to relocate to Roswell*, KOB4 News (Aug. 27, 2021), https://www.kob.com/albuquerque-news/new-mexico-youth-livestock-expo-to-relocate-to-roswell/6219714/.

Plaintiffs argue the Court should not defer to Defendants' judgment because the vaccine requirements allegedly interfere with Plaintiff Valdez's contract, which is purportedly with a state agency. *See* Reply at 8; *United States Tr. Co.*, 431 U.S. at 23 ("When a State impairs the obligation of its own contract, the reserved-powers doctrine has a different basis. The initial inquiry concerns the ability of the State to enter into an agreement that limits its power to act in the future. This doctrine requires a determination of the State's power to create irrevocable contract rights in the first place, rather than an inquiry into the purpose or reasonableness of the subsequent impairment."). However, "the Contract Clause does not require a State to adhere to a contract that surrenders an essential attribute of its sovereignty[,] and "the police power . . . c[an] not be contracted away." *Id.* at 23-24 (internal quotation marks and citation omitted). The vaccine requirements fall comfortably within the State's police powers. *See Dodger's Bar & Grill, Inc. v. Johnson Cty. Bd. of Cty. Comm'rs*, 32 F.3d 1436, 1441 (10th Cir. 1994) ("[T]he police power encompasses 'the authority to provide for the public health, safety, and morals.'") (quoting *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569 (1991)). Accordingly, the alleged fact that Plaintiff Valdez entered into a contract with a state agency is of no moment, and Plaintiffs' contracts clause claims fail regardless.

E. Plaintiffs' state constitutional claims are barred by sovereign immunity and should not be subject to supplemental jurisdiction

Lastly, Plaintiffs bring a claim under the newly enacted New Mexico Civil Rights Act, NMSA 1978, §§ 41-4A-1 to -13 (2021), asserting that the PHOs violate various provisions of the New Mexico constitution. *See* Compl. at 13-14. However, sovereign immunity prohibits Plaintiffs from maintaining such claims in *federal* court. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984); *Ramirez v. Martinez*, No. 20-cv-824 MV/SMV, 2021 U.S. Dist. LEXIS 68516, at *6 (D.N.M. Apr. 7, 2021) (Vázquez, J.) ("The eleventh amendment bars a suit for

damages in federal court when the action is in essence one for recovery of money from the state and the state is the real, substantial party in interest, notwithstanding that individual officials are nominal defendants."). Although the State waived sovereign immunity in passing the New Mexico Civil Rights Act, *see* § 41-4A-9, it did so only for suits brought in New Mexico *state* courts. *See* § 41-4A-3(B) (providing that a individuals "may maintain an action to establish liability and recover actual damages and equitable or injunctive relief in any *New Mexico* district court" (emphasis added)). Accordingly, Plaintiffs' state constitutional claims are barred by sovereign immunity. *See Sossamon v. Texas*, 563 U.S. 277, 285 (2011) ("[A] waiver of sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign. So, for example, a State's consent to suit in its own courts is not a waiver of its immunity from suit in federal court." (internal quotation marks and citations omitted)).[43]

Leaving sovereign immunity aside, the Court should decline supplemental jurisdiction over Plaintiffs' state law claims given Plaintiffs' failure to bring any viable federal claims. *See Merrifield v. Bd. of Cty. Comm'rs*, 654 F.3d 1073, 1085 (10th Cir. 2011) (stating that a district court may decline supplemental jurisdiction when it has "dismissed all claims over which it has original jurisdiction" (quoting 28 U.S.C. § 1367(c)(3)). The Court should also decline supplemental jurisdiction because Plaintiffs' claims raise novel and complex issues of state constitutional law that should be addressed by New Mexico courts. *See* 28 U.S.C. § 1367(c)(1); *see generally* Linda M. Vanzi, et al., *State Constitutional Litigation in New Mexico: All Shield and*

[43] Plaintiffs ignore Defendants' sovereign immunity argument in their Reply and suggest that the Court may simply exercise supplemental jurisdiction over their state claims. *See* Reply at 9-10. However, "[s]upplemental jurisdiction does not render the Eleventh Amendment inapplicable because the Supreme Court has held that neither pendent jurisdiction nor any other basis of jurisdiction may override the Eleventh Amendment." *Mascheroni v. Bd. of Regents of the Univ. of Cal.*, 28 F.3d 1554, 1559 (10th Cir. 1994) (quoting *Pennhurst*, 465 U.S. at 121 (1984)).

No Sword, 48 N.M. L. Rev. 302, 305 (2018) (stating that the New Mexico supreme court has considered only three civil cases involving a claim under the state constitution in the past twenty years).

F. Plaintiffs' federal claims for damages are barred by sovereign and qualified immunity

Given Plaintiffs' failures to state any valid claim for relief, Plaintiffs' request damages necessarily fails as well. Yet even if Plaintiffs *did* assert a valid claim against Defendants, their request for damages based on federal claims are barred by qualified immunity.[44] "The doctrine of qualified immunity protects government officials 'from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known." *Pearson v. Callahan*, 555 U.S. 223, 231 (2009) (internal quotation marks and citations omitted). "A clearly established right is one that is sufficiently clear that every reasonable official would have understood that what he is doing violates that right. . . . Ordinarily . . . there must be a Supreme Court or Tenth Circuit decision on point, or the clearly established weight of authority from other courts must have found the law to be as the plaintiff maintains." *Ullery v. Bradley*, 949 F.3d 1282, 1291 (10th Cir. 2020) (internal quotation marks and citations omitted). Plaintiffs cannot credibly claim that Defendants violated any clearly established rights when Defendants implemented a targeted mandate for a safe and effective vaccine to protect New Mexicans in the midst of an unprecedented pandemic—actions which, as discussed above, the Supreme Court has upheld. *See Jacobson*, 197 U.S. 11; *Northland Baptist Church of St. Paul v.*

[44] Any claims against Defendants in their official capacities would likewise be barred by sovereign immunity. *See Peterson v. Martinez*, 707 F.3d 1197, 1205 (10th Cir. 2013) ("[B]ecause an official-capacity suit is, in all respects other than name, to be treated as a suit against the entity, the Eleventh Amendment provides immunity when [s]tate officials are sued for damages in their official capacity." (internal quotation marks and citation omitted)).

Walz, No. 20-cv-1100 (WMW/BRT), 2021 U.S. Dist. LEXIS 60884, at *19-20 (D. Minn. Mar. 30, 2021) ("Governor Walz issued executive orders in the midst of a novel global pandemic. Certainly, the existence of an ongoing pandemic does not eradicate constitutional rights. But when assessing the facts as they appeared to state actors, ignoring this unprecedented context would result in defining constitutional rights with an excessive degree of generality." (citations omitted)). Accordingly, Plaintiffs' federal claim for damages fails regardless of the merits underlying their claims.

CONCLUSION

For the foregoing reasons, this Court should dismiss Plaintiffs' action with prejudice.

Respectfully submitted,

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

TALISHA VALDEZ, on behalf of herself
and others similarly situated, and
JENNIFER BLACKFORD on behalf of herself
And others similarly situated,

Plaintiffs,

Civil Action. 1:21-cv-00783-MV-JHR

v.

MICHELLE LUJAN GRISHAM,
Officially and Individually, Acting Under the Color of Law,
and
DAVID SCRASE,
Officially and Individually, Acting Under the Color of Law,

Defendants.

NOTICE OF INTERLOCUTORY APPEAL

Notice is hereby given this 13th day of September 2020, pursuant to Fed. R. App. P., Rule and from 28 U.S.C.A. § 1292 that Plaintiffs Jennifer Blackford and Talisha Valdez hereby appeal to the United States Court of Appeals for the Tenth Circuit from the Memorandum Opinion and Order of this Court (ECF Doc. 18), filed this day, Denying Plaintiffs' Request for Preliminary Injunction.

Respectfully submitted this 13th day of September 2021.

WESTERN AGRICULTURE, RESOURCE
AND BUSINESS ADVOCATES, LLP

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IN THE UNITED STATES DISTRICT COURT
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TALISHA VALDEZ, on behalf of herself
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RESPONSE TO DEFENDANTS' MOTION TO DISMISS

COMES NOW, Plaintiffs Talisha Valdez and Jennifer Blackford, by and through undersigned counsel of record Western Agriculture, Resource and Business Advocates, LLP (A. Blair Dunn, Esq. and Jared R. Vander Dussen, Esq.) and provides their response to Defendants' Motion to Dismiss.

INTRODUCTION

Though Defendants are heavily inclined to quote *Jacobsen* for the proposition that it offers them a blank check; they do not want to acknowledge the limits of *Jacobsen*, and the current United States Supreme Court's rulings applying *Jacobsen* to the modern problem of COVID. Putting aside the factual reality inconvenient to the Defendants' argument, that in *Jacobsen*, Mr. Jacobsen, who declined to receive the smallpox vaccine, was afforded the option to pay a $5 fine ($140 in today's dollars). The *Jacobsen* Court clearly enunciated there was a limit to how much the government could trample civil rights during a pandemic, stating in its holding that:

> Before closing this opinion we deem it appropriate, in order to prevent misapprehension as to our views, to observe—perhaps to repeat a thought already sufficiently expressed, namely—that the police power of a state, whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression. Extreme cases can be readily suggested. Ordinarily such cases are not safe guides in the administration of the law. It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health *39 or body would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned. 'All laws,' this court has said, 'should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language which would avoid results of this character. The reason of the law in such cases should prevail over its letter.' *United States* v. *Kirby*, 7 Wall. 482, 19 L. ed. 278; *Lau Ow Bew* v. *United States*, 144 U. S. 47, 58, 36 L. ed. 340, 344, 12 Sup. Ct. Rep. 517.

Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 38–39, 25 S. Ct. 358, 366, 49 L. Ed. 643 (1905).

Moreover, Justice Gorsuch writing in concurrence with the current United States Supreme Court has articulated that even during pandemic public health orders that are not narrowly tailored fail strict scrutiny when they impair fundamental liberties and are therefore unconstitutional, stating:

> Put differently, *Jacobson* didn't seek to depart from normal legal rules during a pandemic, and it supplies no precedent for doing so. Instead, *Jacobson* applied what would become the traditional legal test associated with the right at issue—exactly what the Court does today. Here, that means strict scrutiny: The First Amendment traditionally requires a State to treat religious exercises at least as well as comparable secular activities unless it can meet the demands of strict scrutiny—showing it has employed the most narrowly tailored means available to satisfy a compelling state interest. *Church of Lukumi*, 508 U.S. at 546, 113 S.Ct. 2217.

Roman Catholic Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 70, 208 L. Ed. 2d 206 (2020).

And that is not a one-off decision, like *Jacobsen* before modern day constitutional review,

jurisprudence was in place, and since that decision Justice Gorsuch, joined by Justices Alito and Thomas in another case has reiterated that point, stating:

> In cases implicating this form of "strict scrutiny," courts nearly always face an individual's claim of constitutional right pitted against the government's claim of special expertise in a matter of high importance involving public health or safety. It has never been enough for the State to insist on deference or demand that individual rights give way to collective interests. Of course we are not scientists, but neither may we abandon the field when government officials with experts in tow seek to infringe a constitutionally protected liberty. The whole point of strict scrutiny is to test the government's assertions, and our precedents make plain that it has always been a demanding and rarely satisfied standard. See *Lukumi*, 508 U.S. at 546, 113 S.Ct. 2217. Even in times of crisis—perhaps *especially* in times of crisis—we have a duty to hold governments to the Constitution.

S. Bay United Pentecostal Church v. Newsom, 141 S. Ct. 716, 718, 209 L. Ed. 2d 22 (2021)

Thus, the United States Supreme Court's jurisprudence, both the case cited by Defendants and the cases avoided by Defendants, requires that this Court reach the conclusion that the complaint should not be dismissed.

ARGUMENT

Defendants do not, because they cannot, explain how the Public Health Order (PHO) outlawing nurses from working as nurses in New Mexico does not implicate the long recognized fundamental liberty to engage in one's chosen profession as protected by the Fourteenth Amendment.

Here, Plaintiff Blackford has plausibly alleged and verified that she has protected property interest to engage in her chosen profession and that if the government's PHO mandate is enforced, she is prohibited from working as nurse in New Mexico as long as the order is in effect and she is unvaccinated. It is important to note that her employer has implemented a policy in order to comply with the PHO mandate that has now resulted in her being placed on leave without pay at least for the next 4 months but had not done so prior to

the issuance of the PHO.

Plaintiff Blackford has identified a liberty interest warranting due process of law, Defendants disagree because otherwise their actions most certainly would run afoul of the Due Process Clause's protections by depriving Plaintiff of their ability to earn a livelihood in the occupation of their choosing.[1] For example, the United States Supreme Court in *Barry v. Barchi* has opined as to the constitutionally protected property interest in engaging in one's chosen profession of horse racing, stating "Plaintiffs have a liberty interest in pursuing their profession of horse racing and are entitled to due process of law if they are to be lawfully denied an opportunity to do so." *Barry v. Barchi*, 443 U.S. 55, 64, 99 S.Ct. 2642, 61 L.Ed.2d 365 (1979).

