#### IN THE UNITED STATES DISTRICT COURT

### FOR THE DISTRICT OF COLUMBIA

DAN ALTSCHULD; MARK S. AMATO; ) CYNTHIA MATSUMOTO; MIKE ORLOFF; JEANINE CLARKE; JOSHUA ) CRIBBS; JOHN EDSON; KIMBERLY ELSHOLZ; CHARLES L. CARPENTER; JAMES CERNOCK; KIMBERLY R. CHRISTOFF; AINSLIE M. COVE; JEFFREY DICE; DAVID R. HEIMANN; TROY L. HESS; WESLEY W. HOEKWATER; AUDRA M. MORRIS; MATTHEW D. SEIFERT; JAROD SMITH;) DONLAD E. SNIVELY; JAMIE G. ) STDENNIS; CALEB STEELE; CHRIS ) STINCHFIELD; SUZANNE TAYLOR; ) MICHAEL WEINFURNTER; AARON ) WIERSUM; AMANDA C. WILLIAMS; ) JONATHAN D. WILLIAMS; JOSHUA ) WHITE; JASON MCNABB; MELINA G. ROYER; MICHAEL A. SPELLANE; KEVIN T. COFFMAN; DAVID T. HARMON; SUSAN A. ROGERS; CHERYL L. KOEVOET; KEMMI SANDLER; MARCUS W. THORNTON; ERIN WILLIAMS; B.J. MONTGOMERY; ) DOMINIC W. BIES; STEVEN R. GEORGE; MARTIN J. KNOTT, JR. LARA G. IRVING; ALEX LEWANDOWSKI; TRAVIS MCKINNEY; ) DOUG POPOVICH; SARAH SMITH; AARON WOOODS; MICHAEL WILSON ) JENNIFER C. NICKISCH c/o Federal Practice Group 1750 K Street, NW Suite 900 Washington, DC 20006 Plaintiffs, v. ) GINA M. RAIMONDO

Civil Action No.:

Secretary of Commerce	)
Department of Commerce	)
1401 Constitution Ave NW	)
Washington, DC 20230,	)
<i>b</i> , <i>j</i> , <i>j</i> ,	ý
LLOYD J. AUSTIN, III	ý
Secretary of Defense	ý
Department of Defense	ý
1000 Defense Pentagon	ì
Washington, DC 20301-1000,	
Washington, DC 20301-1000,	
MERRICK B. GARLAND	
Attorney General	
•	
Department of Justice	)
950 Pennsylvania Avenue, NW	)
Washington, DC 20530-0001,	)
	)
ALEJANDRO MARYORKAS	)
Secretary of Homeland Security	)
Department of Homeland Security	)
MS 04854	)
2707 Martin Luther King Jr. Ave,	)
Washington, DC 205, 28-04854	)
	)
SAMANTHA POWER	)
Administrator	)
U.S. Agency for International	)
Development	)
1900 E Street, NW	)
Washington, DC 20415-1000,	)
<i>b</i> , <i>j</i> , <i>j</i> ,	ý
TOM VILSACK	ý
Secretary of Agriculture	ý
Department of Agriculture	Ś
1400 Independence Ave., SW	
Washington, DC 20250,	
washington, DC 20230,	
IENNIEED M. CDANIJOI M	
JENNIFER M. GRANHOLM	)
Secretary of Energy	)
Department of Energy	)
1000 Independence Ave, SW	)
Washington, DC 20585	)
	)
ANTONY BLINKEN	)
Secretary of State	)

Department of State	)
2201 C Street, NW	)
Washington, DC 20520,	)
-	)
MICHAEL S. REGAN	)
Administrator	)
Environmental Protection Agency	)
1200 Pennsylvania Ave, NW	)
Washington, DC 20460,	)
	)
WILLIAM J. BURNS	)
Director	)
Central Intelligence Agency	)
Litigation Division	)
Office of General Counsel	)
Washington, DC 20505,	)
AVRIL HAINES	)
Director	~
Office of the Director of National	~
	~
Intelligence	
1800 F Street, NW	)
Washington, DC 20511,	)
XAVIER BECERRA	
Secretary of Health and Human	Ś
Services	Ś
200 Independence Avenue SW	Ś
Washington, DC 20201	
washington, DC 20201	7
Defendants.	~
Defendants.	
	)

