IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

STEVEN CHURCH; LESLEY CHURCH, ALMA GONZALEZ, DYNIKA BARNWELL, DOUGLAS CZERWINSKI, JASON COFFEY, JOSHUA SCHMIDT, MELINA ROYER, TAMIKA WALLS, JAIME ESPITIA, SOMER STEPHENS, ALEX BERNE, ALAN CAMP, STEPHANIE PERROTTA, CHRISTOPHER AXTELL, GRACE BROWN, KRISTOFOR HALLFRISCH, DOROTHY MORGAN, ANDREW SOTO, and CHRISTOPHER HALL, 1

Plaintiffs,

v.

JOSEPH R. BIDEN, in his official capacity as President of the United States,

The White House 1600 Pennsylvania Ave NW 1st Floor, West Wing Washington, D.C. 20500;

LLOYD J. AUSTIN III, in his official capacity as Secretary of the Department of Defense

1000 Defense Pentagon, Room 3E880 Washington, D.C. 20301;

ANTONY J. BLINKEN, in his official capacity as Secretary of State

The Executive Office Suite 5.600 600 19th Street NW Washington, D.C. 20522

JANET YELLEN, in her official capacity as Secretary of Treasury

1500 Pennsylvania Avenue NW

Civil Action No.: 1:21-cv-2815

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

¹ Plaintiffs contemporaneously file a Motion to Proceed under Pseudonym to Omit Home Addresses from the Complaint. See LCvR 5.1(c)(1).

Room 2134 Washington, D.C. 20220

MERRICK B. GARLAND, in his official capacity as Attorney General of the United States

950 Pennsylvania Avenue NW Washington, D.C. 20530

DEBRA ANN HAALAND, in her official capacity as Secretary of the Interior 1849 C Street NW Washington, D.C. 20240

THOMAS J. VILSACK, in his official capacity as Secretary of Agriculture 1400 Independence Avenue SW Washington, D.C. 20250

GINA M. RAIMONDO, in her official capacity as Secretary of Commerce 1401 Constitution Ave NW Washington, D.C. 20230

MARTIN J. WALSH, in his official capacity as Secretary of Labor 200 Constitution Avenue NW Washington, D.C. 20210

XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services 200 Independence Avenue SW Washington, D.C. 20201;

MARCIA L. FUDGE, in her official capacity as Secretary of Housing and Urban Development 451 7th Street SW Washington, DC 20410

PETER BUTTIGIEG, in his official capacity as Secretary of Transportation 1200 New Jersey Avenue SE Washington, DC 20590

JENNIFER M. GRANHOLM, in her official capacity as Secretary of Energy 1000 Independence Avenue SW Washington, D.C. 20585

MIGUEL CARDONA, in his official capacity as Secretary of Education 400 Maryland Avenue SW Washington, DC 20202

DENIS McDONOUGH, in his official capacity as Secretary of Veteran Affairs 810 Vermont Ave NW Washington, D.C. 20420

ALEJANDRO MAYORKAS, in his official capacity as Secretary of Homeland Security 2707 Martin Luther King Jr. Avenue SE Washington, D.C. 20528

CLARENCE W. NELSON II, in his official capacity as Administrator of the National Aeronautics and Space Administration 300 E Street SW Washington, D.C. 20546

KILOLO KIJAKAZI, in her official capacity as Acting Commissioner of the Social Security Administration
Office of General Counsel, Room 617
6401 Security Boulevard
Baltimore, MD 21235

ROBIN CARNAHAN, in her official capacity as Administrator of General Services Administration
1800 F Street NW
Washington, DC 20405

Defendants.

COMES NOW, Plaintiffs Steven Church, Lesley Church, Alma Gonzalez, Dynika Barnwell, Douglas Czerwinski, Jason Coffey, Joshua Schmidt, Melina Royer, Tamika Walls, Jaime Espitia, Somer Stephens, Alex Berne, Alan Camp, Stephanie Perrotta, Christopher Axtell, Grace Brown, Kristofor Hallfrisch, Dorothy Morgan, Andrew Soto, and Christopher Hall (collectively, "Plaintiffs"), by and through undersigned counsel, and file this action against Defendants Joseph R. Biden, in his official capacity as President of the United States, Lloyd J. Austin III, in his official capacity as Secretary of the Department of Defense, Antony J. Blinken, in his official capacity as Secretary of State, Janet Yellen, in her official capacity as Secretary of Treasury, Merrick B. Garland, in his official capacity as Attorney General of the United States, Thomas J. Vilsack, in his official capacity as Secretary of Agriculture, Gina M. Raimondo, in her official capacity as Secretary of Commerce, Martin J. Walsh, in his official capacity as Secretary of Labor, Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services, Marcia L. Fudge, in her official capacity as Secretary of Housing and Urban Development, Peter Buttigieg, in his official capacity as Secretary of Transportation, Jennifer N. Granholm, in her official capacity as Secretary of Energy, Miguel Cardona, in his official capacity as Secretary of Education, Denis McDonough, in his official capacity as Secretary of Veteran Affairs, Alejandro Mayorkas, in his official capacity as Secretary of Homeland Security, Clarence W. Nelson II, in his official capacity as Administrator of the National Aeronautics and Space Administration, Kilolo Kihakazi, in her official capacity as Acting Commissioner of the Social Security Administration, and Robin Carnahan, in her official capacity as Administrator of General Services Administration (collectively, "Defendants" or "federal government") on the grounds and in the amount set forth as follows:

URGENCY OF THIS ACTION REQUIRES EMERGENCY RELIEF

For nearly two months, the Task Force created by President Biden and the various executive agencies have pointed fingers at each other as to why "no guidance" has been issued.