Thus, the right of citizens to support themselves by engaging in a chosen occupation is deeply rooted in our nation's legal and cultural history and has long been recognized as a component of the liberties protected by the Fourteenth Amendment. Over a century ago, the Supreme Court recognized that "[i]t requires no argument to show that the right to work for a living in the common occupations of the community is of the very essence of the personal freedom and opportunity that it was the purpose of the [Fourteenth] Amendment to secure." *Truax v. Raich*, 239 U.S. 33, 41, 36 S.Ct. 7, 60 L.Ed. 131 (1915) (holding that a state anti-alien labor statute violated both equal protection and due process). Later, in striking down a law banning the teaching of foreign languages in school, the Supreme Court observed that the Fourteenth

[1] "The right to work, I had assumed, was the most precious liberty that man possesses. Man has indeed as much right to work as he has to live, to be free, to own property. The American ideal was stated by Emerson · in his essay on Politics, 'A man has a right to be employed, to be trusted, to be loved, to be revered.' It does many men little good to stay alive and free and propertied, if they cannot work. To work means to eat. It also means to live. For many it would be better to work in jail, than to sit idle on the curb. The great values of freedom are in the opportunities afforded man to press to new horizons, to pit his strength against the forces of nature, to match skills with his fellow man." *Barsky v. Board of Regents of University of State of New York*, 347 U.S. 442, 472 (1954) (Douglas, J, dissenting).

Amendment guaranteed the right, *inter alia*, "to engage in any of the common occupations of life ...." *Meyer v. Nebraska*, 262 U.S. 390, 399, 43 S.Ct. 625, 67 L.Ed. 1042 (1923). Despite later jurisprudence following the *Lochner* era, *Lochner v. New York*, 198 U.S. 45, 25 S.Ct. 539, 49 L.Ed. 937 (1905), de-emphasizing economic substantive due process, our Supreme Court has never repudiated the recognition that a citizen has the right to work for a living and pursue his or her chosen occupation.

The Third Circuit has recognized "[t]he right to hold specific private employment and to follow a chosen profession free from unreasonable governmental interference comes within both the 'liberty' and the 'property' concepts of the Fifth and Fourteenth Amendments." *Piecknick v. Comm. of Pa.*, 36 F.3d 1250, 1259 (3d. Cir. 1994) (citing *Greene v. McElroy*, 360 U.S. 474, 492, 79 S.Ct. 1400, 3 L.Ed.2d 1377 (1959); *Truax*, 239 U.S. at 41, 36 S.Ct. 7). However,

> [t]he Constitution only protects this liberty from state actions that threaten to deprive persons of the right to pursue their chosen occupation. State actions that exclude a person from one particular job are not actionable in suits ... brought directly under the due process clause. It is the liberty to pursue a calling or occupation, and not the right to a specific job, that is secured by the Fourteenth Amendment.

Id. (internal citations and quotation marks omitted). Thus, Defendants here are flat wrong, Plaintiff Blackford and the many others similarly situated most certainly have a right to engage in their chosen professions of nursing, other healthcare employees, congregate caregivers or detention officers. There is no question, then, that the Fourteenth Amendment recognizes a liberty interest in citizens—the Plaintiffs here—to pursue their chosen occupation. The dispositive question is not whether such a right exists, but rather, the level of infringement upon the right that may be tolerated.

It is supremely troubling that these Defendants do not recognize the fundamental liberty interest of the individual to decide what should be injected into their person, otherwise recognized

as the common law right to bodily integrity. The Supreme Court has recognized that "no right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pac. R. Co. v. Botsford,* 141 U.S. 250, 251, 11 S. Ct. 1000, 1001, 35 L. Ed. 734 (1891). Moreover, the Supreme Court has clearly held that "[T]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty. *Washington v. Harper*, 494 U.S. 210, 229, 110 S. Ct. 1028, 1041, 108 L. Ed. 2d 178 (1990).

In *Harper*, the Court was not dealing with a free person, but rather an incarcerated person, and as of yet citizens of New Mexico should not be treated as prisoners. Justice Stevens dissented in *Harper*, arguing that the majority had "virtually ignore[d] the several dimensions" of the liberty interest it recognized. *Id.* at 237. He noted that a forced administration of medication is especially troubling if it "creates a substantial risk of permanent injury and premature death." *Id.* He also recognized that such intrusions are "degrading" when performed against the will of a competent person. *Id.*

In *Riggins v. Nevada*, 504 U.S. 127 (1992), the Court applied the test from *Harper*, finding that the state did not meet its burden to establish both the need for the drug and its medical appropriateness for the Defendant specifically finding that the state was obligated to show that the medication was the least intrusive means of achieving an "essential" state purpose. *Id.* at 138. In *Cruzan v. Director, Missouri Department of Health,* 497 U.S. 261 (1990), the Court unequivocally acknowledged that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Id.* at 278.

Nor can defendants explain how punishing children whose parents have made a decision not to vaccinate their children withstands scrutiny that the PHO does not violate the long recognized fundamental liberty to rear children. Just like the concept that Americans enjoy a fundamental liberty to decide what is injected into their bodies, parents hold a fundamental liberty interest in determining what medications are injected into their children. The Supreme Court in numerous decisions concerning the right to marry recognized this as:

> A third basis for protecting the right to marry is that it safeguards children and families and thus draws meaning from related rights of childrearing, procreation, and education. See *Pierce v. Society of Sisters*, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925); *668 *Meyer*, 262 U.S., at 399, 43 S.Ct. 625. The Court has recognized these connections by describing the varied rights as a unified whole: "[T]he right to 'marry, establish a home and bring up children' is a central part of the liberty protected by the Due Process Clause." *Zablocki*, 434 U.S., at 384, 98 S.Ct. 673 (quoting *Meyer*, *supra*, at 399, 43 S.Ct. 625).

Obergefell v. Hodges, 576 U.S. 644, 667–68, 135 S. Ct. 2584, 2600, 192 L. Ed. 2d 609 (2015).

I. The Failure to Recognize Clearly Articulated Fundamental Liberty Interests is Fatal to the Motion.

Defendants make no effort to explain or to provide any analysts to this Court as to why they can satisfy strict scrutiny that the PHO is narrowly tailored to meet their compelling or essential purpose. As demonstrated above, this Court does not even need to perform a *Washington v. Glucksberg*, 521 U.S. 702, analysis to the alleged liberty interests because they have already been recognized as fundamental by the United States Supreme Court. There is no real debate that right to engage in ones chose profession (*Barchi*) or the right to rear children (*Obergefell*) are not fundamental rights recognized previously by the Supreme Court. Moreover, to argue that the most sacred right as recognized as such by the Supreme Court to bodily integrity is not fundamental is tragically laughable; but more importantly means that it is at least quasi-fundamental, not subject to a rational basis test. Importantly, even if bodily integrity is not a "fundamental" right, it is at

least a "quasi" fundamental right subject to intermediate scrutiny. It is well settled that, under *Plyler v. Doe,* "infringements on certain 'quasi-fundamental' rights, *like bodily integrity*, also mandate a heightened level of scrutiny." *United States v. Harding,* 971 F.2d 410, 412 n.1 (9th Cir. 1992) (emphasis added).

Thus, because Defendants' motion wholly fails to address whether or not the PHO can withstand either strict or intermediate scrutiny and relies solely on a rational basis test argument, it must fail.

II. The Defendants Power from the State to Impair Contracts for Public Welfare is Limited.

As is typical for Defendants, they find a blank check with unlimited power everywhere in the law and in every jurisprudence under the umbrella of public health during the COVID pandemic. This quite simply is not the case, as with *Jacobsen*, when it come to impairment of contracts, the Supreme Court has set limits stating that "[T]he states' inherent power to protect the public welfare may be validly exercised under the Contract Clause even if it impairs a contractual obligation so long as it does not destroy it." *U.S. Tr. Co. of New York v. New Jersey,* 431 U.S. 1, 26, 97 S. Ct. 1505, 1520, 52 L. Ed. 2d 92 (1977); *citing* 134 N.J.Super., at 190, 338 A.2d, at 870-871. Here the Defendants' PHO unequivocally destroys both contracts. It destroys the employment contract of Plaintiff Blackford by requiring her employer terminate her or prevent her from work to remain compliant with the PHO and it destroyed the contract of every unvaccinated child to exhibit livestock at the State Fair by making performance impossible by prohibiting their entry onto the Fair grounds. It is worth noting that when Congress does this, they are still required to pay damages to any harmed party under the Fifth Amendment.

Here, because the destruction of the contracts is fully realized, this Court must examine the limit of state's actions to impair a contract as to the reasonableness of the conditions and of a

character appropriate to the public purpose as the Supreme Court has warned "private contracts are not subject to unlimited modification under the police power." *U.S. Tr. Co. of New York,* 431 U.S. at 22. Thus, Court must evaluate that limit, "[a]ssuming that this stated interest is a 'broad and general social or economic problem,' and therefore, a legitimate public purpose, the Court must then address the reasonableness and necessity of the regulation. *Universal Ins. Co. v. Dep't of Justice,* 866 F. Supp. 2d 49, 69 (D.P.R. 2012), *on reconsideration in part* (June 22, 2012). Essentially, a review as to reasonableness of this a particular measure, this Court must therefore conduct some review of the tailoring of the PHO's actions.

First, with regard to cancelling the contracts of the State Fair Exhibitors, no argument can be made that it was in any way tailored to address specifics of the youth livestock exhibitors. Youth exhibitors are in large outdoor or indoor barn arenas which social distancing and masking are easily accomplished. Moreover, the PHO targeted the state fair while allowing the Pride Fest an event with thousands of people to attend without the requirement for vaccination on the Fairground after the issuance of the PHO but before the State Fair occurred.[2] As to the destruction of the employment contracts of healthcare workers like Plaintiff Blackford (despite the disingenuous and unsubstantiated argument that the employers would have imposed that condition on those contracts regardless of the requirement of the PHO that they do so), Plaintiff has provided examples to this Court of the well understood fact that the vaccinated are as susceptible to contracting the disease and spreading the disease as the unvaccinated. There is no documentation that unvaccinated workers in the affected industries were being infected at any greater rate or severity than the vaccinated workers, that they were responsible for a greater rate of spread, that masking and other physical measures were not working, or that other treatments were not available

[2] https://www.krqe.com/video/proof-vaccination-not-required-for-pride-fest/6912073/

short injection of gene modification therapies that work to treat Covid and slow its spread. *See* Exhibits 5, 7 and 8. It is simply not a reasonable condition to place the workers who by all accounts serve as no greater threat for spread of the disease to terminate them from their chosen professions and given the character of the government actions should still be evaluated under strict scrutiny for reasonableness and necessity.

III. The Motion Fails Regarding Dismissal of the State Law Claims as Well.

Because the majority of the thrust of argument rests on the erroneous assertion that the constitutional claims are evaluated on a rational basis review, so does this part of the argument in the Motion fail as well. But, beyond arguments regarding Eleventh Amendment immunity must gain no purchase with this Court, Plaintiffs are not asking this Court to broadly construe the language of the New Mexico Civil Rights Act regarding waiver of sovereign immunity for claims brought in federal court. Plaintiffs are merely asking that this Court construe nearly identical language, identically to the way it has been construed for decades. The New Mexico Tort Claims act states:

> Exclusive original jurisdiction for any claim under the Tort Claims Act shall be in the district courts of New Mexico. Appeals may be taken as provided by law.

NMSA 1978 § 41-4-18. Whereas, the language of the New Mexico Civil Rights Act states:

> A person who claims to have suffered a deprivation of any rights, privileges or immunities pursuant to the bill of rights of the constitution of New Mexico due to acts or omissions of a public body or person acting on behalf of, under color of or within the course and scope of the authority of a public body may maintain an action to establish liability and recover actual damages and equitable or injunctive relief in any New Mexico district court.

NMSA 1978 § 41-4A-3. Moreover, the waiver of sovereign immunity actually codified in the New Mexico Civil Rights Act says nothing about limiting that waiver only to state district courts stating:

> The state shall not have sovereign immunity for itself or any public body within the state for claims brought pursuant to the New Mexico Civil Rights Act, and the public body or person acting on behalf of, under color of or within the course and scope of the authority of the public body provided pursuant to the New Mexico Civil Rights Act shall not assert sovereign immunity as a defense or bar to an action.

NMSA 1978 § 41-4A-9.

Defendants cannot reasonably ask this Court to interpret nearly identical language in a new statute in a way that is wholly inconsistent with decades of interpretation from this District and even this Court.

IV. There is Clear Supreme Court Precedent for All Three Constitutional Claims Raised that Precludes Qualified Immunity.

Defendants supply this Court with no analysis or jurisprudence to support that qualified immunity should be appropriate in this instance. Whereas Plaintiff has supplied this Court with Supreme Court jurisprudence that clearly establishes a claim of deprivation of a property interest in a chosen profession (*Barchi*), a claim for denial of bodily integrity (*Cruzan*) and a claim for violation a parental rights *(Obergefell*).