# **COMPLAINT**

On September 9, 2021, President Biden issued Executive Orders 14042 and 14043,

mandating that federal employees and contractors provide proof of having been inoculated with

an unlicensed COVID-19 vaccine, or face disciplinary consequences in their jobs. In rushing to

force COVID-19 vaccinations on the federal workforce, the President's edicts violate

longstanding statutory prohibitions against inoculations with unlicensed vaccines, as well as the

individual rights of government employees and contractors under the Rehabilitation Act and the Americans with Disabilities Act. Accordingly, plaintiffs who are representative of nearly every Federal Agency respectfully request relief from this Court in the form of injunctive relief stopping this illegal and unnecessarily broad and wide-ranging program.

#### PARTIES

- Plaintiffs Dan Altschuld, Mark S. Amato, Cynthia Matsumoto, and Mike Orloff are employees of the Department of Defense; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- Plaintiff Curtis Thompson is an employee of the Department of Commerce; Plaintiff either has not provided his vaccination status to his employer or has not yet received the mandated COVID-19 vaccine.
- Plaintiffs Jeanine Clarke, Joshua Cribbs, John Edson, and Kimberly K. Elsholz are employees of the Department of Justice; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- 4. Plaintiffs Charles L. Carpenter, James Cernock, Kimberly R. Christoff, Ainslie M. Cove, Jeffrey Dice, David R. Heimann, Troy L. Hess, Welsey K. Hoekwater, Audra M. Morris, Matthew D. Seifert, Jarod Smith, Donald E. Snively, Jamie G. StDennis, Caleb Steele, Chris Stinchfield, Suzanne Taylor, Michael Weinfurnter, Aaron Wiersum, Amanda C. Williams, and Jonathan D. Williams are employees of the Department of Homeland Security; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.

- 5. Plaintiff Joshua White is a federal government contractor on a federal government contract in which the Department of Homeland Security is the customer; Plaintiff either has not provided his vaccination status to the customer or has not yet received the mandated COVID-19 vaccine.
- Plaintiff Jason McNabb is an employee of the United States Agency for International Development; Plaintiff either has not provided his vaccination status to his employer or has not yet received the mandated COVID-19 vaccine.
- Plaintiffs Melina G. Royer and Michael Spellane are employees of the Department of Agriculture; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- Plaintiffs Kevin T. Coffman, David T. Harmon, and Susan A. Rogers are employees of the Department of Energy; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- 9. Plaintiffs Cheryl L. Koevoet, Kemmi Sadler, Marcus W. Thornton, and Erin Williams are employees of the Department of State; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- 10. Plaintiff B.J. Montgomery is a federal government contractor on a federal government contract in which the Department of State is the customer; Plaintiff either has not provided his vaccination status to the customer or has not yet received the mandated COVID-19 vaccine.
- 11. Plaintiffs Dominic W. Bies and Steven R. George are employees of the Environmental Protection Agency; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.

- 12. Plaintiffs Martin J. Knott, Jr., Lara G. Irving, Alex Lewandowski, Travis McKinney, Doug Popovich, Sarah Smith, and Aaron Woods are employees of the Central Intelligence Agency; Plaintiffs either have not provided their vaccination status to their employer or have not yet received the mandated COVID-19 vaccine.
- 13. Plaintiff Michael Wilson is an employee of the Office of the Director of National Intelligence; Plaintiff either has not provided his vaccination status to his employer or has not yet received the mandated COVID-19 vaccine.
- 14. Plaintiff Jennifer C. Nickisch is an employee of the Department of Health and Human Services; Plaintiff either has not provided her vaccination status to her employer or has not yet received the mandated COVID-19 vaccine.
- 15. Defendant Gina M. Raimondo, Secretary of Commerce, Department of Commerce, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 16. Defendant Lloyd J. Austin, III, Secretary of Defense, Department of Defense, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 17. Defendant Merrick B. Garland, Attorney General, Department of Justice, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22,

#### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 7 of 22

2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.