Plaintiffs, who are federal executive agency employees and active-duty service members file this action against President Biden and the head of each of their respective agencies to put an end to Defendants abject failure to execute their duties in accord with the U.S. Constitution and federal statutory law. Irrespective as to who has refused to promulgate the guidance and accommodate Plaintiffs' sincerely held religious beliefs, Plaintiffs have now sat all responsible parties down at the same table.

Plaintiffs have sincerely held religious beliefs that prohibit them from complying with the vaccine mandate imposed by President Biden by signing Executive Order 14043 on September 9, 2021 ("E.O. 14043") or Secretary of Defense Lloyd Austin III's Order issued on August 24, 2021. ("DoD Order") (collectively, "Vaccine Mandates"). Absent the relief requested, Plaintiffs, along with hundreds of thousands of other federal employees and active-duty service members will be terminated, discharged or separated on or before **November 22, 2021**.

While reasonable minds can disagree as to the magnitude of the COVID-19 pandemic, the Supreme Court reminds us that "even in a pandemic, the Constitution cannot be put away and forgotten." Roman Catholic Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 68 (2021) (emphasis added). Contemporaneous with the commencement of this action Plaintiffs have filed an Application for a Temporary Restraining Order ("TRO") and Preliminary Injunction to maintain the status quo of our federal governmental operations and to put an end to this involuntary game of Monty Hall millions of Americans have been compelled to involuntary play. And while the

² To be "fully vaccinated" by the deadline of November 22, 2021, Plaintiffs (and all other federal employees) must receive (1) the second dose of the two-dose BioNTech and Moderna vaccine series; or (2) the J&J single-dose vaccine no less than two weeks prior to November 22; thus, **the salient date relevant for the emergency relief requested is** November 8, 2021. As of the date of this filing, the Johnson & Johnson ("J&J") shot is the only vaccine available to Plaintiffs that satisfies the rapidly approaching November 22 deadline. The J&J vaccine is not FDA-approved.

currency of this game is not exclusively money but also the rights to life, liberty, and property, it would be imprudent to not address the magnitude of the economic impact of this case.

To summarize:

First, E.O. 14043 on its face states that "the Pfizer-BioNTech COVID-19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA) and this is patently false.³

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA)

Second, E.O. 14043 facially only applies to *some* federal employees of the Executive Brach; specifically, E.O. 14043 only applies to the "agencies" as defined by 5 U.S.C. § 105 – it does not apply to federal employees of the Executive Brach who work for the White House, the Food & Drug Administration, or the National Institute of Health, among others.

Third, some federal executive "agency" employees, such as Plaintiff Hallfrisch, have received religious accommodations while all other federal Executive Branch employees who share identical religious beliefs have *not* received religious accommodations;

Fourth, the only available COVID-19 vaccines are only available under EUA; not full-licensure and therefore, as recipients of EUA-authorized medical products, Plaintiffs must "[be] informed . . . [of] the **option to accept or refuse administration of the product**." See FDCA § 564(e)(1)(A)(ii)(III); and

Fifth, DoD personnel have (1) repeatedly lied to active-duty service members about the product used for inoculation; (2) lied in claiming the DoD would receive the FDA-approved

³ The Food and Drug Administration, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), available at: https://www.fda.gov/media/144414/download

COMIRNATY "early next week" (i.e., prior to Sept. 3); (3) the Director of the DiLorenzo Clinic confirmed that as of October 15, 2021, "Pfizer has not made any Comirnaty" and "[t]here is no expected date when [the DoD] will receive Comirnaty" and the DoD OIG COVID-19 Coordinator has confirmed that the Pentagon does not have COMIRNATY nor does it know when, if ever, it will receive it; (4) DoD official medical immunization records falsely reflect that COMIRNATY has been administered despite it never being in the DoD's possession; and (5) Defendants Biden and Austin have deprived Plaintiffs 1st Lt. Soto and Cpl. Hall's requests for accommodations for their sincerely held religious beliefs have been denied unlawfully and they now face administrative separation and are subject to adverse administrative disciplinary action because of their religious sincerely held beliefs and absent any "undue hardship" imposed on Defendants by accommodating Plaintiffs beliefs.

Absent the injunctive relief Plaintiffs request herein, Plaintiffs will suffer irreparable harm as their fundamental rights are trampled and they lose their jobs for no reason beyond their sincerely held religious beliefs. If Defendants are not enjoined from enforcing the Vaccine Mandates, hundreds of thousands of federal workers and military personnel will be forcibly removed from our government and Armed Forces, thrusting our nation into a state more vulnerable than the United States has experienced in a quarter of a millennium. Allowing Defendants to continue enforcing the Vaccine Mandate that was issued to save lives will only cause more lives to be lost, or at the very minimum, subject 360 million American lives to dangers far greater than COVID-19.

To do so would be unfathomable.

⁴ *See infra*, ¶135.

JURISDICTION & VENUE

- 1. This action arises under the Free Exercise Clause of the First Amendment, the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb to 2000bb-4, ("RFRA"), the Equal Protection Clause of the Fifth Amendment to the United States Constitution, and under the Emergency Use Authorization provisions of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 ("FDCA").
 - 2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 1343(a).
- 3. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this district.
- 4. This Court is authorized to grant declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, implemented through Fed. R. Civ. P. 57.