CONCLUSION

Because Defendants' Motion suffers from a variety of fatal flaws, this Court should deny the Motion.

Respectfully submitted this 13th day of September 2021.

WESTERN AGRICULTURE, RESOURCE
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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2021, I filed the foregoing via the CM/ECF filing system and caused a copy to be served upon counsel for Defendants via email.

/s/ A. Blair Dunn
A. Blair Dunn, Esq.

MERCOLA
Take Control of Your Health

EXHIBIT 5

60% of Those Older Than 50 Who Die From COVID Are Double Vaxxed

Analysis by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE -

- As of August 15, 2021, 68% of COVID patients admitted to hospital in the U.K. who were over the age of 50 had received one or two doses of COVID injections. By mid-August, 59% of serious cases in Israel were also among those who had received two COVID injections, mirroring U.K. data
- Only in the 50 and younger category were a majority, 74%, of British COVID patients unvaccinated. Those claiming we're in a pandemic of the unvaccinated fail to differentiate between age groups
- The same applies to COVID deaths in the U.K. Unvaccinated make up the majority of deaths only in the under-50 age group. In the over-50 group, the clear majority, 70%, are either partially or fully "vaccinated"
- We cannot rely on U.S. data to get a clear idea of how the COVID shots are working, as the CDC has chosen to only track breakthrough cases that result in hospitalization and/or death
- Reanalysis of Pfizer's, Moderna's and Janssen's COVID trial data using the proper endpoint show the shots are hurting the health of the population, and if mass vaccination continues we face "a looming vaccine-induced public health catastrophe"
- A new study shows that vaccinated individuals are up to 13 times more likely to get infected with the new Delta variant than unvaccinated individuals who have had a natural COVID infection

The oft-repeated refrain right now is that we're in a "pandemic of the unvaccinated," meaning those who have not received the COVID jab make up the bulk of those hospitalized and dying from the Delta variant. For example, August 20, 2021, England's chief medical officer professor Chris Whitty tweeted:[1,2]

> *"Four weeks working on a COVID ward makes stark the reality that the majority of our hospitalized COVID patients are unvaccinated and regret delaying. Some are very sick including young adults. Please don't delay your vaccine."*

Curiously, if you take the time to actually look at the data, you'll find that this blanket statement is rather deceptive. Here's a graphic published in the Evening Standard, sourced from Public Health England:[3]

As you can see, as of August 15, 2021, 58% of COVID patients admitted to hospital who were over the age of 50 had actually received two doses of COVID injections and 10% had received one dose. So, partially or fully "vaccinated" individuals made up 68% of hospitalizations.

Only in the 50 and younger category were a majority, 74%, of hospitalizations among the unvaccinated. Whitty, however, completely neglected to differentiate between the age groups. The same applies to deaths. Unvaccinated only make up the majority of COVID deaths in the under-50 age group. In the over-50 group, the clear majority, 70%, are either partially or fully "vaccinated."

It's also unclear whether hospitals in the U.K. (and elsewhere) are still designating anyone who is admitted and tests positive with a PCR test as a "COVID patient." If so, people with broken bones or any number of other health problems who have no symptoms of COVID-19 at all might be unfairly lumped into the "unvaccinated COVID patient" total.

Israeli Data Show COVID Jab Is Failing in Over-50s

In Israel, where vaccine uptake has been very high due to restrictions on freedom for those who don't comply,[4] data show those who have received the COVID jab are 6.72

times more likely to get infected than people with natural immunity.[5,6,7]

The fully "vaccinated" also made up the bulk of serious cases and COVID-related deaths in July 2021, as illustrated in the graphs below.[8] The red is unvaccinated, yellow refers to partially "vaccinated" and green fully "vaccinated" with two doses. By mid-August, 59% of serious cases were among those who had received two COVID injections,[9] mirroring the data coming out of the U.K.

In an August 16, 2021, Science article,[10] Israeli Minister of Health Nitzan Horowitz is quoted saying the nation has entered a "critical time" in the race against the pandemic. Horowitz allegedly was given a third booster shot August 13, 2021, the day they began offering a third dose to people over the age of 50.

From Public Health England's data, it seems clear that the COVID shots are failing to protect people over the age of 50 in the U.K. as well, so it's probably only a matter of time before booster shots are rolled out there too. And, provided the COVID injections are the same irrespective of country, there's every reason to assume the same trends will emerge in other countries, including the U.S.

This is precisely what Ran Balicer, chief innovation officer at Clalit Health Services, Israel's largest health maintenance organization (HMO), told Science: "If it can happen here, it can probably happen everywhere."[11]

Israeli Data Considered the Best Around

The data coming out of Israel is considered by many to be the best we have, and can give us a glimpse of what to expect elsewhere. As explained by Science magazine:[12]

> *"Israel is being closely watched now because it was one of the first countries out of the gate with vaccinations in December 2020 and quickly achieved a degree of population coverage that was the envy of other nations — for a time.*
>
> *The nation of 9.3 million also has a robust public health infrastructure and a population wholly enrolled in HMOs that track them closely, allowing it to*

produce high-quality, real-world data on how well vaccines are working.

'I watch [Israeli data] very, very closely because it is some of the absolutely best data coming out anywhere in the world,' says David O'Connor, a viral sequencing expert at the University of Wisconsin, Madison.

'Israel is the model,' agrees Eric Topol, a physician-scientist at Scripps Research. 'It's pure mRNA vaccines. It's out there early. It's got a very high level population [uptake]. It's a working experimental lab for us to learn from.'

Israel's HMOs … track demographics, comorbidities, and a trove of coronavirus metrics on infections, illnesses, and deaths. 'We have rich individual-level data that allows us to provide real-world evidence in near–real time,' Balicer says …

Now, the effects of waning immunity may be beginning to show in Israelis vaccinated in early winter; a preprint[13] published last month … found that protection from COVID-19 infection during June and July dropped in proportion to the length of time since an individual was vaccinated.People vaccinated in January had a 2.26 times greater risk for a breakthrough infection than those vaccinated in April."

Where Will It End?

According to Science magazine, breakthrough cases are now multiplying at breakneck speed. "There are so many breakthrough infections that they dominate and most of the hospitalized patients are actually vaccinated," Uri Shalit, a bioinformatician at the Israel Institute of Technology told Science.[14]

Nearly 1 million Israelis over the age of 50 have now received a third booster of Pfizer's mRNA shot. Time will tell whether this will worsen the rate of breakthrough cases or tame it.

Dvir Aran, a biomedical data scientist at the Israel Institute of Technology doesn't seem very hopeful, telling Science the surge is already so steep, "even if you get two-thirds of

those 60-plus [boosted], it's just gonna give us another week, maybe two weeks until our hospitals are flooded" again.[15]

The obvious question is, what then?! Will the answer be a fourth injection before the year is over? Will we be looking at quarterly injections? Monthly injections? Biweekly? Weekly? Where and when does it end? It is fairly easy to predict that this can only end very badly.

US Tracks Only Fraction of Breakthrough Infections

Unfortunately, we cannot rely on U.S. data to get a clear idea of how the COVID shots are working, as the U.S. Centers for Disease Control and Prevention has chosen not to track all breakthrough cases. As reported by ProPublica,[16] May 1, 2021, the CDC stopped tracking and reporting all breakthrough cases, opting to log only those that result in hospitalization and/or death.

As noted in the article, this irrational decision has "left the nation with a muddled understanding of COVID-19's impact on the vaccinated." It also prevents us from understanding how variants are spreading and whether those who have received the jab can still develop so-called "long-haul syndrome."

Individual states are also setting their own criteria for how they collect data on breakthrough cases, and this patchwork muddies the waters even further. Despite these limitations, what little data we do have is starting to mirror that of Israel and the U.K.

August 18, 2021, the CDC released three reports,[17,18,19] which show the protection you get from the COVID shot is rapidly waning.

> *"Among nursing home residents, one of the studies showed vaccine effectiveness dropped from 74.7% in the spring to just 53.1% by midsummer,"*ProPublica writes.[20] *"Similarly, another report found that the overall effectiveness among vaccinated New York adults dropped from 91.7% to just under 80% between May and July.*

The new findings prompted the Biden administration to announce on Wednesday that people who got a Moderna or Pfizer vaccine will be offered a booster shot eight months after their second dose. The program is scheduled to begin the week of Sept. 20 but needs approval from the Food and Drug Administration and a CDC advisory committee.

This latest development is seen by some as another example of shifting public health messaging and backpedaling that has accompanied every phase of the pandemic for 19 months through two administrations. A little more than a month ago, the CDC and the FDA released a joint statement saying that those who have been fully vaccinated 'do not need a booster shot at this time' …

The CDC tracked all breakthrough cases until the end of April, then abruptly stopped without making a formal announcement. A reference to the policy switch appeared on the agency's website in May about halfway down the homepage.

'I was shocked,' said Dr. Leana Wen, a physician and visiting professor of health policy and management at George Washington University. 'I have yet to hear a coherent explanation of why they stopped tracking this information' …

Sen. Edward Markey, D-Mass., became alarmed after the Provincetown outbreak and wrote to CDC director Dr. Rochelle Walensky on July 22, questioning the decision to limit investigation of breakthrough cases. He asked what type of data was being compiled and how it would be shared publicly[21] *... Markey asked the agency to respond by Aug. 12. So far the senator has received no reply …"*

Vaxxed Are Up to 13 Times More Likely to Get Delta Variant

While the U.S. is lax about recording breakthrough infections, researchers in Israel have some breaking news: They have been keeping track, and their studies[22] show that vaccinated individuals are up to 13 times more likely to get the Delta variant of COVID-19 than those who were not vaccinated, but had recovered from a COVID infection.

As explained by ScienceMag:[23] The study "found in two analyses that people who were vaccinated in January and February were, in June, July and the first half of August, six to 13 times more likely to get infected than unvaccinated people who were previously infected with the coronavirus. In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was 27 times higher among the vaccinated, and the risk of hospitalization eight times higher."

The study also said that, while vaccinated persons who also had natural infection did appear to have additional protection against the Delta variant, the vaccinated were still at a greater risk for COVID-19-related-hospitalizations compared to those without the vaccine, but who were previously infected. Vaccinees who hadn't had a natural infection also had a 5.96-fold increased risk for breakthrough infection and a 7.13-fold increased risk for symptomatic disease.

One thing to note here is that the wording of this is important: The study does not say that getting a vaccine helps protect you if you've had a natural infection; rather, it says that natural protection helps boost the vaccine. Either way, even if you do have natural infection in combination with the vaccination, vaccinees are still at an increased risk for a breakthrough infection.

"This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity," the study authors concluded.

Fully Vaxxed Speak Out

Back America, in an August 24, 2021, article,[24] The Defender cites data from seven states (California, Colorado, Massachusetts, Oregon, Utah, Vermont and Virginia) that keep more detailed records than most. In six of these states, breakthrough infections accounted for 18% to 28% of all new COVID diagnoses in the past several weeks, as well as 12% to 24% of all COVID-related hospitalizations.

In Los Angeles, breakthrough cases have risen from 5% in April and 13% in July to a current of 30%. Fully vaxxed celebrities and elected officials have now started speaking out after getting COVID. As reported by The Defender: [25]

> *"Melissa Joan Hart, the former 'Sabrina the Teenage Witch' star is 'really mad' she has a breakthrough case. Hart shared on Instagram Aug. 19 … 'I got COVID. I am vaccinated. And I got COVID. And it's bad. It's weighing on my chest, it's hard to breathe' …*
>
> *Celebrity Hilary Duff, **revealed** she had COVID on Instagram Aug. 20. Duff said she was experiencing a bad headache, brain fog, sinus pressure and a loss of taste and smell despite being vaccinated …*
>
> *Slipknot singer Corey Taylor, 47, was devastated after testing positive for COVID and was forced to call off his upcoming appearance at a Michigan pop culture convention this weekend, Rolling Stone reported. 'I wish I had better news,' said Taylor in a recorded video message last week on Facebook. 'I woke up today and tested positive and I'm very, very sick' …*
>
> *Rev. Jesse Jackson, and his wife, Jacqueline, remained under doctors' observation Monday*[August 23, 2021] *at a Chicago hospital after getting COVID … Jackson, a Chicago civil rights leader, was fully vaccinated and received his first dose in January during a publicized event where he urged others to receive the vaccine as soon as possible …*
>
> *Three U.S. senators — John Hickenlooper (D-Colo.), Angus King (I-Maine) and Roger Wicker (R-Miss.) — announced Aug. 19 they tested positive for COVID despite being fully vaccinated, CBS News reported …*
>
> *The news came days after **Texas Gov. Greg Abbott**, who also was fully vaccinated, tested positive for COVID. Illinois state Sen. Dan McConchie announced Aug. 21 he had a 'breakthrough' case of COVID."*

CDC Has Also Hidden Breakthrough Cases in Other Ways

The CDC also cooked the books on COVID breakthrough cases in other ways. Originally, the CDC recommended labs use a CT of 40[26] when testing for SARS-CoV-2 infection. This, despite using a CT above 35 was known to create a false positive rate of 97%.[27] By using an exaggerated CT, healthy people were deemed stricken with COVID-19.