- 18. Defendant Alejandro Maryorkas, Secretary of Homeland Security, Department of Homeland Security, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 19. Defendant Samantha Power, Administrator, United States Agency for International Development, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 20. Defendant Tom Vilsack, Secretary of Agriculture, Department of Agriculture, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination status, or face disciplinary action, up to and including termination or removal from the contract.
- 21. Defendant Jennifer M. Granholm, Secretary of Energy, Department of Energy, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination status, or face disciplinary action, up to and including termination or removal from the contract.
- 22. Defendant Antony Blinken, Secretary of State, Department of State, has implemented the

Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.

- 23. Defendant Michael Regan, Administrator, Environmental Protection Agency, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 24. Defendant William J. Burns, Director, Central Intelligence Agency, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 25. Defendant Avril Haines, Director, Office of the Director of National Intelligence, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said vaccination, or face disciplinary action, up to and including termination or removal from the contract.
- 26. Defendant Xavier Becerra, Secretary of Health and Human Services, Department of Health and Human Services, has implemented the Executive Orders by mandating that all employees of the Agency and all contractors who do business with the Agency be "fully vaccinated" against COVID-19 by November 22, 2021, and provide proof of said

vaccination, or face disciplinary action, up to and including termination or removal from the contract.

#### JURISDICTION AND VENUE

- 27. This action is brought under the Administrative Procedures Act (APA), 5 U.S.C. § 701, *et seq.*, challenging the Executive Orders' purposeful evasion of the statutory requirements set forth under Sections 501 and 503 of the Rehabilitation Act 1973, as amended (29 U.S.C. §§ 791, 793), Title I of the American with Disabilities Act (ADA) of 1990, as amended (42 U.S.C. § 12101, *et seq.*) and the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 360bbb-3, *et seq.*).
- 28. Both the Rehabilitation Act and the ADA preclude employers from discriminating against federal employees and federal government contractors on the basis of an actual or perceived disability. The Acts further preclude employers from conducting disability-related inquiries of employees that are not shown to be "job-related and consistent with business necessity." 29 C.F.R. § 1630.14(c). An inquiry is determined to be "job related and consistent with business necessity" when the employer has a "reasonable belief, based on objective evidence" that the "employee will pose a direct threat due to a medical condition."<sup>1</sup> "The determination that an employee poses a direct threat must be based on an individualized assessment of the employee's present ability to safely perform the essential functions of the job." 29 C.F.R. § 1630.2(r).
- 29. The FDCA authorizes the use of medical products not yet licensed by the Food and Drug Administration (FDA) under "emergency use," but only when the individual is "informed of

<sup>&</sup>lt;sup>1</sup> Equal Employment Opportunity Commission (EEOC) Enforcement Guidance on the ADA and Psychiatric Disabilities at 15, 8 FEP Manual (BNA) 405:7468-69 (1997) (hereinafter "The ADA and Psychiatric Disabilities").

### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 10 of 22

the option to accept or refuse the 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)(ii)(III).

- 30. The APA permits judicial review of an Executive Order, as implemented by an Agency, which is not in accordance with law or is without observance of procedure required by law. 5 U.S.C. §§ 702, 704. 706; *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996). The declaratory relief requested herein is proper under 5 U.S.C. §§ 706(1)-(2).
- 31. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is the judicial district in which Defendants are located and is where a substantial part of the events or omissions giving rise to the claim occurred.