PARTIES

I. PLAINTIFFS

5. Plaintiff Steven D. Church ("Mr. Church") is an adult resident of Virginia and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Church serves as the Staffing Recruitment and Operations Center ("SROC") Director under the Assistant Secretary of Administration for the Department of Health and Human Services ("HHS"). Prior to serving in this capacity, Mr. Church has served our government for twenty-five (25) years, first as an active-duty service member in the 101st Airborne Division of the United States Army followed by more than two decades of service as a civilian federal employee. Mr. Church is also an ordained minister and a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Church lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United

States and Xavier Becerra, in his official capacity as Secretary of the Department Health and Human Services.

- 6. Plaintiff Lesley Church ("Mrs. Church") is an adult resident of Virginia and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mrs. Church serves as the Director of Operational Support for the Office of the Inspector General ("OIG") for the United States Department of Defense ("DoD"). Mrs. Church also serves as the DoD OIG COVID-19 coordinator and is responsible for *inter alia* coronavirus case reporting and tracking and coordinated and scheduled vaccinations for DOD OIG employees. Following up on behalf of employees' inquiries about COMIRNATY availability, Mrs. Church was informed that the Pentagon does not have COMIRNATY and does not know when COMIRNATY will be available. Additionally, Mrs. Church is a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Mrs. Church lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Lloyd J. Austin III, in his official capacity as Secretary of the Department of Defense.
- 7. Plaintiff Alma Gonzalez is an adult resident of Georgia and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Gonzalez is a Contact Representative for the U.S. Department of Treasury ("USDT"). Ms. Gonzalez is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Gonzalez lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Janet Yellen, in her official capacity as Secretary of Treasury.
 - 8. Plaintiff Dynika Barnwell is an adult resident of Maryland and a federal employee

within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Barnwell is a Budget Analyst for the U.S. Department of Commerce ("DOC"). Ms. Barnwell is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Barnwell lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Gina M. Raimondo, in her official capacity as Secretary of Commerce.

- 9. Plaintiff Douglas Czerwinski is an adult resident of Florida and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Czerwinski is an AST in Experimental Facility Development for the U.S. National Aeronautics and Space Administration ("NASA"). Mr. Czerwinski is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Czerwinski lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Clarence W. Nelson II, in his official capacity as Administrator of the National Aeronautics and Space Administration.
- 10. Plaintiff Jason Coffey is an adult resident of California and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Coffey is a Special Agent for the Federal Bureau of Investigation ("FBI"), an agency within the U.S. Department of Justice ("DOJ"). Special Agent Coffey is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Special Agent Coffey lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Merrick B. Garland, in his official capacity as Attorney General of the United States.
 - 11. Plaintiff Joshua Schmidt is an adult resident of Illinois and a federal employee

within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Schmidt is a Customs and Border Protection Agent for the U.S. Department of Homeland Security ("DHS"). Mr. Schmidt is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Schmidt lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Alejandro Mayorkas, is his official capacity as the Secretary of the Department of Homeland Security.

- 12. Plaintiff Melina Royer is an adult resident of Louisiana and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Royer is a Conservationist for the U.S. Department of Agriculture ("USDA"). Ms. Royer is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Royer lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Thomas J. Vilsack, in his official capacity as Secretary of Agriculture.
- 13. Plaintiff Tamika Walls is an adult resident of Virginia and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Walls is a Senior Program Analyst for the U.S. Department of Housing and Urban Development ("HUD"). Ms. Walls is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Walls lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Marcia L. Fudge, in her official capacity as Secretary of Housing and Urban Development.
- 14. Plaintiff Jaime Espitia is an adult resident of Illinois and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Espitia is an Investigator for the

Occupational Safety and Health Administration ("OSHA"), an agency within the U.S. Department of Labor ("DOL"). Mr. Espitia is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Espitia lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Martin J. Walsh, in his official capacity as Secretary of Labor.

- 15. Plaintiff Somer Stephens is an adult resident of Tennessee and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Stephens is a General Engineer for the U.S. Department of Energy ("DOE"). Ms. Stephens is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Stephens lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Jennifer N. Granholm, in her official capacity as Secretary of Energy.
- 16. Plaintiff Alex Berne is an adult resident of Florida and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Berne is a Claims Specialist for the U.S. Social Security Administration ("SSA"). Mr. Berne is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Berne lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Kilolo Kijakazi is the Acting Commissioner of the Social Security Administration.
- 17. Plaintiff Alan Camp is an adult resident of Colorado and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Camp is a Project Manager for the U.S. General Services Administration ("GSA"). Mr. Camp is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs.

Mr. Camp lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Robin Carnahan, in her official capacity as Administrator of General Services Administration.