In May 2021, the CDC lowered the CT from 40 to 28 or lower — but only when doing PCR testing on individuals who have received the COVID jab.[28] Unvaccinated were still tested using a CT of 40. The end result is obvious: "Vaccinated" individuals became far less likely to test positive for SARS-CoV-2 infection while unvaccinated were still exceedingly getting false positives. As noted by Off-Guardian:[29]

> *"This is a policy designed to continuously inflate one number, and systematically minimize the other. What is that if not an obvious and deliberate act of deception?"*

How the CDC Invented the 'Pandemic of Unvaxxed' Narrative

The CDC also played fast and loose with the data when it invented the "pandemic of the unvaccinated" narrative[30] that we're now being indoctrinated with. In a July 16, 2021, White House press briefing,[31] CDC director Dr. Rochelle Walensky claimed "over 97% of people who are entering the hospital right now are unvaccinated."

> **“Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe. ~ Dr. Bart Classen, Trends in Internal Medicine”**

As it turns out, that statistic is based on hospitalization data from January through June 2021, when the majority of Americans had not yet gotten the COVID jab. January 1, 2021, only 0.5% of the U.S. population had received a COVID shot. By mid-April, an estimated 31% had received one or more shots,[32] and as of June 30, just 46.9% were "fully vaccinated."[33]

COVID Shots 'Proven to Cause More Harm Than Good'

While the official narrative is that the COVID shots may be "less than perfect" but are still better than the alternative (i.e., getting the infection when you're unvaccinated), Dr. Bart Classen published a study[34] in the August 2021 issue of Trends in Internal Medicine, disputing this claim.

The study,[35] "U.S. COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, 'All Cause Severe Morbidity,'" details a core problem with Pfizer's, Moderna's and Janssen's (Johnson & Johnson) trials.

All three employ a surrogate primary endpoint for health, namely "severe infections with COVID-19." This, Classen says, "has been proven dangerously misleading," and many fields of medicine have stopped using disease-specific endpoints in clinical trials and have adopted "all-cause mortality and morbidity" instead.

The reason for this is because if a person dies from the treatment or is severely injured by it, even if the treatment helped block the progression of the disease they're being treated for, the end result is still a negative one.

To offer an extreme example of what you can do with a disease-specific endpoint, you could make the claim that shooting people in the head is a cure for cancer, because no one who got the treatment — who got shot in the head — died from cancer.

When reanalyzing the clinical trial data from these COVID shots using "all-cause severe morbidity" as the primary endpoint, the data reveal they actually cause far more harm than good.

The proper endpoint was calculated by adding together all severe events reported in the trials, not just COVID-19 but also all other serious adverse events. By doing this, severe COVID-19 infection gets the same weight as other adverse events of equivalent severity. According to Classen:[36]

> *"Results prove that none of the vaccines provide a health benefit and all pivotal trials show a statistically significant increase in 'all cause severe morbidity' in the vaccinated group compared to the placebo group.*
>
> *The Moderna immunized group suffered 3,042 more severe events than the control group. The Pfizer data was grossly incomplete but data provided showed the vaccination group suffered 90 more severe events than the control group, when only including 'unsolicited' adverse events.*
>
> *The Janssen immunized group suffered 264 more severe events than the control group. These findings contrast the manufacturers' inappropriate surrogate endpoints:*
>
> *Janssen claims that their vaccine prevents 6 cases of severe COVID-19 requiring medical attention out of 19,630 immunized; Pfizer claims their vaccine prevents 8 cases of severe COVID-19 out of 21,720 immunized; Moderna claims its vaccine prevents 30 cases of severe COVID-19 out of 15,210 immunized.*
>
> *Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe."*

To make the above numbers more clear and obvious, here are the prevention stats in percentages:

- Pfizer 0.00036%
- Moderna 0.00125%

- Janssen 0.00030%

Where Do We Go From Here?

If you've already gotten one or two shots, there's nothing you can do about that. It seems pretty obvious, though, if you objectively analyze the data, that your best bet is to say no to any and all future boosters, as each additional shot can magnify the damage and increase your risk of serious side effects.

If you develop symptoms of SARS-CoV-2 infection, there are several treatment protocols available that have been shown to be effective. Options include the Zelenko protocol,[37] the MATH+ protocols[38] and nebulized hydrogen peroxide, as detailed in Dr. David Brownstein's case paper[39] and Dr. Thomas Levy's free e-book, "**Rapid Virus Recovery**."

Whichever treatment protocol you use, make sure you begin treatment as soon as possible, ideally at first onset of symptoms. Also, realize that if you've gotten one or more COVID shots, your risk of severe infection may actually be greater, not lesser, than had you not gotten the injections. This appears particularly true if you're over the age of 50. So, do not delay treatment if you develop symptoms.

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EXHIBT 8

Massive 'Horse' Lies About Nobel Prize Winning Treatment

Analysis by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE -

- KFOR news ran a fake story in which a doctor claimed emergency rooms in Oklahoma were inundated with people who used horse ivermectin paste as a treatment for COVID-19 and overdosed
- The story turned out to be pure fiction, as no such cases have occurred. Still, KFOR has not retracted the story or issued a correction
- The idea that ivermectin is a horse dewormer that poses a lethal risk to humans is a deceptive narrative aimed at dissuading people from using a safe and effective drug against COVID-19
- While ivermectin is used as a dewormer in animals, it is also a human drug, approved by the FDA since the mid-1990s. It's on the World Health Organization's list of essential medicines for several parasitic diseases and, like many other drugs, ivermectin is used off-label for other diseases and conditions
- In addition to being antiparasitic, ivermectin also has potent antiviral properties and has even been shown to protect against SARS-CoV-2 spike protein damage

In recent days, another big, fat lie has been allowed to circulate unchecked and unverified in headlines across the media landscape. "Ivermectin: Why Are U.S. Anti-Vaxxers Touting a Horse Dewormer as a Cure for COVID?" asks the Independent.[1] Similar headlines — all focusing on "horse dewormer" — have been plastered across many other media outlets.

It appears Oklahoma's KFOR news was the first to run a fake story that made this false narrative explode. September 1, 2021, KFOR reported that emergency rooms were overrun with patients who had overdosed on horse ivermectin. The claim was supposedly made by doctor Dr. Jason McElyea. According to KFOR:[2]

> *"Dr. McElyea said patients are packing his eastern and southeastern Oklahoma hospitals after taking ivermectin doses meant for a full-sized horse, because they believed false claims the horse de-wormer could fight COVID-19.'The ERs are so backed up that gunshot victims were having hard times getting to facilities where they can get definitive care and be treated,' he said."*

Fake News Alert

Other media outlets ran with the story, including Rolling Stone magazine,[3] The Daily Mail,[4] the Independent,[5] Newsweek,[6] The Guardian,[7] Yahoo News[8] — which later published a story saying a hospital was "disputing" the claim — and MSNBC's Rachael Madow.[9]

There was just one problem. It was a fake story. A few days after the story made major media rounds, the Sequoyah Northeastern Health System issued a public notice and posted it on its website homepage, dismissing McElyea's claims as pure fiction:

Message from the administration of Northeastern Health System - Sequoyah:

Although Dr. Jason McElyea is not an employee of NHS Sequoyah, he is affiliated with a medical staffing group that provides coverage for our emergency room.

With that said, Dr. McElyea has not worked at our Sallisaw location in over 2 months.

NHS Sequoyah has not treated any patients due to complications related to taking ivermectin. This includes not treating any patients for ivermectin overdose.

All patients who have visited our emergency room have received medical attention as appropriate. Our hospital has not had to turn away any patients seeking emergency care.

We want to reassure our community that our staff is working hard to provide quality healthcare to all patients. We appreciate the opportunity to clarify this issue and as always, we value our community's support.

NHSSEQUOYAH

However, rather than retract the article, which would be appropriate for a piece that turns out to be fictional from start to finish, Rolling Stone simply posted an "update" at the top of the article, noting Sequoyah's rebuttal. KFOR has issued no correction at all, as of September 7, 2021. The Guardian issued an update at the bottom of its article, but did not include the hospital's statement that NO patients have been treated for ivermectin overdose.

Hundreds of news articles have also brought attention to alleged rises in ivermectin-related calls to poison control centers around the U.S. These too, it turns out, are based on the flimsiest of data. For example, in Kentucky, poison control reports having received six calls relating to ivermectin paste overdose, compared to an average of one per year.

The department of health in Mississippi similarly noted that while calls to poison control involving ivermectin paste have seen a slight increase, all cases have been mild and none have required hospitalization due to toxicity.[10] Clearly, people are not dying from horse ivermectin overdoses, and they're certainly not dying from appropriately-dosed and prescribed oral ivermectin.

False Narrative Alert

This idea that ivermectin is a horse dewormer that poses a lethal risk to humans is pure horse manure, shoveled at us in an effort to dissuade people from using a safe and effective drug against COVID-19.

The intent is clear. What our so-called health agencies and the media are trying to do is confuse people into thinking of ivermectin as a "veterinary drug," which simply isn't true. Ultimately, what they're trying to do is back up the Big Pharma narrative that the only thing at your disposal is the COVID shot. As noted in a recent HuffPost article:[11]

> *"Health experts — the kind who practice on humans — agree that the best way to prevent yourself from catching the virus is to get vaccinated, wear a face mask and stay out of crowds."*

In an August 21, 2021, Twitter post,[12] the Food and Drug Administration said, "You are not a horse. You are not a cow. Seriously, y'all. Stop it," linking to an FDA article on why you should not use ivermectin to prevent or treat COVID-19.

The MSNBC report in the video above is another perfect example of the deceptive narrative being spun around ivermectin. The host blatantly mixes data points together, talking about ivermectin horse paste in one breath and rising prescriptions for ivermectin in the other, as if doctors are now prescribing veterinary drugs just to appease desperate patients. He then goes on to refer to doctors' success with ivermectin as "anecdotal."

Comedian and podcast host Joe Rogan, who recently developed COVID-19 and treated it with ivermectin and a slew of other remedies, is also being badmouthed for daring to

share his success story. NPR, for example, reported:[13]

> *"Joe Rogan has told his Instagram followers he has been taking ivermectin, a deworming veterinary drug formulated for use in cows and horses, to help fight the coronavirus. The Food and Drug Administration has warned against taking the medication, saying animal doses of the drug can cause nausea, vomiting and in some cases severe hepatitis."*

Did Rogan take horse ivermectin paste? No. Did he take animal doses of it? No. As you can see in the video above, Rogan talked with "multiple doctors" who told him to take it and, ultimately, he did take it and he got well, remarkably quickly. Yet NPR blatantly blends veterinary and human use together, as if to insinuate that he did take horse-level doses of it.

It's worth noting that the FDA is not warning against low-dose oral ivermectin as routinely prescribed for human use. They're warning against animal doses, which no licensed medical doctor would prescribe. In short, doctors are not prescribing ivermectin for horses, nor are they prescribing it at horse dosages.

Ivermectin Is an Essential Human Drug

While ivermectin is used as a dewormer in animals, it is also a human drug, approved by the FDA since the mid-1990s for the treatment of river blindness.[14] It's also on the World Health Organization's list of essential medicines for several parasitic diseases.[15]

> **“ Ivermectin has several different properties. In addition to being antiparasitic, it also has potent antiviral properties and has even been shown to protect against SARS-CoV-2 spike protein damage. ”**

Like many other drugs, ivermectin is also used off-label for other diseases and conditions. Systemic lupus and papulopustolar rosacea,[16] for example, are sometimes

treated with ivermectin. In 2018, a patent was filed to treat certain autoimmune disorders with ivermectin.[17]

When used preventatively for COVID-19, or as treatment for acute SARS-CoV-2 infection, ivermectin is being used off-label, but there's nothing unusual or suspect about this at all. Many drugs are used "off label." So, when media warn that "ivermectin is not approved by the FDA for the treatment of COVID-19," that essentially means nothing. It certainly doesn't mean the drug isn't FDA approved at all, or that it's only approved for animals.

The fact is, ivermectin has several different properties. In addition to being antiparasitic, it also has potent antiviral properties and has even been shown to protect against SARS-CoV-2 spike protein damage.

Research shows ivermectin impairs the spike protein's ability to attach to the ACE2 receptor on human cell membranes.[18] The drug can also help prevent blood clots by binding to SARS-CoV-2 spike protein. This prevents the spike protein from binding to CD147 on red blood cells and triggering clumping.[19]

As for safety, more than 4 billion doses have been given to (human) patients since 1998, and only 28 cases of serious adverse events have been reported in that time.[20] Yet the FDA now claims ivermectin should not be used for COVID-19 because the drug may cause "serious harm," is "highly toxic" and may cause "seizures," "coma and even death"[21] — warnings that are far more applicable to COVID shots.