### STATEMENT OF FACTS

#### **Development of Vaccines**

- 32. Upon best information and belief, the novel COVID-19 infection first arrived in the United States in or around January 2020. Just a few short months later, then President Trump directed the immediate development of a vaccine under Operation "Warp Speed."
- 33. True to the Operation's name and the novelty of the virus, equally novel mRNA vaccines were rapidly produced in short order. For the first time in vaccine history, a vaccine was created that did not introduce an inactive version of the virus into the human body, but rather was designed to "teach our cells how to make a protein—or even just a piece of a protein—that triggers and immune response inside our bodies."<sup>2</sup> From this endeavor were born three vaccines that were, and are, widely available in the United States: the Pfizer-BioNTech

<sup>&</sup>lt;sup>2</sup> Centers for Disease Control (CDC), Understanding mRNA COVID-19 Vaccines, available at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html</u> (last visited Oct. 8, 2021).

#### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 11 of 22

COVID-19 vaccine, the Moderna COVID-19 vaccine, and Johnson & Johnson's Janssen COVID-19 vaccine.<sup>3</sup> All three vaccines are not licensed by the FDA; rather, they have been authorized for emergency use under 21 U.S.C. § 360bbb-3 and remain under emergency use authorization as of the time of this filing.

34. On August 23, 2021, the FDA licensed a COVID-19 vaccine originally developed by BioNTech Manufacturing GmbH, a German company, to be jointly manufactured with Pfizer. The companies were authorized to market the vaccine under the name "COMIRNATY."<sup>4</sup> Although co-manufactured by Pfizer, COMIRNATY is legally distinct from the Pfizer-BioNTech COVID-19 vaccine that was, and is, available in the United States; the Pfizer-BioNTech COVID-19, which is the only Pfizer vaccine available in the United States, remains under emergency use authorization.<sup>5</sup>

### **Issuance of Mandates**

35. President Biden announced the issuance of Executive Orders 14042 and 14043 during a speech he gave on September 9, 2021. He emphasized that while "fully vaccinated" individuals are "highly protected from severe illness even if [they] get Covid-19," and that

<sup>3</sup> The Johnson & Johnson vaccine is a viral vector vaccine, not mRNA. CDC, Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety, available at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html</u> (last visited Oct. 12, 2021).

<sup>5</sup> See FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent 2019 (COVID-19) (Aug. 23, 2021), available at: <u>https://www.fda.gov/media/144414/download</u> (last visited Oct. 7, 2021).

<sup>&</sup>lt;sup>4</sup> FDA, Pfizer-BioNTech COVID-19 EUA LOA reissued August 23, 2021, (Aug. 23, 2021), available at: <u>https://www.fda.gov/media/151710/download</u> (last visited Oct. 7, 2021).

#### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 12 of 22

being fully vaccinated renders these individuals "as safe as possible," the orders were being issued "to protect vaccinated workers from unvaccinated co-workers."<sup>6</sup>

- 36. Order 14043 requires each Agency to "implement, to the extent consistent with applicable law, a program to require COVID-19 vaccination for all of its Federal employees." Exec. Order No. 14043, at § 2. The Agencies are to receive all implementation guidance from the Safer Federal Workforce Task Force (Task Force). *Id.*
- 37. The Task Force has set a deadline of November 22, 2021 for all federal employees to be vaccinated.<sup>7</sup> "Employees will be considered fully vaccinated for COVID-19 2 weeks after they have received the requisite number of doses of a COVID-19 vaccine approved or authorized for emergency use by the U.S. Food and Drug Administration."<sup>8</sup> The Task Force lists the scheduled deadlines for each vaccine; conspicuously omitted from the Force's site is reference to the COMIRNATY vaccine.<sup>9</sup>
- 38. "Employees who are on maximum telework or working remotely are not excused from this requirement."<sup>10</sup> All federal employees, regardless if the employee has previously contracted COVID-19, is required to receive the vaccination.<sup>11</sup>
- 39. Federal employees who fail to comply with the requirement to be fully vaccinated by November 22, 2021, "are in violation of a lawful order."<sup>12</sup> "Employees who violate lawful

<sup>6</sup> President Biden, Remarks on Fighting the COVID-19 Pandemic, available at: <u>https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/</u> (last visited Oct. 8, 2021).