- 18. Plaintiff Stephanie Perrotta is an adult resident of New York and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Perrotta is a Veterans and Military Crisis Line Social Service Assistant for the U.S. Department of Veterans Affairs ("VA"). Ms. Perrotta is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Perrotta lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Denis McDonough, in his official capacity as Secretary of Veteran Affairs
- 19. Plaintiff Christopher Axtell is an adult resident of Iowa and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Axtell is an Operations Supervisor for Air Traffic Control within the U.S. Department of Transportation ("DOT"). Mr. Axtell is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Mr. Axtell lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Peter Buttigieg, in his official capacity as Secretary of Transportation.
- 20. Plaintiff Grace Brown is an adult resident of Maryland and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Brown is a Management Analyst for the U.S. Department of Education ("DoED"). Additionally, Ms. Brown is also a devout Christian who cannot in morality receive the vaccine without compromising her closely held religious beliefs. Ms. Brown lodges all counts in this four (4) count Verified Complaint against

Defendants Joseph R. Biden, in his official capacity as President of the United States and Miguel Cardona, in his official capacity as Secretary of Education.

- Plaintiff Kristofor Hallfrisch is an adult citizen of the United States domiciled in 21. the State of Texas and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Mr. Hallfrisch is a Special Agent for the U.S. Department of State ("DOS"). Mr. Hallfrisch is also a devout Christian who cannot in morality receive the vaccine without compromising his closely held religious beliefs. Because of his sincerely held religious beliefs, DOS granted Special Agent Hallfrisch a religious exemption and accommodation in accord with constitutional and federal statutory law and the provisions of E.O. 14043. Special Agent Hallfrisch's accommodation does not change his work environment, it does not impact his ability to dutifully perform the functions of his job, and otherwise impose no burden or undue hardship on his employer. DOS merely stated Special Agent Hallfrisch is to abide by CDC guidance. Despite this, however, President Biden and Secretary Blinken, by and through their officers, agents, or subordinates, have continued to engage in a relentless barrage of demands that Special Agent Hallfrisch provide information about his religion. However, on October 11, 2021, the Department of State attempted to revoke the exemption and accommodation to which he is lawfully entitled. Special Agent Hallfrisch lodges Count IV of this four (4) count Verified Complaint against Defendant Joseph R. Biden, in his official capacity as President of the United States and Secretary Blinken, in his official capacity as Secretary of State.
- 22. Plaintiff Dorothy Morgan is an adult resident of Maryland and a federal employee within the meaning intended pursuant to E.O. 14043. Specifically, Ms. Morgan is a Training Administrator for the Bureau of Land Management, an agency within the U.S. Department of Interior ("DOI"). Ms. Morgan is also a devout Christian who cannot morally receive the vaccine

without compromising her closely held religious beliefs. Ms. Morgan lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Debra Ann Haaland, in her official capacity as Secretary of the Interior.

- 23. Plaintiff Andrew Soto is an adult resident of North Carolina and an active-duty service member within the meaning of the Vaccine Mandate Secretary Austin issued on August 24, 2021. Specifically, Mr. Soto is a First Lieutenant in the United States Marine Corps and a devout Christian who cannot morally receive the vaccine without compromising his closely held religious beliefs. In light of his religious beliefs, First Lieutenant Soto submitted a request for a religious exemption four days later, on August 28, 2021; however, on September 29, 2021, the Department of the Navy denied First Lieutenant Soto's request. As such, First Lieutenant Soto lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Lloyd J. Austin III, in his official capacity as Secretary of Defense.
- 24. Plaintiff Christopher Hall is an adult resident of Illinois and an active-duty service member within the meaning of the Vaccine Mandate Secretary Austin issued on August 24, 2021. Specifically, Mr. Hall is a Corporal in the United States Marine Corps and a devout Christian who cannot morally receive the vaccine without compromising his closely held religious beliefs. In light of his religious beliefs, Corporal Hall submitted a request for a religious exemption four days later, on August 28, 2021; however, on September 29, 2021, the Department of the Navy denied Corporal Hall's request. As such, Corporal Hall lodges all counts in this four (4) count Verified Complaint against Defendants Joseph R. Biden, in his official capacity as President of the United States and Lloyd J. Austin III, in his official capacity as Secretary of Defense.

II. DEFENDANTS

Defendant Joseph R. Biden is the President of the United States, and he is sued in his official capacity. As President, Defendant Biden is the head of the federal government and Commander-in-Chief of the United States Armed Forces, and is responsible for enacting, implementing, and enforcing the Vaccine Mandates. On his first day in office, President Biden signed Executive Order 13991 ("E.O. 13991") and created the Safter Federal Workforce Task Force ("Task Force") which, under Defendant Biden's authority, promulgates and issues all policy-related guidance to the varies heads of the agencies defined by 5 U.S.C. § 105.

26. Defendant Lloyd J. Austin III is the Secretary of the Department of Defense ("DoD") and he is sued in his official capacity. On or about August 24, 2021, Secretary Austin issued a DoD Order that operates as a blanket vaccination mandate for all active-duty service members and is responsible for overseeing and ensuring that his order complies with the United States Constitution and federal statutory law, including requirements that *inter alia* all active-duty military personnel are afforded their constitutional rights, including the right to freely exercise their religion. Defendant Austin is also responsible for supervising all civilian DoD employees and the branches of the U.S. Armed Forces concerning the promulgation, implementation, and enforcement of the policies and regulations that govern military service in all branches of the U.S. Armed Services and Departments, including the Department of the Army, Department of the Navy,⁵ and Department of the Air Force;⁶ and for ensuring the legality of these policies and regulations. In this role, he is responsible for the maintenance and enforcement of the Departments of the Military, including all medical and records departments related to the Pentagon, DiLorenzo Clinic, or TRICARE program.

⁵ The Department of the Navy has jurisdiction over the United States Marines Corps.