Ivermectin Suitable for All Treatment Stages

Since early on, the Frontline COVID-19 Critical Care Alliance (FLCCC) has been trying to get the truth out about ivermectin. The FLCCC's prophylaxis and early outpatient COVID-19 protocol is known as I-MASK+[22] while the hospital treatment is called I-MATH+.[23] All include ivermectin. As noted by the FLCCC in a news release:[24]

> *"The data shows the ability of the drug Ivermectin to prevent COVID-19, to keep those with early symptoms from progressing to the hyper-inflammatory phase*

of the disease, and even to help critically ill patients recover.

… numerous clinical studies — including peer-reviewed randomized controlled trials — showed large magnitude benefits of Ivermectin in prophylaxis, early treatment and also in late-stage disease. Taken together … dozens of clinical trials that have now emerged from around the world are substantial enough to reliably assess clinical efficacy."

FLCCC president and chief medical officer Dr. Pierre Kory has testified to the benefits of ivermectin before a number of COVID-19 panels, including the Senate Committee on Homeland Security and Governmental Affairs in December 2020[25] and the National Institutes of Health COVID-19 Treatment Guidelines Panel in January 2021.[26]

The two protocols — I-MASK+[27] and I-MATH+[28] — are available for download on the FLCCC Alliance website in multiple languages. The clinical and scientific rationale for the I-MATH+ hospital protocol has also been peer-reviewed and was published in the Journal of Intensive Care Medicine[29] in mid-December 2020.

Strong Evidence for Ivermectin

April 24 through 25, 2021, Dr. Tess Lawrie, director of Evidence-Based Medicine Consultancy Ltd.,[30] hosted the first International Ivermectin for COVID Conference online.[31]

Twelve medical experts[32] from around the world — including Kory — shared their knowledge, reviewing mechanism of action, protocols for prevention and treatment, including so-called long-hauler syndrome, research findings and real world data. All of the lectures, which were recorded via Zoom, can be viewed on Bird-Group.org.[33]

A one-page summary of the clinical trial evidence for ivermectin is available on the FLCCC website,[34] while a listing of all ivermectin trials done to date, with links to the published studies, can be found on c19Ivermectin.com.[35] So, what does the evidence show? In summary, studies have demonstrated ivermectin:[36]

- Lowers viral load.
- Inhibits replication of many viruses, including SARS-CoV-2 and seasonal influenza viruses. An observational study[37] from Bangladesh, which looked at ivermectin as a pre-exposure prophylaxis for COVID-19 among health care workers, found only four of the 58 volunteers who took 12 mg of ivermectin once per month for four months developed mild COVID-19 symptoms, compared to 44 of the 60 health care workers who had declined the medication.
- Inhibits inflammation through several pathways and protects against organ damage.
- Prevents transmission of SARS-CoV-2 when taken before or after exposure.
- Speeds recovery and lowers risk of hospitalization and death in COVID-19 patients — The average reduction in mortality, based on 18 trials, is 75%.[38] A WHO-sponsored review[39] suggests ivermectin can reduce COVID-19 mortality by as much as 83%.

Who's Actually Following the Science?

As noted in an August 3, 2021, review paper in New Microbes New Infections, titled "Ivermectin: A Multifaceted Drug of Nobel-Prize Honored Distinction With Indicated Efficacy Against a New Global Scourge, COVID-19":[40]

> *"In 2015, the Nobel Committee for Physiology or Medicine, in its only award for treatments of infectious diseases since six decades prior, honored the discovery of ivermectin (IVM), a multifaceted drug deployed against some of the world's most devastating tropical diseases.*
>
> *Since March 2020, when IVM was first used against a new global scourge, COVID-19, more than 20 randomized clinical trials (RCTs) have tracked such inpatient and outpatient treatments. Six of seven meta-analyses of IVM*

treatment RCTs reporting in 2021 found notable reductions in COVID-19 fatalities, with a mean 31% relative risk of mortality vs. controls.

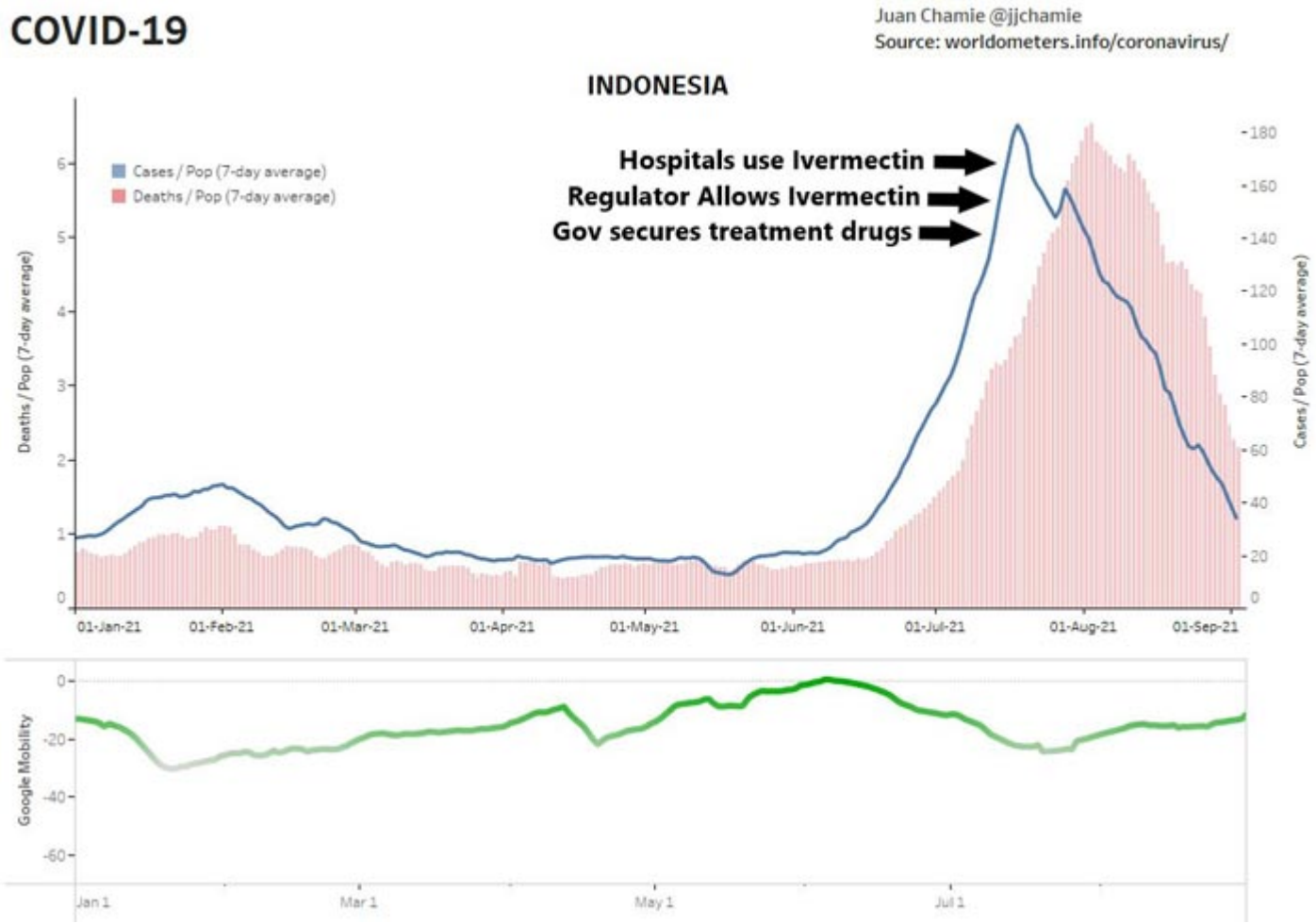
During mass IVM treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments. Reductions in deaths correlated with the extent of IVM distributions in all 25 states with p < 0.002.

Sharp reductions in morbidity using IVM were also observed in two animal models, of SARS-CoV-2 and a related betacoronavirus. The indicated biological mechanism of IVM, competitive binding with SARS-CoV-2 spike protein, is likely non-epitope specific, possibly yielding full efficacy against emerging viral mutant strains."

Despite the evidence, the American Medical Association (AMA), the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP) are now banding together to call on doctors to immediately stop prescribing ivermectin for COVID outside of clinical trials.[41]

Hopefully, doctors will evaluate the evidence for themselves and do what makes sense and is best for their patients, rather than cater to Big Pharma. Indeed, as the U.S. wants to eliminate all use of ivermectin, other countries are starting to use more of it. India, for example, has added ivermectin for COVID-19 to its list of essential medicines.

The Tokyo Metropolitan Medical Association also added ivermectin to its home treatment protocol August 13, 2021, and Indonesia's government not only authorized the use of the drug but also created a website showing real-time availability of the drug. Hospitals in Indonesia started using ivermectin July 22, 2021. By the first week of August, cases and deaths were plummeting.[42]



The 'Delta Variant' Is Vaccine Injuries, Whistleblower Claims

In a recent Stew Peters program, a nurse blows the whistle on several commonly-held beliefs. She points out that her hospital was never, not even during the height of the pandemic 2020, over capacity due to COVID patients. Disturbingly, she notes that most hospital personnel are still unaware that the PCR test is completely unreliable, and care is all based on that test.

Even if you do not have any COVID symptoms, a positive test will land you on the COVID ward, where standard protocol calls for Remdesivir and, if you have low oxygen, being put on a ventilator. She says most patients get worse on Remdesivir, which has been shown to cause heart and kidney problems. She points out that for a short time, the drug was given in combination with ivermectin, and during that time, patient outcomes were much better. Ivermectin was then removed from the protocol.

As for the Delta variant, there are no commercial tests that will identify variants, although genetic sequencing in a research lab would be able to differentiate them. The nurse stresses that she's never seen "Delta" specified on any patient chart — a claim that raises the question how officials are able to claim that most COVID-19 patients are now infected with the Delta variant.

She's also reporting seeing a significant number of vaccine injuries, yet she's not aware of a single instance where the injury was reported to the U.S. Vaccine Adverse Effect Reporting System (VAERS). Whenever she's brought her suspicions to the doctor, she's been rebuffed and the vaccine link has been dismissed.

The most shocking take-home from this interview is that the supposed surge in Delta cases are in fact mislabeled vaccine injuries, according to this whistleblower.

> *"The Delta variant is the vaccine injuries,"* she tells Peters. *"It's common knowledge around the staff that is aware of what's going on, [who are] paying attention [and] aren't in denial."*

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EXHIBIT 9

Curcumin COVID-19 Studies

Analysis by Dr. Joseph Mercola ✔ Fact Checked

STORY AT-A-GLANCE -

- Curcumin, the major biologically active phenolic compound in turmeric, ranks in the top five out of 25 compounds for effectiveness in lowering severity of COVID-19 and death rates from COVID
- The top drug, proxalutamide, is an androgen antagonist that limits the expression of transmembrane protein serine 2 (TMPRSS2), a receptor the virus uses to infect cells. One study found curcumin could also decrease expression up to 50%
- Curcumin has poor absorption and rapid metabolism and elimination. It must be combined with another compound to improve bioavailability, such as piperine found in black pepper; a recently tested supplement, CURCUGEN, was found to have better bioavailability than the standard reference product
- Evidence shows curcumin also reduces pain and inflammation in those with arthritis, may improve cognitive function, and could help reduce chronic inflammation associated with cardiovascular disease, obesity and insulin resistance

Curcumin is the major biologically active polyphenolic compound of turmeric and gives the spice its yellow color. Recent research shows the biological activity of curcumin reduces the severity of COVID-19. The results rank curcumin in the top five substances of 25 tested when used early to reduce illness and death from COVID.[1]

Turmeric is a perennial plant in the ginger family and found native to southern India and Indonesia.[2] Like ginger, it is the underground rhizome that is used in cooking and for

medicinal purposes. Traditionally, it was used in Ayurvedic medicine and traditional Chinese medicine.[3]

The cosmetic and fabric industry has also found uses for turmeric, having been used to dye fabric for more than 2,000 years.[4] According to Linus Pauling Institute,[5] evidence continues to mount showing that curcumin can exert antioxidant, anticancer, anti-inflammatory and neuroprotective activities.

Clinical trials are underway to evaluate the safety and efficacy of the compound as an adjuvant or as a treatment for patients with several types of cancer, including pancreatic, lung, prostate and colorectal cancers. The variety of positive health benefits found with curcumin may be a result of its highly pleiotropic capability, or ability of interacting with a variety of molecular targets.[6]

In the current environment, researchers have been studying anti-inflammatory compounds in an effort to reduce the severity of COVID-19. After multiple studies, curcumin outranks zinc, quercetin, melatonin and remdesivir, which ranked 24 out of the 25 substances.[7]

Curcumin in Top Five Substances to Improve COVID Outcomes

The ranking was based on several studies performed in 2020 and 2021. In one study,[8] researchers engaged 41 patients who met the inclusion criteria of mild to moderate COVID-19. There were 21 in the group who received nanocurcumin and 20 received a placebo.