<sup>7</sup> Safer Federal Work Force Task Force, Frequently Asked Questions, "Vaccinations," available at: <a href="https://www.saferfederalworkforce.gov/faq/vaccinations/">https://www.saferfederalworkforce.gov/faq/vaccinations/</a> (last visited Oct. 12, 2021).
<sup>8</sup> Id.

- <sup>11</sup> Id.
- $^{12}$  Id.

<sup>&</sup>lt;sup>9</sup> Id.

 $<sup>^{10}</sup>$  Id.

#### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 13 of 22

orders are subject to discipline, up to and including termination or removal."<sup>13</sup> The Task Force permits Agencies to "initiate the enforcement process as soon as November 9, 2021, for employees who fail to submit documentation to show that they have completed receiving required vaccination dose(s) by November 8."<sup>14</sup>

- 40. The Task Force states that employees are permitted to request exceptions, but provides nothing further outside of an admonishment that, "All agency personnel designated to receive requests for accommodations should know how to handle requests consistent with the Federal employment nondiscrimination laws that may apply."<sup>15</sup> "If the employee's request for an exception is denied, and the employee does not comply with the vaccination requirement, the agency may pursue disciplinary action, up to and including removal from Federal service."<sup>16</sup>
- 41. The Task Force provides a link to a "medical exception" request, but the medical exception focuses solely on whether a medical provider determines the individual employee has a "medical condition" which renders the circumstances unsafe for the employee to receive the vaccine.<sup>17</sup> The exception does not allow for a provider to determine if the unvaccinated employee poses a direct threat to others by being unvaccinated.<sup>18</sup>
- 42. Medical exceptions are typically based on "contradictions," or reasons why the vaccine should not be given to the individual. The only contradiction listed for the Pfizer-BioNTech COVID-19 vaccine, the Moderna COVID-19 vaccine, and the Johnson & Johnson/Janssen

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> Id.

<sup>&</sup>lt;sup>15</sup> Id.

<sup>&</sup>lt;sup>16</sup> Id.

 <sup>&</sup>lt;sup>17</sup> Template – Request for a Medical Exception to the COVID-19 Vaccination, available at: <u>https://www.saferfederalworkforce.gov/downloads/DISABILITY%20REQUEST%20FORM%20-%2020211004\_510pm%20-%20MH508.pdf</u> (last visited Oct. 8, 2021).
<sup>18</sup> Id.

COVID-19 vaccine is "severe allergic reaction (e.g., anaphylaxis) to any component of the" respective vaccine.<sup>19</sup>

- 43. Each Defendant Agency has fully implemented this guidance.
- 44. Order 14042 applies to all federal government service contractors and subcontractors operating on new contracts issued after the date of the order, or on extensions, renewals, or exercised options which occur on existing contracts on or after October 15, 2021. Exec. Order No. 14043, at §§ 5.(a), 6.(a). Agencies are "strongly encouraged" to implement the Order on all applicable existing contracts. *Id.*, at § 6.(c). The Order directs the Task Force to provide "explanations of protocols required of contractors and subcontractors to comply with workplace safety guidance." *Id.*, at § 2.(b).
- 45. With respect to Order 14042, the Task Force prescribes:

Prior to contractor employees being subject to a contractual requirement to be vaccinated, agencies need to ask about the vaccination status of those onsite contractor employees. Onsite contractor employees must attest to the truthfulness of the response they provide. If an onsite contractor employee chooses not to provide a response, they will be treated as not fully vaccinated for the purpose of agency safety protocols.<sup>20</sup>

46. The Task Force further advises:

Agencies are strongly encouraged to incorporate vaccination requirements into contracts that are not covered by Executive Order 14042, consistent with applicable law. This might include, for example, incorporating vaccination requirements into contracts in advance of when they are otherwise required by the Executive Order or incorporating requirements into contracts that are not covered by the Executive Order.<sup>21</sup>

<sup>20</sup> See Safer Federal Work Force, Frequently Asked Questions, n. 7, *supra*.