⁶ The Department of the Air Force has jurisdiction over the United States Air Force and United States Space Force.

- Defendant Antony J. Blinken is the Secretary of State ("DOS") and he is sued in his official capacity. Secretary Blinken is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOS. In this capacity, Secretary Blinken issued a directive, in accordance with E.O 14043, mandating that all DOS employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Blinken has taken steps to ensure that no DOS employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- Defendant Janet Yellen is the Secretary of Treasury ("USDT") and she is sued in her official capacity. Defendant Yellen is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of USDT. In this capacity, Defendant Yellen issued a directive, in accordance with E.O 14043, mandating that all USDT employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Yellen has taken steps to ensure that no USDT employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 29. Defendant Merrick B. Garland is the Attorney General of the United States and the head of the Department of Justice ("DOJ") and he is sued in his official capacity. Defendant Garland is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOJ. In this capacity, Defendant Garland issued a directive, in accordance with E.O 14043, mandating that all DOJ employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task

Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Garland has taken steps to ensure that no DOJ employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

- 30. Defendant Debra Ann Haaland is the Secretary of the Interior ("DOI") and she is sued in her official capacity. Defendant Haaland is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOI. In this capacity, Defendant Haaland issued a directive, in accordance with E.O 14043, mandating that all DOI employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Haaland has taken steps to ensure that no DOI employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 31. Defendant Thomas J. Vilsack is the Secretary of the Department of Agriculture ("USDA") and he is sued in his official capacity. Defendant Vilsack is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of USDA. In this capacity, Defendant Vilsack issued a directive, in accordance with E.O 14043, mandating that all USDA employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Vilsack has taken steps to ensure that no USDA employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 32. Defendant Gina Raimondo is the Secretary of the Department of Commerce ("DOC") and she is sued in her official capacity. Defendant Raimondo is responsible for

implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOC. In this capacity, Defendant Raimondo issued a directive, in accordance with E.O 14043, mandating that all DOC employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Raimondo has taken steps to ensure that no DOC employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

- 33. Defendant Martin J. Walsh is the Secretary of the Department of Labor ("DOL") and he is sued in his official capacity. Defendant Walsh is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOL. In this capacity, Defendant Walsh issued a directive, in accordance with E.O 14043, mandating that all DOL employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Walsh has taken steps to ensure that no DOL employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 34. Defendant Xavier Becerra is the Secretary of the Department of Health and Human Services ("HHS") and he is sued in his official capacity. Defendant Becerra is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of HHS. In this capacity, Defendant Becerra issued a directive, in accordance with E.O 14043, mandating that all HHS employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Becerra has taken steps to

ensure that no HHS employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

- 35. Defendant Marcia L. Fudge is the Secretary of the Department of Housing and Urban Development ("HUD") and she is sued in her official capacity. Defendant Fudge is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of HUD. In this capacity, Defendant Fudge issued a directive, in accordance with E.O 14043, mandating that all HUD employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Fudge has taken steps to ensure that no HUD employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 36. Defendant Peter Buttigieg is the Secretary of the Department of Transportation ("DOT") and he is sued in his official capacity. Defendant Buttigieg is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOT. In this capacity, Defendant Buttigieg issued a directive, in accordance with E.O 14043, mandating that all DOT employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Buttigieg has taken steps to ensure that no DOT employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 37. Defendant Jennifer M. Granholm is the Secretary of the Department of Energy ("DOE") and she is sued in her official capacity. Defendant Granholm is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DOE. In

that all DOE employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Granholm has taken steps to ensure that no DOE employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

- 38. Defendant Miguel Cardona is the Secretary of the Department of Education ("DoED") and he is sued in his official capacity. Defendant Cardona is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DoED. In this capacity, Defendant Cardona issued a directive, in accordance with E.O 14043, mandating that all DoED employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Cardona has taken steps to ensure that no DoED employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 39. Defendant Denis McDonough is the Secretary of the Department of Veterans Affairs ("V.A.") and he is sued in his official capacity. Defendant McDonough is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of V.A. In this capacity, Defendant McDonough issued a directive, in accordance with E.O 14043, mandating that all V.A. employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant McDonough has taken steps to ensure that no V.A. employee receives an exemption from the Vaccine Mandate for lawful

reasons, whether religious, medical, or otherwise.

- 40. Defendant Alejandro Mayorkas is the Secretary of the Department of Homeland Security ("DHS") and he is sued in his official capacity. Defendant Mayorkas is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of DHS. In this capacity, Defendant Mayorkas issued a directive, in accordance with E.O 14043, mandating that all DHS employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Mayorkas has taken steps to ensure that no DHS employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- A1. Defendant Clarence W. Nelson II is the Administrator of the National Aeronautics and Space Administration ("NASA") and he is sued in his official capacity. Defendant Nelson is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of NASA. In this capacity, Defendant Nelson issued a directive, in accordance with E.O 14043, mandating that all NASA employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Nelson has taken steps to ensure that no NASA employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.
- 42. Defendant Kilolo Kijakazi is the Acting Commissioner of the Social Security Administration ("SSA") and she is sued in her official capacity. Defendant Kijakazi is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of SSA. In this capacity, Defendant Kijakazi issued a directive, in accordance with E.O 14043, mandating

that all SSA employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Kijakazi has taken steps to ensure that no SSA employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

Administration ("GSA") and she is sued in her official capacity. Defendant Carhahan is responsible for implementing and enforcing the Vaccine Mandate for *inter alia* all federal employees of GSA. In this capacity, Defendant Carhahan issued a directive, in accordance with E.O 14043, mandating that all GSA employees be inoculated against COVID-19 or before November 22, 2021. As part of that directive, and in whole, in part, or in conjunction with the Task Force's acts, omissions pressures, instructions, directions, suggestions, or guidance, Defendant Carhahan has taken steps to ensure that no GSA employee receives an exemption from the Vaccine Mandate for lawful reasons, whether religious, medical, or otherwise.