The researchers monitored symptoms and laboratory data, finding that symptoms in the intervention group resolved significantly faster and patients' oxygen saturation was higher after just two days of treatment. It remained higher than the control group through 14 days. Researchers also found it noteworthy that none of the patients who received the nanocurcumin deteriorated during the 14-day follow-up period, but 40% of the control group did.

A second study[9] using nanocurcumin recruited 40 patients with COVID-19 to look at inflammatory cytokine expression. They were divided into 20 patients who received nanocurcumin and 20 who received a placebo. The researchers measured cytokine secretion of interleukin-1 beta (IL-1B), IL-6, tumor necrosis factor-alpha and IL-18. They concluded that the data demonstrated nanocurcumin modulates:

> *"… the increased rate of inflammatory cytokines especially IL-1β and IL-6 mRNA expression and cytokine secretion in COVID-19 patients, which may cause an improvement in clinical manifestation and overall recovery."*

Another study published in Frontiers in Pharmacology[10] in early 2021 measured the differences in mortality between a control group and intervention group, each of which included 70 patients. The control and intervention groups received conventional COVID-19 treatment.

In addition, those in the intervention group received curcumin with piperine twice a day and those in the control group received probiotics twice a day. The researchers found patients who had mild, moderate and severe symptoms in the intervention group showed early symptomatic recovery and less deterioration.

Overall, they had better clinical outcomes and a lower death rate than the control group. Based on their results the researchers also concluded that curcumin may be a therapeutic option to prevent post COVID thromboembolic events.

Curcumin's Action Is Similar to Proxalutamide

The drug in the No. 1 position for early treatment of COVID-19 is proxalutamide. It is an androgen receptor antagonist that was in clinical trials for the treatment of prostate cancer and breast cancer.[11] At the start of the COVID-19 outbreak, the company found the drug could limit the expression of transmembrane protein serine 2 (TMPRSS2) and ACE-2 receptors, both which play a critical role in severity of COVID-19.

Ability of the virus to enter pneumocytes depends on TMPRSS2 that is expressed on the surface of human cells in much the same way as ACE-2.[12] Interestingly, TMPRSS2 is

regulated by an androgen receptor, which means that the ability of the virus to infect the cells is directly dependent on androgenic status.

Past research indicated that men who had androgenetic alopecia hair loss had a greater risk of severe disease and men taking antiandrogenic drugs had a reduced risk of severe disease. This led to the hypothesis that proxalutamide would be beneficial, as it is an androgen receptor antagonist.

The hypothesis was supported in a study[13] that engaged 236 men and women with COVID-19. By Day 7, the virus was not detected using a PCR test with a cycle threshold of greater than 40 in 82% of the subjects taking proxalutamide. The average time it took patients to show clinical remission in the treatment group was 4.2 days versus 21.8 days in the placebo group.

In one study[14] evaluating the ability of three polyphenols to suppress SARS-CoV-2 viral penetration into human cells, researchers found that curcumin treatments decreased the TMPRSS2 activity by up to 50%. This is similar to the mechanism demonstrated by proxalutamide in the recent studies.

Curcumin Alone Has Poor Bioavailability

Turmeric and curcumin have been challenging to study since curcumin has a low bioavailability when taken orally, which researchers attribute to the body's limited ability to absorb the compound, as well as rapid metabolism and elimination.[15] However, researchers have found there are different compounds, that when taken with curcumin, can raise bioavailability and therefore enhance the multiple health benefits attributed to curcumin.

For example, piperine is an alkaloid found in black pepper, which is responsible for the distinct taste. On its own, it has several health benefits, including anti-inflammatory effects and insulin resistance properties.[16] When scientists combine it with curcumin it can raise the bioavailability of curcumin by up to 2,000%[17] by blocking the metabolic pathway,[18] thus increasing the amount available in the body.

One study published in the journal Medicine[19] in 2021 addressed the issues of bioavailability of curcumin as it relates to conflicting dosing strategies and the ability to compare research data. The writers described clinical trials in which purified curcumin was given in relatively large doses, up to 12 grams per day, without achieving measurable plasma levels.[20]

In addition to combining curcumin with piperine to raise bioavailability, the writers acknowledge manipulating curcumin in other ways can also enhance bioavailability, such as reduced particle size, emulsions, essential oil complexes or the addition of whey protein or surfactants.

The study sought to establish the bio bioavailability of CURCUGEN,[21] which is a curcuminoids formulation of turmeric and curcuminoids. The patent-pending supplement has an increased dispersion in water, which the researchers cite is a known mechanism of improving bioavailability.[22]

At the completion of the study, 17 healthy men between 18 years and 45 years participated in the double-blind, randomized crossover study.[23] People who were using any products or food with turmeric within the 14 days before the study started were excluded. The researchers used several serum measurements to determine bioavailability, including the bioactive metabolite, tetrahydrocurcumin.

They found individuals taking CURCUGEN had 39 times higher the amount of free curcumin, 31 times higher the amount of tetrahydrocurcumin, 49.5 times the amount of total curcumin and 52.5 times the amount of total curcuminoids over the compared standard curcumin reference product.[24]

Curcumin May Reduce Pain in Those With Arthritis

A 2019 report from the Arthritis Foundation[25] found that there were 54.4 million people in the U.S. between 2013 and 2015 that had been diagnosed by their physician with arthritis. Conservatively, they estimate this number will increase 49% to 78.4 million people by 2040.

This represents 25.9% of all adults. Additionally, the number whose activities are limited due to their arthritis are estimated to jump from 43.5% of all people with the condition in 2015 to 52% by 2040. The condition is painful, and people often turn to anti-inflammatory and pain medications to relieve the discomfort.

The Arthritis Foundation[26] lists topical and oral nonsteroidal anti-inflammatory drugs, steroid, hyaluronic acid, platelet rich plasma and stem cell injections as a means of reducing pain and thus potentially improving activity levels.

However, many of these treatments come with a list of side effects and are not always well tolerated. Since the safety and nontoxicity of curcumin, even at high doses, has been documented in human trials[27] studies have evaluated whether the anti-inflammatory effects of curcumin could help those with osteoarthritis, which is the most common form of arthritis.[28]

One study[29] engaged 139 people with knee osteoarthritis for a randomized, open-label, active controlled clinical study to receive either curcumin or diclofenac twice daily for 28 days. Baseline measurements were taken before the interventions began and then again at Days 7, 14 and 28.

The main outcome measure was pain. Researchers also had secondary outcome measures that included anti-ulcer effect, anti-flatulent effect, altered weight and a global assessment of therapy. By Days 14 and 28, there was no statistically significant difference between those taking curcumin and those taking diclofenac in pain measurements.

Those taking curcumin had fewer episodes of flatulence and by Day 28, had a statistically significant weight loss and anti-ulcer effect. No patient using curcumin required an H2 blocker, while 28% of those using diclofenac needed an H2 blocker to reduce excess stomach acid. Researchers found that curcumin had a similar effect in reducing pain to diclofenac but was better tolerated and had fewer side effects.

Additional Health Benefits for Curcumin

Natural plants have been used for medicinal purposes throughout history, and turmeric is not an exception. There is evidence it was used in human health as far back as 4,000 years ago and modern medicine has seen over 3,000 papers published on it within the last 25 years.[30]

In addition to pain relief, curcumin has also demonstrated the ability to make significant changes in cognitive function and mood in older adults who took the supplement for at least four weeks.[31] Researchers found significant improvement in working memory, general fatigue and state of calmness. Additionally, it significantly reduced total and LDL cholesterol.

A second study[32] performed at the University of California Los Angeles and published in the American Journal of Geriatric Psychiatry examined the effects of curcumin on individuals who had no history of dementia. The study's first author, Dr. Gary Small, said in a press release:[33]

> *"Exactly how curcumin exerts its effects is not certain, but it may be due to its ability to reduce brain inflammation, which has been linked to both Alzheimer's disease and major depression."*

The study followed 40 people between ages 50 and 90 who had mild memory complaints. Researchers found those who took the curcumin had significant improvements in memory and attention abilities, as well as mild improvement in mood and significantly fewer amyloid and tau signals in the amygdala and hypothalamus, areas of the brain that control some memory and emotional functions.[34]

One paper published in 2019[35] postulated that since chronic inflammation plays such a significant part in obesity, cardiovascular diseases and impaired glucose tolerance, increasing the bioavailability of curcumin may help modulate many of these lifestyle-related diseases.

A meta-analysis of three studies[36] that included 326 patients, also found that curcumin has a beneficial effect on irritable bowel syndrome symptoms, and another analysis showed curcumin a being effective and well-tolerated agent for the treatment of some skin diseases.[37]

Researchers continue to evaluate the effects curcumin has on many conditions driven by chronic inflammation, including rheumatoid arthritis, ulcerative colitis, cognitive decline, major depressive disorders and premenstrual syndrome.[38]

Although curcumin is generally recognized as safe (GRAS),[39] it has been found to increase the risk of bleeding in people taking medications that affect platelet aggregation, such as Lovenox, heparin or warfarin. People who are on chemotherapy should consult with their physician before including curcumin as it has inhibited chemotherapy-induced apoptosis in the lab.[40]

Additionally, curcumin may interfere with the metabolism of some drugs used in the U.S. and piperine, sometimes included with curcumin to increase bioavailability, may also affect the elimination and bioavailability of certain drugs.

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself And others similarly situated,

Plaintiffs,

Civil Action. 1:21-cv-00783-MV-JHR

v.

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

AMENDED *OPPOSED* MOTION FOR STAY AND INJUNCTION PENDING APPEAL

COMES NOW, Plaintiffs, through undersigned counsel, with their request for this Court to issue a stay of the proceedings before the Court and injunction barring that the Public Health Order (PHO) at issue in this matter may be enforced requiring individuals covered by the PHO to be fully vaccinated as a condition of their employment:

1. Out of an abundance of caution pursuant to Rule 8 Fed. R. App. P. Plaintiffs respectfully request that this Court issue an injunction pending an appeal of this Court's order denying the request for preliminary injunction requested the same relief. ECF. Doc. Nos. 18.
2. Plaintiffs respectfully offer that this case plainly satisfies Rule 8(a)'s "impracticable" exception, as it will likely be futile to ask this Court for the same relief the Court has just denied to them in rejecting their injunction motion. *See In re Flint Water Cases*, 960 F.3d 820, 825 (6th Cir. 2020), *Planned Parenthood of Greater Tex. Surgical Health Servs. v.*

Abbott, 734 F.3d 406, 410–11 (5th Cir. 2013), and *Homas v. City of Albuquerque*, 264 F.3d 1240, 1243 (10th Cir. 2001)).

3. For further explanation in support of the instant Motion Plaintiffs offer that Court made its determinations that no irreparable harm was sufficiently alleged without allowing Plaintiffs an opportunity at hearing to present evidence of them which by way of proof would have established that Plaintiff Blackford (as see declared previously to the Court) has been constructively terminated from her employment as a nurse and is prohibited from obtaining employment as a nurse anywhere else in the state as a result of the PHO.
4. The district court rendered its decision without oral argument and without an evidentiary hearing.
5. The Plaintiff further requests this honorable Court stay its proceeding during the pendency of the interlocutory appeal or any applications for injunctive relief to the Supreme Court of the United States.
6. The Plaintiff also apprises this Court of a similar proceeding in United States District Court for the Northern District of New York in which the Honorable David N Hurd granted temporary relief to the plaintiffs. (Exhibit 1).

WHEREFORE, Plaintiffs respectfully request that Court issue an injunction pending appeal that bars the Defendants from enforcing order or guidance requiring individuals be fully vaccinated to continue in their employment and stay the matter before the Court.

Respectfully submitted,

WESTERN AGRICULTURE, RESOURCE AND BUSINESS ADVOCATES, LLP

By: */s/ A. Blair Dunn*

EXHIBIT 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

- -

Dr. A, Nurse A., Dr. C., Nurse D., Dr. F., Dr. G., Therapist I., Dr. J., Nurse J., Dr. M., Nurse N., Dr. O., Dr. P., Technologist P., Dr. S., Nurse S., and Physician Liaison X.,

Plaintiffs,

-v- 1:21-CV-1009

KATHY HOCHUL, Governor of the State of New York, in her official capacity, DR. HOWARD A. ZUCKER, Commissioner of the New York State Department of Health, in his official capacity, and LETITIA JAMES, Attorney General of the State of New York, in her official capacity,

Defendants.

- -

DAVID N. HURD
United States District Judge

ORDER

On August 26, 2021, the New York State Department of Health ("DOH") promulgated a regulation that mandates COVID-19 vaccination of health care workers. This regulation requires personnel employed at general hospitals and nursing homes to receive their first dose of a COVID-19 vaccine

by September 27, 2021, and for personnel employed at other covered entities to receive a vaccine by October 7, 2021. Unlike a previously applicable Public Health Order, this new regulation excludes any religious exemption. The named plaintiffs are seventeen medical professionals employed in the State of New York who allege that their sincere religious beliefs compel them to refuse the COVID-19 vaccines that are currently available.