<sup>&</sup>lt;sup>19</sup> FDA, *Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine*, available at: <u>https://www.fda.gov/media/144413/download</u> (last visited Oct. 8, 2021); FDA, *Moderna COVID-19 Vaccine Fact Sheet for Health Care Providers*, available at: <u>https://www.fda.gov/media/144637/download</u> (last visited Oct. 8, 2021); CDC, Janssen COVID-19 Vaccine, available at: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html</u> (last visited Oct. 8, 2021).

<sup>&</sup>lt;sup>21</sup> *Id*.

47. Each Agency has implemented this guidance in its dealings with contractors and have indicated that any contractor who is not vaccinated will be removed from the respective contract.

## **Evolving Science: Vaccinated v. Unvaccinated**

## No Difference in Viral Load

48. At the time the Executive Orders were issued, it was presumed that the unvaccinated, not the vaccinated, were the sole source of COVID-19 spread. Recent studies suggest otherwise. On September 29, 2021, a preliminary report from a study conducted by the Genome Center, University of California, Davis, stated that a review of both vaccinated and unvaccinated individuals resulted in the following:

A total of 869 samples, 500 from HYT and 369 from UeS, were included in the analysis. All analyzed samples from HYT were asymptomatic at the time of collection and 75% of the positive samples were from unvaccinated individuals (N=375). Positive samples from UeS were from both symptomatic (N=237) and asymptomatic individuals (N=132). The frequency of vaccine breakthroughs among the UeS samples (171 fully vaccinated, 198 unvaccinated) was greater than among the HYT samples reflecting the different types of populations sampled. The Delta variant was the predominant variant detected in both populations (Supplementary Table 1).

There were no statistically significant differences in mean [cycle threshold] Ctvalues of vaccinated (UeS: 23.1; HYT: 25.5) vs. unvaccinated (UeS: 23.4; HYT: 25.4) samples. In both vaccinated and unvaccinated, there was great variation among individuals, with Ct-values of 30 in both UeS and HYT data (Fig. 1A, 1B). Similarly, no statistically significant differences were found in the mean Ct-values of asymptomatic (UeS: 24.3; HYT: 25.4) vs. symptomatic (UeS: 22.7) samples, overall or stratified by vaccine status (Fig. 1B). Similar Ct-values were also found among different age groups, between genders, and vaccine types (Supplemental Figure 1).

In all groups, there were individuals with low Ct-values indicative of high viral loads. A total of 69 fully vaccinated individuals had Ct-values <20. Of these, 24 were asymptomatic at the time of testing.

Exhibit 1, at 6. The study goes on to note:

A substantial proportion of asymptomatic, fully vaccinated individuals in our study had low Ct-values, indicative of high viral loads. Given that low Ct-values are indicative of high levels of virus, culture positivity, and increased transmission [11], our detection of low Ct-values in asymptomatic, fully vaccinated individuals is consistent with the potential for transmission from breakthrough infections prior to any emergence of symptoms.

*Id.* at 7.

49. The findings of this study were consistent with others conducted in Massachusetts and Singapore, in which "individuals with vaccination breakthroughs caused by the Delta variant had similar Ct-values as unvaccinated individuals." *Id*. Ultimately, this means the unvaccinated individual who contracts COVID-19 and has the same Ct-values as a vaccinated person who contracts COVID-19 is no more likely to spread the virus than the vaccinated individual.

## The Efficacy of Natural Immunity

50. The internet is replete with multiple studies confirming the lasting immunity to COVID-19 experienced by individuals who have previously contracted COVID-19. One notable one is from the Cleveland Clinic, which found that individuals previously infected with COVID-19 did not suffer reinfection, and that ultimately, "Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination." Exhibit 2, at 2.