STATEMENT OF FACTS

A. THE FEDERAL VACCINE MANDATES

44. On January 20, 2021, President Biden issued Executive Order No. 139917 ("E.O. 13991"), which *inter alia* established the Safer Federal Workforce Task Force ("Task Force") Among other things, E.O. 13991 states the Task Force "shall provide ongoing guidance to heads of agencies on the operation of the Federal Government . . . and shall address . . . vaccine administration [and] . . . circumstances under which exemptions might appropriately be made to agency policies in accordance with CDC guidelines, such as for mission-critical purposes." *Id.* §

⁷ Exec. Order 13991, see Exhibit 1.

4(e)(ix), (xii).

- 45. From his first day in office, as demonstrated in E.O. 13991, President Biden has revered CDC guidelines as the holy grail of not only medical authority–but *legal* authority, too. Indeed, the exemptions to agency policy should be promulgated in accordance with **the United States Constitution**, or at a minimum, federal statutory law.
- 46. On August 24, 2021, the day after the FDA-approved the COMIRNATY COVID-19 vaccine (as discussed further below), Secretary Austin issued a DoD Order⁸ requiring all active-duty servicemembers to be vaccinated against COVID-19 or face adverse employment action, up to and including dishonorable discharge.
- 47. On September 9, 2021, President Biden signed Executive Order No. 140439 ("E.O. 14043"), which *inter alia* ordered all agencies to implement a program "requiring COVID-19 vaccination for all of its federal employees, with exceptions only as required by law"¹⁰ (the "Vaccine Mandate"). In addition to making vaccination against COVID-19 a condition of employment for federal employees, E.O. 14043 also states, "the Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order."¹¹
- 48. On September 13, 2021, the Task Force published Guidance titled "COVID-19 Workplace Safety: Agency Model Safety Principles." The Guidance, entirely devoid of any

⁸ Sec. Austin, *Memorandum for SeniorPentagon Leadership Commanders of the Combatant Commands Defense Agency and DoD Field Activity Directors*, (Aug. 24, 2021); see Exhibit 2.

⁹ Exec. Order 14043; see Exhibit 3.

¹⁰ "Vaccine Mandate" shall mean "requiring COVID-19 vaccination for all of its federal employees, with exceptions only as required by law." Exec. Order No. 14043, § 2, 88 F.R. 175 (Sept. 9, 2021).

¹¹ "Requirement" shall mean the directive that "the Task Force shall issue guidance within 7 days of the date of [E.O. 14043] on agency implementation of programs "requiring COVID-19 vaccination for all of its federal employees, with exceptions only as required by law." *Id.*

¹² Safer Federal Workforce, COVID-19 Workplace Safety: Agency Model Safety Principles, WHITE HOUSE (Sept. 13, 2021); see Exhibit 4.

information as to religious exemptions: (1) sets a deadline of November 22 federal employees to be "fully vaccinated"; (2) reiterates the Biden Administration's policy for a "safer" federal workforce; and (3) delegates decision-making authority to the heads of each respective agency.¹³

49. Indeed, the Task Force violated E.O. 14043 on its face by not including guidance as to exceptions as provided by law–but the egregiousness as to *why* the Task Force refused to give the agencies guidance is conscious shocking.

B. THE TASK FORCE'S SCHEME TO CIRCUMVENT THE FIRST AMENDMENT AND DEPRIVE PLAINTIFF'S OF THEIR FREE EXERCISE OF RELIGION

- 50. Since the day President Biden issued the Vaccine Mandate, hundreds of thousands of federal government employees have been in complete disarray. Federal employees with serious, life-threatening conditions and others with sincerely held religious beliefs, such as Plaintiffs, have frantically sought guidance on how to obtain reasonable accommodations.
- 51. Due to the rapidly approaching deadline and Defendants' full awareness that Plaintiffs have the fundamental right to engage in the free exercise of religion, Defendants concocted a scheme that imposes a "deadline" to submit religious exemption requests to help "evaluate the scope" of how many federal employees have sincerely held religious beliefs prohibiting compliance with the vaccine requirement. After determining the scope, the Task Force instructed the agencies to "collect information" through a questionnaire calculated to elicit information the agencies can then use as the basis for denying a respondent's exemption request.
- 52. Video Footage from an October 8, 2021 Task Force Zoom call¹⁴ involving nearly 200 high-level officials from various agencies reveals Samuel Berger, a former Senior Advisor in

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¹³ The term "agency" means an Executive agency as defined in 5 U.S.C. § 105 (excluding the Government Accountability Office). *Id.* at § 3.

¹⁴ Samuel Berger, COVID-19 Guidance Zoom Meeting, SAFER FEDERAL WORKFORCE TASK FORCE (Oct. 8, 2021); see Exhibit 5.

the Obama Administration and the former Vice President of Democracy for John Podesta's Center for American Progress ("CAP") discussing the methodical approach each agency is to take when dealing with religious exemptions.