On September 13, 2021, plaintiffs filed this 42 U.S.C. § 1983 action alleging this "vaccination mandate" violates the First and Fourteenth Amendments, the Supremacy Clause, and the Equal Protection Clause of the U.S. Constitution. Plaintiffs sought to proceed pseudonymously. Plaintiffs also moved for a temporary restraining order ("TRO") and a preliminary injunction that would enjoin defendants from, *inter alia*, enforcing the vaccine mandate "to the extent it categorically requires health care employers to deny or revoke religious exemptions from COVID-19 vaccination mandates."

Upon review of plaintiffs' memorandum of law and supporting documentation, it is

ORDERED that

1. Plaintiffs' motion for a temporary restraining order is GRANTED;

2. Defendants, their officers, agents, employees, attorneys and successors in office, and all other persons in active concert or participation with them,

are temporarily ENJOINED from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the vaccine mandate such that:

(a) The vaccine mandate is suspended in operation to the extent that the DOH is barred from enforcing any requirement that employers deny religious exemptions from COVID-19 vaccination or that they revoke any exemptions employers already granted before the vaccine mandate issued;

(b) The DOH is barred from interfering in any way with the granting of religious exemptions from COVID-19 vaccination going forward, or with the operation of exemptions already granted;

(c) The DOH is barred from taking any action, disciplinary or otherwise, against the licensure, certification, residency, admitting privileges or other professional status or qualification of any of the plaintiffs on account of their seeking or having obtained a religious exemption from mandatory COVID-19 vaccination; and

(d) As noted *supra*, since the August 26, 2021 regulation does not require hospital and nursing home employees to receive a vaccine until September 27, 2021, the TRO does not, as a practical matter, go into effect until that date.

3. Plaintiffs shall serve defendants with (1) this Order; (2) the operative complaint and supporting exhibits; and (3) the motion for a temporary restraining order and preliminary injunction no later than Thursday, September 16, 2021 at 12:00 p.m.;

4. Defendants are to advise the Court if they oppose plaintiffs' request for a preliminary injunction pending an expedited resolution of the merits of the main issue for a permanent injunction;

5. If yes, defendants shall file and serve all submissions in opposition to the plaintiffs' motion for a preliminary injunction before Wednesday, September 22, 2021 at 5:00 p.m.;

6. No reply is permitted;

7. Defendants shall further advise the Court if they oppose plaintiffs' request to proceed pseudonymously;

8. If yes, defendants shall file and serve all submissions in opposition to the plaintiffs' request to proceed pseudonymously before Wednesday, September 22, 2021 at 5:00 p.m.;

9. No reply is permitted; and

10. If yes, defendants shall SHOW CAUSE at an in-person oral argument to be held at 10:00 a.m. on Tuesday, September 28, 2021 at the United States Courthouse in Utica, New York why the TRO should not be converted to a

preliminary injunction in accordance with Rule 65 of the Federal Rules of Civil Procedure.

IT IS SO ORDERED.

United States District Judge

Dated: September 14, 2021 at 10:00 a.m.
Utica, New York.

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself and others similarly situated,

Plaintiffs,

v. **Case No. 1:21-cv-00783-MV-JHR**

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS PLAINTIFFS' VERIFIED COMPLAINT

Defendants Governor Michelle Lujan Grisham, and Secretary Tracie Collins (collectively, "Defendants"), by and through their counsel of record, hereby submit their reply in support of their Motion to Dismiss Plaintiffs' Verified Complaint [Doc. 17] ("Motion to Dismiss") pursuant to Federal Rule of Civil Procedure 12(b)(6). As grounds for this reply, Defendants state as follows.

INTRODUCTION

This suit represents yet another attempt to have the courts overturn elected officials' constitutional measures enacted to protect lives and safety during an unprecedented pandemic. Plaintiffs fail to offer any argument in defense of their action that has not already been rejected by courts across the country—including the nation's highest court. The Court should dismiss Plaintiffs' claims with prejudice, as they make no new colorable claims.

DISCUSSION

I. What *Jacobson* does and does not stand for

Defendants wish to make abundantly clear that, contrary to Plaintiffs' assertion, Defendants do not read *Jacobson* as a "blank check." Response to Defendants' Motion to Dismiss [Doc. 20] ("Response") at 1. Rather, Defendants rely on *Jacobson* for the proposition that the Constitution does not forbid rational measures aimed at stemming the spread of an infectious virus that do constitute a "plain, palpable invasion" of fundamental rights. *Jacobson v. Massachusetts*, 197 U.S. 11, 31 (1905). Defendants agree with *Jacobson*'s final remarks that Courts can (and should) intervene when states exert their police power in an "arbitrary and oppressive" manner. *Id.* at 38-39. But, as the Court expressly held, such was not the case for a general vaccine mandate like the one at issue here. *See id.* Even Justice Gorsuch's concurrence in *Roman Catholic*, which Plaintiffs rely on, *see* Response at 2, supports Defendants' actions:

> In *Jacobson*, individuals could accept the vaccine, pay the fine, or identify a basis for exemption. The imposition on Mr. Jacobson's claimed right to bodily integrity, thus, was avoidable and relatively modest. It easily survived rational basis review, and might even have survived strict scrutiny, given the opt-outs available to certain objectors.

Roman Catholic Diocese v. Cuomo, 141 S. Ct. 63, 71 (2020) (Gorsuch, J. concurring). Simply put, *Jacobson* clearly forecloses Plaintiffs' substantive due process and equal protection claims—as this Court has preliminarily recognized. *See* [Doc. 18 at 10-21].

II. Plaintiffs fail to explain how the vaccine mandate infringes on a fundamental right

Plaintiffs bear the burden of demonstrating that the challenged measure infringes on a fundamental right. *See ETP Rio Rancho Park, LLC v. Grisham*, No. CIV 21-0092 JB/KK, 2021 U.S. Dist. LEXIS 36354, at *114 n.4 (D.N.M. Feb. 26, 2021) ("In those [cases] challenging legislative action, plaintiffs must show the law impermissibly or irrationally burdens a fundamental

right." (quoting Hon. Timothy M. Tymkovich, Joshua Dos Santos, Joshua J. Craddock, *A Workable Substantive Due Process*, 95 Notre Dame L. Rev. 1961, 1964 (2020)). Plaintiffs fail to do so.

First, with regard to Plaintiff Blackford, there is no general fundamental right to work in a chosen profession. *See Guttman v. Khalsa*, 669 F.3d 1101, 1118 (10th Cir. 2012) (holding that the "right to practice in [one's] chosen profession . . . does not invoke heightened scrutiny."). Even if there was such a right, Plaintiffs have not attempted to carefully describe how Blackford has a fundamental right to work as an unvaccinated nurse during a pandemic. *See Washington v. Glucksberg*, 521 U.S. 702, 771 n.11 (1997) ("[T]he task of determining whether the concrete right claimed by an individual in a particular case falls within the ambit of a more generalized protected liberty requires explicit analysis when what the individual wants to do could arguably be characterized as belonging to different strands of our legal tradition requiring different degrees of constitutional scrutiny."). Rather, Plaintiffs confuse having a protected liberty interest for purposes of *procedural* due process with having a fundamental right for purposes of *substantive* due process. *See* Response at 4-5 (quoting *Barry v. Barchi*, 443 U.S. 55, 64 (1979), and *Piecknick v. Comm. of Pa.*, 36 F.3d 1250, 1259 (3d. Cir. 1994)). Plaintiffs also rely on dissenting opinions and *Lochner*-era caselaw that has long since been abandoned. *See id.* (quoting *Barsky v. Board of Regents of University of State of New York*, 347 U.S. 442, 472 (1954) (Douglas, J, dissenting), and *Truax v. Raich*, 239 U.S. 33, 41 (1915)). Suffice it to say, this is insufficient to meet their burden of proof. *See United States v. Romain*, 393 F.3d 63, 74 (1st Cir. 2004) ("A dissenting opinion is, of course, not binding precedent[.]"); *Armendariz v. Penman*, 75 F.3d 1311, 1318 (9th Cir. 1996) (stating that *Lochner* "symbolizes an era in which the Court, invalidating economic legislation, engaged in a level of judicial activism which was unprecedented in its time and unmatched since").

Second, Plaintiffs fail to explain how they have a fundamental right to refuse a vaccine during a pandemic. True, the Supreme Court has "assumed" and strongly suggested that individuals have some right to refuse unwanted medical treatment. *See, e.g.*, *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 279 (1990); *Glucksberg*, 521 U.S. at 720; *Washington v. Harper*, 494 U.S. 210, 221-22 (1990); *Riggins v. Nevada*, 504 U.S. 127, 138 (1992). "But in these . . . this liberty interest has remained confined either by duly enacted and constitutional state laws or the state's legitimate interests that it had rationally pursued in regulation." *Klaassen v. Trs. of Ind. Univ.*, No. 1:21-CV-238 DRL, 2021 U.S. Dist. LEXIS 133300, at *60 (N.D. Ind. July 18, 2021). Moreover, "[t]he rights recognized (or assumed) in these cases weren't 'simply deduced from abstract concepts of personal autonomy[,]' . . . [t]hey were rooted in longstanding common law rules or legal traditions consistent with this Nation's history." *Id.* at *61 (quoting *Glucksberg*, 521 U.S. at 725. In contrast, there is no longstanding history of allowing individuals to refuse vaccination against communicable diseases. *See id.* at *62; *see generally Jacobson*, 197 U.S. 11. And this makes sense, as the refusal to receive a safe and effective vaccine affects more than just the individual but jeopardizes the health of others. *See Klaassen*, 2021 U.S. Dist. LEXIS 133300, at *61 ("Vaccines address a collective enemy, not just an individual one."). Accordingly, Plaintiffs find no help in the cases on which they rely.

Lastly, Plaintiff Valdez does not explain how the State Fair vaccine requirement interferes with her right to raise her children. *See* Response at 7. When the issue is framed properly, it becomes clear there is no such interference. Like every other parent, Valdez has the power to decide whether her children will be vaccinated; she simply does not have the power to force the State to allow her unvaccinated children to attend one of the State's largest mass gatherings. Surely, this cannot be a fundamental right. Indeed, Courts across the country have previously

rejected Plaintiffs' argument in the context of mandatory school vaccinations. *See, e.g.*, *Workman v. Mingo Cty. Bd. of Educ.*, 419 Fed. Appx. 348, 355 (4th Cir. 2011) ("[T]he question presented by the facts of this case is whether the special protection of the Due Process Clause includes a parent's right to refuse to have her child immunized before attending public or private school where immunization is a precondition to attending school. We agree with other courts that have considered this question in holding that [the parent] has no such fundamental right." (internal quotation marks and citations omitted)). The Supreme Court has also consistently recognized that a state may constitutionally require school children to be immunized. *See Zucht v. King*, 260 U.S. 174 (1922); *Prince v. Massachusetts*, 321 U.S. 158 (1944). Thus, the State Fair vaccine requirement does not violate any fundamental right to raise one's children.

III. Plaintiffs' purported contracts do not defeat a reasonable exercise of the police power such as vaccine mandates during a pandemic, and their Contracts Clause claims are moot

Plaintiffs not only lack any legal support for their Contracts Clause claims, but their claims are now moot. Plaintiffs again misconstrue case law to try to support their position. Plaintiffs cite *U.S. Trust Co of N.Y. v. New Jersey*, 431 U.S. 1 (1977), for the proposition that the Contracts Clause prevents the State from using its police power to destroy an individual contract. *See* Response at 8. However, the quotation relied upon by Plaintiffs is not the Court's holding, but rather a restatement of the district court's conclusion *rejected* by the Court. *U.S. Trust Co.,* 431 U.S. at 26 ("The trial court's 'total destruction' test is based on what we think is a misreading of *W.B. Worthen Co. v. Kavanaugh*, 295 U.S. 56 (1935)."). Instead, it is "commonplace that the Contract Clause does not obliterate the police power of the States." *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 241 (1978); *see also Manigault* v. *Springs*, 199 U.S. 473, 480 (1905) (holding the police power "is an exercise of the sovereign right of the Government to protect the

lives, health, morals, comfort and general welfare of the people, and is paramount to any rights under contracts between individuals."). Plaintiffs' argument that the Contracts Clause prohibits a state's police power from destroying contractual obligations is therefore inaccurate. Rather, the extent a state's police power may impact private contract "depends on the nature of the contractual relationship with which the challenged law conflicts." *U.S. Tr. Co.*, 431 U.S. at 22. However, the "States must possess broad power to adopt general regulatory measures without being concerned that private contracts will be impaired, or even destroyed, as a result. Otherwise, one would be able to obtain immunity from state regulation by making private contractual arrangements." *Id.*

Plaintiffs also misapply the test to determine whether a state law violates the Contracts Clause. Plaintiffs argue the PHO was not "in any way tailored to address specifics of the youth livestock exhibitors," and complain that attendees to the City of Albuquerque's Pride Fest[1] were not subject to a similar vaccination requirement. Response at 9. The two-step test for a Contracts Clause analysis does not require any of tailoring of a state law to existing contracts. Instead, the first issue "is whether the state law has 'operated as a substantial impairment of a contractual relationship.'" *Sveen v. Melin*, 138 S. Ct. 1815, 1821-22, (2018) (quoting *Allied*, 438 U.S. at 244). "In answering that question, the Court has considered the extent to which the law undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights." *Id.* at 1822. "If such factors show a substantial impairment," the Court will then assess "whether the state law is drawn in an 'appropriate' and 'reasonable' way to advance 'a significant and legitimate public purpose.'" *Id.* (quoting *Energy Reserves Group, Inc. v. Kansas Power & Light Co.,* 459 U.S. 400, 411–412 (1983)). Additionally, courts will

[1] Plaintiffs' argument fails to recognize that Pride Fest is not a State-sponsored event, like the State Fair.