## Genetic Variance

51. For purposes of the ADA and Rehabilitation Act (which require "individual assessments" to determine "direct threat"), one of the most informative studies (published in July 2021) researched why some individuals, to include those living in the same households, had drastically different reactions to the virus, with some contracting the illness and becoming sick and/or symptomatic, and others not contracting the virus at all. The study found that it is

the "genetic makeup of an individual [that] contributes to susceptibility and response to viral infection." Exhibit 3, at 1.

## FIRST CAUSE OF ACTION (Administrative Procedure Act)

## Agency Implementation of Executive Orders 14042 and 14043 Require Employers to Conduct Unlawful Medical Inquiries in Violation of the Rehabilitation Act and ADA.

- 52. All preceding paragraphs are incorporated by reference as though fully set forth herein.
- 53. The APA permits federal District Courts to review Presidential Executive Orders as they are implemented by the Agencies; the federal District Courts have authority to enjoin the Agencies from enforcing unlawful Executive Orders.
- 54. Both Orders are in violation of statutes, as they require the Agencies to conduct unlawful medical inquires.
- 55. Employers cannot conduct disability-related inquiries of employees that are not shown to be job related or consistent with business necessity. An inquiry is determined to be job related and consistent business necessity when the employer has a reasonable belief, based on objective evidence, that the employee will pose a direct threat due to a medical condition.
- 56. "The determination that an employee poses a direct threat must be based on an individualized assessment of the employee's present ability to safely perform the essential functions of the job." 29 C.F.R. § 1630.2(r).
- 57. "This assessment shall be based on a reasonable medical judgment that relies on the most current medical knowledge and/or on the best available objective evidence." *Id*.
- 58. Factors for this consideration include:
  - (1) The duration of the risk;
  - (2) The nature and severity of the potential harm;

### Case 1:21-cv-02779-TSC Document 1 Filed 10/19/21 Page 18 of 22

(3) The likelihood that the potential harm will occur; and

(4) The imminence of the potential harm.

- Id.
- 59. Under this mandate, as being implemented by the Agencies, no such individual can, or will, be conducted, thus making the requirement to inform of one's vaccine status in the first instance, and unlawful disability-related inquiry.
- 60. A disability-related inquiry is one that seeks to determine if the individual has a disability. Communicable diseases are considered disabilities. *School Bd. of Nassau County, Fla. v. Arline*, 480 U.S. 273, 289 (1987). By its very nature, requiring an individual to be vaccinated assumes that at some point the unvaccinated individual will contract COVID-19, a communicable disease.
- 61. But this inquiry cannot be deemed job related because there is no individual assessment being performed to determine individual threat. The rigidity of the vaccination mandate *i.e.*, receive the vaccine or face termination—does not allow for this necessary, individualized assessment.
- 62. Not only does the science indicate that to whom and how the disease can be contracted varies by individuals, but there is now indication that regardless of this disparity, there is no difference in potential for transmission by a vaccinated versus an unvaccinated individual who does contract the disease.
- 63. The science is nuanced, and so is an individual assessment. Because the mandates, as implemented by the Agencies, do not allow for this individual assessment, the mandates, as they are being implanted by the Agencies, result in a direct violation of the Rehabilitation Act and the ADA.

64. Accordingly, because the mandates, as implanted by the Agencies, are in direct violation of controlling law, this Court must declare the mandates unlawful and enjoin the Agencies from enforcing them.

# SECOND CAUSE OF ACTION (Administrative Procedure Act)

## Agency Implementation of Executive Orders 14042 and 14043 Require Employers to Discriminate Based on a Perceived Disability.