- 53. The Task Force advised each agency¹⁵ to establish a deadline which the agencies are not to enforce because there is no deadline imposed on the fundamental right to freely exercise religion but rather, to use as a "forcing function" that will induce all or nearly all federal employees with sincerely held religious beliefs to submit their requests.
- 54. Once all or nearly all federal employees have submitted their religious exemption requests, the agencies, individually or in conjunction with the Task Force, can then "evaluate the scope" of how many federal employees wish to exercise their fundamental right to freely exercise their religion.
- 55. The Task Force then directed the agencies to refrain from issuing any decisions, because "once you grant an exemption to an individual in a job category, it is very hard to say that you're not going to grant [an exemption] to a similarly situated person."
- 56. The Task Force further instructed the agencies to "take their time" and the agencies "should not feel rushed that they have to take steps immediately" because it is important to "collect information" on federal employees, such as Plaintiffs, whose sincerely held religious beliefs prohibit them from complying with the vaccine requirement.
- 57. To collect this information, the Task Force advised it provided the agencies with a religious exemption form with questions that are intended to elicit information from federal employees seeking religious exemptions. The Task Force directed the agencies to "work bearing"

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¹⁵ The term "agency" means an Executive agency as defined in 5 U.S.C. § 105 (excluding the Government Accountability Office). *See* Exec. Order No. 14043 at § 3. It does not include the White House ("WH"), Centers for Disease Control and Prevention ("CDC"), the National Institute of Health ("NIH").

in mind that a fair bit of thought went into the range of questions and the kind of information that [the questions] would provide." The Task Force then gives the agencies authority to refuse to provide accommodations under whatever circumstances each agency so chooses.

- 58. Rather than advising the agencies under what circumstances the refusal to provide an accommodation would constitute a violation of federal law or deprivation of fundamental rights, the Task Force merely emphasized how important it is for the agencies to "figure[e] it out as quickly as possible . . . because [the agencies are] not going to run an accommodation in those places—and that's totally fine."
- 59. As a result, Defendants have either failed to implement a process by which Plaintiffs and other federal employees are able to submit religious exemptions or implemented a process for Plaintiffs to provide information to Defendants to which they are not entitled in violation of current EEOC Guidance, federal statutory law, and Plaintiffs' fundamental First Amendment right to engage in the free exercise of religion.

C. PLAINTIFFS' RELIGIOUS EXEMPTION REQUESTS

60. On October 12, 2021, Mr. Church submitted to HHS a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Church articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Church has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for HHS or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Church is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident, including working from

home just as he has for the last 584 consecutive days. With such accommodations, Mr. Church remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity, and the aforesaid reasonable accommodation does not pose an undue hardship on his employer. Despite this, Mr. Church's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

61. On October 12, 2021, Mrs. Church submitted to the DoD a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Mrs. Church articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Mrs. Church has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the DoD or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Mrs. Church is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident, including working from home with minimal on-site visits where she wears a mask and socially distances. With such accommodations, Mrs. Church remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Mrs. Church's request for a religious exemption and accommodation has

not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

62. On September 29, 2021, Special Agent Hallfrisch submitted to the Deputy Chief of Mission of his assigned post at the U.S. Embassy in Djibouti a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Hallfrisch articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Hallfrisch has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for DOS or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Special Agent Hallfrisch is amenable to continuing to work in the environment he has worked since the outset of the pandemic, which he has done for nearly two years without incident. In fact, in July 2020, DOS even relocated Special Agent Hallfrisch and his family to Addis Ababa, Ethiopia on a commercial flight and then transported them to Djibouti on a private flight because the Djibouti airport remained closed due to the pandemic. Being that DOS went so far as to fund and utilize private air travel into a closed airport to accommodate Special Agent Hallfrisch, it is without a doubt that DOS can easily accommodate Special Agent Hallfrisch now-and indeed, DOS has done so. On September 29, 2021, the Deputy Chief of Mission at the U.S. Embassy in Dibouti informed Special Agent Hallfrisch that his religious exemption request had been approved:

Exemption Request Approval Top of Next Page

From: Tomaszewicz, Andrea J (Djibouti)

To: Hallfrisch, Kristofor R (Djibouti)

Subject: RE: Request for Reasonable Accommodation Date: Wednesday, September 29, 2021 4:47:13 PM

Dear Kris,

I approve your request for an exemption to the vaccine requirement. As part of this reasonable accommodation, I request that you follow CDC guidance for unvaccinated individuals. Should there be a situation where post guidance differs from CDC guidance, you and I will discuss on a case-by-case basis.

Please let me know if you have any questions or concerns.

Andrea

Andrea J. Tomaszewicz
Deputy Chief of Mission
U.S. Embassy Djibouti
tomaszewiczaj@state.gov
+253 (office)
+253 (mobile)

Special Agent Hallfrisch is fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has received clearly does not pose an undue hardship on his employer. Since October 11, 2021, however, President Biden and Secretary Blinken, by and through their directors, officers, agents, or subordinates, have engaged in a series of retaliatory and harassing behavior demanding to obtain irrelevant medical and religious information to which they are not lawfully entitled. As a result, and despite having a religious exemption that accommodates his religious beliefs, Special Agent Hallfrisch, imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising his sincerely held religious beliefs.