"refuse to second-guess the [government']s determinations that [the measures] are the most appropriate ways of dealing with the problem." *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 506 (1987); *see also United States Tr. Co. v. New Jersey*, 431 U.S. 1, 22-23 (1977) ("As is customary in reviewing economic and social regulation, however, courts properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.").

As recently stated by the Court, Plaintiffs have failed to establish any substantial impairment of any contractual relationship. *See* Memorandum Opinion and Order [Doc 18] ("Order") at 23. Plaintiffs have not provided any copies of the purported contracts. Regardless, Defendant's compelling interest of preventing the spread of COVID-19 is reasonably and appropriately advanced through the PHO, as there is substantial evidence that vaccines are an effective in preventing the strain on New Mexico's healthcare system and protect the State's population. *See generally* [Doc. 17 at 10-12]; Order at 17-18. Requiring the workers who interact with vulnerable populations living in close proximity is a reasonable measure to protect persons within hospitals and congregate care facilities and employees from the risk of severe illness or death. *See id.* The PHO's vaccine requirement for all vaccine-eligible persons entering the State Fair was similarly reasonable, as it assisted in preventing a superspreading event caused by the thousands of attendees.

Regardless, Plaintiffs' Contracts Clause claims are moot. Unsurprisingly, Plaintiffs ignore in their response the fact that the junior livestock show was cancelled, and the State Fair offered full refunds to participants such as Valdez.[2] *See* Order at 24-25; *see generally* Response. Plaintiffs do not assert any allegations that Valdez's purported contract does not contain any cancellation

[2] *See 2021 Junior Livestock Refund Application*, N.M. State Fair, https://statefair.exponm.com/p/participate/competitions/livestock-shows (last visited Sept. 2, 2021).

provisions. *See generally* [Doc. 1]. Therefore, Valdez's Contracts Clause claim is moot, as Valdez could not only receive a refund of the consideration she paid to the State Fair, but also her children exhibited their animals at the New Mexico Youth Livestock Expo in Roswell.[3] *See* Order at 25.

Blackford's claim is similarly moot because her employer, Presbyterian, instituted its own private vaccine mandate for its entire workforce.[4] Order at 23-24. As stated by Presbyterian's president and CEO, Dale Maxwell, "'[Presbyterian] take[s] care of the most vulnerable people in the state of New Mexico. . . and I believe . . . we should take every measure possible to deliver the safest environment.'" Order at 24. Plaintiffs however reject the Court's reliance on this statement and assert it is "disingenuous and unsubstantial" to argue that Presbyterian would have imposed the condition on the contracts regardless of the PHO. Response at 9. However, Plaintiffs offer no support that Presbyterian only issued its even broader mandate due to the PHO or that they would rescind it absent the State's vaccine requirement. *See* Order at 24. Rather, it appears that even if Presbyterian did not institute its own vaccine requirements it would subject to the just as expansive federal mandate that all employers with 100 or more employees ensure their workers are vaccinated or tested weekly.[5] Accordingly, Blackwell has no reasonable expectation she would

[3] Gabriel Chavez, *Youth Livestock Expo underway in Roswell*, KRQE (Sept. 16, 2021) https://www.krqe.com/news/new-mexico/youth-livestock-expo-underway-in-roswell/; Karin Brulliard, *A vaccine mandate fractures a state fair, leaving children as 'pawns'*, The Washington Post (Sept. 26, 2021), https://www.washingtonpost.com/nation/2021/09/26/covid-public-vaccine-mandates/ (containing image of Plaintiff Talisha Valdez with her daughters at the Youth Livestock Show in Roswell).

[4] Colleen Heild, *Presbyterian requires vaccines for entire workforce of 13,000*, Santa Fe New Mexican (Aug. 18, 2021), https://www.abqjournal.com/2420650/presbyterian-requires-vaccines-for-entire-workforce-of-13000-ex-pnm-is-asking-all-staff-to-get-vaccinated-or-be-tested-weekly.html; [Doc 1-4]; *see also* [Doc. 10 at 5 (noting this fact); Doc 18 at 23-24 (same)].

[5] The White House, *Path Out of the Pandemic President Biden's COVID-19 Action Plan*, https://www.whitehouse.gov/covidplan/ (last visited Sept. 24, 2021) ("The Department of Labor's Occupational Safety and Health Administration (OSHA) is developing a rule that will require all

be entitled to continue her employment without being vaccinated. *See* Order at 24. Plaintiffs' Contracts Clause claims therefore fail as a matter of law.

IV. Sovereign and qualified immunity bar any claim for damages

Finally, even if the Court finds that all or part of Plaintiffs' claims survive dismissal, their claims for damages are clearly barred by sovereign and qualified immunity. Plaintiffs argue their state law claims brought under the New Mexico Civil Rights Act (NMCRA) may proceed because NMSA 1978, Section 41-4A-3 (2021), "says nothing about limiting waiver only to state district courts." Response at 11. But that is not the test. "It is settled that a waiver of sovereign immunity cannot be implied but must be unequivocally expressed." *E.F.W. v. St. Stephen's Indian High Sch.*, 264 F.3d 1297, 1304 (10th Cir. 2001) (quoting *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978)). Thus, "[a] state's waiver of sovereign immunity in its own courts does not constitute abandonment of its Eleventh Amendment immunity in the federal courts. Indeed, even a general waiver of sovereign immunity, apparently indeterminate in its scope or locus of effect, would be insufficient in this respect." *Griess v. Colorado*, 841 F.2d 1042, 1044 (10th Cir. 1988) (citing *Edelman v. Jordan*, 415 U.S. 651, 677 n.19 (1974), and *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 241 (1985). Although the NMCRA was not as explicit in cabining the State's waiver of sovereign immunity as the NMTCA, it did not clearly waive immunity for federal suits and must therefore "be strictly construed, in terms of its scope, in favor of the sovereign." *Sossamon v. Texas*, 563 U.S. 277, 285 (2011).

employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result on at least a weekly basis before coming to work. OSHA will issue an Emergency Temporary Standard (ETS) to implement this requirement. This requirement will impact over 80 million workers in private sector businesses with 100+ employees.").

Plaintiffs similarly fail to shoulder their burden of demonstrating that Defendants are not entitled to qualified immunity with respect to the federal claims. "A motion to dismiss based on qualified immunity imposes the burden on the plaintiff to show both that [1] a constitutional violation occurred and [2] that the constitutional right was clearly established at the time of the alleged violation." *Doe v. Woodard*, 912 F.3d 1278, 1289 (10th Cir.) (internal quotation marks and citation omitted). In a half-hearted attempt to meet this burden, Plaintiffs cite to *Barchi*, 443 U.S. 55, *Cruzan*, 497 U.S. 261, and *Obergefell v. Hodges*, 576 U.S. 644 (2015). *See* Response at 11. But none of these cases deal with the imposition of vaccine mandates, let alone vaccine mandates imposed in response to a pandemic. *See Woodard*, 912 F.3d at 1289 (stating that "it is a longstanding principle that clearly established law should not be defined at a high level of generality" (internal quotation marks and citation omitted). In contrast, *Jacobson* provides clearly established law *affirming* the validity of such a vaccine mandate. Plaintiffs' federal claims for damages must therefore fail.

CONCLUSION

For the foregoing reasons, this Court should dismiss Plaintiffs' action with prejudice.

Respectfully submitted,

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

TALISHA VALDEZ, on behalf of herself and others similarly situated, and JENNIFER BLACKFORD on behalf of herself and others similarly situated,

Plaintiffs,

v. **Case No. 1:21-cv-00783-MV-JHR**

MICHELLE LUJAN GRISHAM, Officially and Individually, Acting Under the Color of Law, and DAVID SCRASE, Officially and Individually, Acting Under the Color of Law,

Defendants.

RESPONSE TO MOTION FOR STAY AND INJUNCTION PENDING APPEAL

Defendants Governor Michelle Lujan Grisham and Secretary David R. Scrase (collectively, "Defendants"), by and through their counsel of record, hereby submit their response in opposition to Amended Plaintiffs' Opposed Motion for Stay and Injunction Pending Appeal [Doc. 23] ("Motion"). As grounds for this response, Defendants state as follows.

1. After thorough analysis, the Court denied Plaintiffs' requested preliminary injunctive relief contained in their Verified Complaint for Civil Rights Violations Under 42 U.S.C.A. §1983; Violations of Rights Protected by the New Mexico Civil Rights Act; Emergency Request for a Temporary Restraining Order; Requst [sic] for Preliminary Injunction, Permanant [sic] injunctive relief and Damages [Doc. 1]. *See generally* [Doc. 18].

2. Plaintiffs nonetheless request that this Court grant it the same injunctive relief it just denied. *See* Motion. "Such a request demands a significantly higher justification than a request

for a stay because, unlike a stay, an injunction does not simply suspend judicial alteration of the status quo but grants judicial intervention that has been withheld by lower courts." *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, J., concurring) (quoting *Respect Maine PAC v. McKee*, 562 U.S. 996 (2010). "This power is used where the legal rights at issue are indisputably clear and, even then, sparingly and only in the most critical and exigent circumstances." *Id.* (internal quotation marks and citations omitted).

3. Plaintiffs fail to support their request with any citations to authorities that would support their requested relief. *See generally id.* Although Plaintiffs cite an *ex parte* TRO granted against the enforcement of a New York requirement that hospital and nursing home personnel be vaccinated, the district court only granted the TRO because "[u]nlike a previously applicable Public Health Order, this new regulation excludes any religious exemption." Ex. 1 to Motion at 2. In contrast to the New York regulation, the PHO at issue in this case contains such an exemption.[1]

4. Despite complaining that the Court did not allow Plaintiffs an opportunity to present evidence at a hearing of their irreparable harm, *see* Motion at 2, Plaintiffs had (and took) the opportunity to submit evidence with their request for preliminary injunctive relief. *See* [Docs. 1-3, 1-4, 14-1, 14-2, 14-3]. Regardless, a hearing was not necessary because Plaintiffs are "proceeding on a legal theory which cannot be sustained" and "ha[ve] not presented a colorable factual basis to support the claim on the merits of the contention of irreparable harm." *Montoya v. Albuquerque Pub. Schs*, No. 01-00173 MV/RLP, 2001 U.S. Dist. LEXIS 27957, at *7 (D.N.M. Aug. 1, 2001) (Vázquez, J.) (quoting *Bradley v. Pittsburgh Bd. of Educ.*, 910 F.2d 1172, 1175-76

[1] N.M. Dep't of Health, *Public Health Order* at 3-4 (Sept. 15, 2021), https://cv.nmhealth.org/wp-content/uploads/2021/09/091521-PHO-Vaccinations.pdf.

(3rd Cir. 1990)); *see also* [Doc. 18 at 27-28 (holding that a loss of employment does not equate to irreparable harm)]

5. Plaintiffs also request the Court "stay its proceeding during the pendency of the interlocutory appeal or any applications for injunctive relief to the Supreme Court of the United States," Motion at 2 ¶ 5, but fail to explain why this Court should grant such a request when the Court simply denied Plaintiffs' motion (as opposed to granting an injunction). *See Homans v. City of Albuquerque*, 264 F.3d 1240, 1243 (10th Cir. 2001) (stating that an appellant requesting a stay pending appeal must address "(a) the likelihood of success on appeal; (b) the threat of irreparable harm if the stay or injunction is not granted; (c) the absence of harm to opposing parties if the stay or injunction is granted; and (d) any risk of harm to the public interest" (quoting 10th Cir. R. 8.1). Significantly, Plaintiffs fail to explain how they will be irreparably harmed in simply continuing the ordinary course of litigation *that they initiated*. *See Renegotiation Board v. Bannercraft Clothing Co., Inc.*, 415 U.S. 1, 24 (1974) ("Mere litigation expense, even substantial and unrecoupable cost, does not constitute irreparable injury").

6. Given the foregoing, the Court should deny Plaintiffs' request for an injunction and stay pending appeal.

Respectfully submitted,

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