- 65. All preceding paragraphs are incorporated by reference as though fully set forth herein.
- 66. The APA permits federal District Courts to review Presidential Executive Orders as they are implemented by the Agencies; the federal District Courts have authority to enjoin the Agencies from enforcing unlawful Executive Orders.
- 67. Both Orders are in violation of statutes, as they require the Agencies to discriminate against individuals on the basis of a perceived disability.
- 68. Both the Rehabilitation Act and the ADA prohibit discrimination of federal employees and federal government contractors on the basis of a perceived disability.
- 69. Communicable diseases are considered disabilities. Through the issuance of these mandates, it is presumed that an unvaccinated individual at some point will contract COVID-19, a communicable disease.
- 70. Each Agency, in wholly adopting the Task Force's guidance, has stated that refusal to receive the vaccination will result in termination of employment or removal from a contract. In other words, the Agency presumes that at some point, the unvaccinated individual will contract COVID-19, and is terminating the individual (or in the case of contractors, removing the contractor from the contract with the Agency) on this presumption alone.
- 71. This is discrimination based on a perceived disability. For this reason, the mandates, as being

implemented by the Agency, cause the Agencies to violate long-standing statutes, and therefore must be found unlawful. This Court should declare the mandates unlawful, and enjoin the Agencies from enforcing the mandates.

# THIRD CAUSE OF ACTION (Administrative Procedure Act)

## **Executive Orders 14042 and 14043, as Implemented by the Agencies, Violates the FDCA by Requiring Individuals to Involuntarily Receive an Unlicensed Vaccine.**

- 72. All preceding paragraphs are incorporated by reference as though fully set forth herein.
- 73. The APA permits federal District Courts to review Presidential Executive Orders as they are implemented by the Agencies; the federal District Courts have authority to enjoin the Agencies from enforcing unlawful Executive Orders.
- 74. Defendant Agencies are using both Orders to force federal employees and contractors to receive COVID-19 vaccines.
- 75. Not one single vaccine available in the United States is FDA licensed; each has only been granted an emergency use authorization status.
- 76. The FDCA clearly proscribes that a vaccine which has been authorized for emergency use only may not be administered to an individual unless the individual is given an opportunity to refuse or accept the vaccine. In other words, the individual must be given the opportunity to engage in informed consent to the vaccine.
- 77. By requiring each federal employee and contractor to receive an unlicensed vaccine that has been authorized for emergency use only, the Orders, as implemented by the Agencies, have simply bypassed this statutory requirement.
- 78. Accordingly, this Court should find and declare the Orders unlawful as they are in violation of the FDCA, and further enjoin the Agencies from implementing the unlawful orders.

## **RELIEF**

Wherefore, Plaintiffs respectfully pray that this Honorable Court:

- Declare the Orders unlawful as they violate the Rehabilitation Act and ADA by requiring the Agencies to undertake unlawful medical inquiries;
- Declare the Orders unlawful as they violate the Rehabilitation Act and ADA by requiring the Agencies to discriminate against individuals based on a perceived disability;
- Declare the Orders unlawful as they violate the FDCA's requirement for informed consent and opportunity to refuse an FDA unlicensed vaccine;
- 4. Issue a nationwide order preliminarily and permanently enjoining the Agencies from enforcing Executive Orders 14042 and 14043;
- Award reasonable attorneys' fees and allowable costs under the Equal Access to Justice Act; and
- 6. Award any further relief this Honorable Court deems necessary or appropriate in order to accord full and complete relief.

Dated: October 19, 2021

Respectfully submitted,

<u>/s/ Eric. S. Montalvo</u> Eric S. Montalvo, DC Bar No. 993206 FEDERAL PRACTICE GROUP 1750 K Street N.W., Suite 900 Washington, D.C. 20006 Telephone: (202)862-4360 Facsimile: (888)899-6053 emontalvo@fedpractice.com

<u>/s/ Carol A. Thompson</u> Carol A. Thompson, DC Bar No. 1658143 FEDERAL PRACTICE GROUP 1750 K Street N.W., Suite 900 Washington, D.C. 20006 Telephone: (202)862-4360 Facsimile: (888)899-6053 cthompson@fedpractice.com *Application for Admission Pending* 

Counsel for Plaintiff