63. On October 8, 2021, Ms. Brown submitted to the DoED a request for religious

exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Brown articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Brown has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the DoED or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Brown is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. Ms. Brown rarely if ever interacts with others in person and if necessary, would be willing to self-check symptoms, wear a mask and social distance. With such accommodations, Ms. Brown remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Brown's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

64. Following the issuance of President Biden's Vaccine Mandate, Ms. Gonzalez submitted to the USDT a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Gonzalez articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Gonzalez has never exhibited or demonstrated

any behavior, and no factors exist, that give rise to an objective basis for the USDT or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Gonzalez is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Gonzalez remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Gonzalez's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

65. On October 7, 2021, Ms. Barnwell submitted to the DOC a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Barnwell articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Barnwell has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the DOC or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Barnwell is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Barnwell remains fully capable of performing the

essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Barnwell's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

66. On October 14, 2021, Mr. Czerwinski submitted to NASA a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Czerwinski articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Czerwinski has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for NASA or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Czerwinski is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. Since March 2020, Mr. Czerwinski has worked from home. When he is required to go on-site, Mr. Czerwinski has worn a mask, socially distanced, and wash his hands frequently. With such accommodations, Mr. Czerwinski remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity, and the aforesaid reasonable accommodation does not pose an undue hardship on his employer. Despite this, Mr. Czerwinski's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

67. On September 24, 2021, Special Agent Coffey submitted to the DOJ a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Special Agent Coffey articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Special Agent Coffey has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the DOJ or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Special Agent Coffey is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Special Agent Coffey remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Special Agent Coffey's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

- 68. Following the issuance of President Biden's Vaccine Mandate, Mr. Schmidt submitted to DHS a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Schmidt articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Schmidt has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for DHS or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Schmidt is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Mr. Schmidt remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Mr. Schmidt's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other lifealtering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.
- 69. Following the issuance of President Biden's Vaccine Mandate, Ms. Royer submitted to the USDA a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Royer articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Royer has never exhibited or demonstrated

any behavior, and no factors exist, that give rise to an objective basis for the USDA or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Royer is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Royer remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Royer's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

70. Following the issuance of President Biden's Vaccine Mandate, Ms. Walls submitted to HUD a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Walls articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Walls has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for HUD or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Walls is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Walls remains fully capable of

performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Walls' request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

71. Following the issuance of President Biden's Vaccine Mandate, Mr. Espitia submitted to DOL a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Espitia articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Espitia has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for DOL or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Espitia is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Mr. Espitia remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Mr. Espitia's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional

opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

- 72. Following the issuance of President Biden's Vaccine Mandate, Ms. Stephens submitted to DOE a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Stephens articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Stephens has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for DOE or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Stephens is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Stephens remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Stephens' request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.
- 73. Following the issuance of President Biden's Vaccine Mandate, Mr. Berne submitted to SSA a request for religious exemption from the Vaccine Mandate as an

accommodation of his sincerely held beliefs. Mr. Berne articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Berne has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for SSA or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Berne is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Mr. Berne remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Mr. Berne's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

74. Following the issuance of President Biden's Vaccine Mandate, Mr. Camp submitted to the GSA a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Camp articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Camp has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the GSA or any entity within the federal government to question either the nature or the sincerity of his religious beliefs,

observances, or practices. Mr. Camp is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Mr. Camp remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Mr. Camp's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Executive Order 14043.

75. Following the issuance of President Biden's Vaccine Mandate, Ms. Perrotta submitted to the VA a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Perrotta articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Perrotta has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the VA or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Perrotta is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Perrotta remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does

not pose an undue hardship on her employer. Despite this, Ms. Perrotta's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

76. Following the issuance of President Biden's Vaccine Mandate, Mr. Axtell submitted to DOT a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Mr. Axtell articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel him to abstain from receiving any of the currently available COVID-19 vaccines. Mr. Axtell has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for DOT or any entity within the federal government to question either the nature or the sincerity of his religious beliefs, observances, or practices. Mr. Axtell is amenable to continuing to work with the reasonable accommodations in place and within which he has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Mr. Axtell remains fully capable of performing the essential functions and duties of his job without compromising the safety of the federal workforce or his productivity and the reasonable accommodation he has requested does not pose an undue hardship on his employer. Despite this, Mr. Axtell's request for a religious exemption and accommodation has not been approved, and he imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from

complying with Executive Order 14043.

Following the issuance of President Biden's Vaccine Mandate, Ms. Morgan 77. submitted to DOI a request for religious exemption from the Vaccine Mandate as an accommodation of her sincerely held beliefs. Ms. Morgan articulated that she has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Ms. Morgan has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the DOI or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Ms. Morgan is amenable to continuing to work with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Ms. Morgan remains fully capable of performing the essential functions and duties of her job without compromising the safety of the federal workforce or her productivity and the reasonable accommodation she has requested does not pose an undue hardship on her employer. Despite this, Ms. Morgan's request for a religious exemption and accommodation has not been approved, and she imminently faces severe adverse employment action including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of her sincerely held religious beliefs prohibiting her from complying with Executive Order 14043.

78. Following the issuance of Secretary Austin's Vaccine Mandate, First Lieutenant Soto submitted to the Department of the Navy a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. First Lieutenant Soto articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel her to

abstain from receiving any of the currently available COVID-19 vaccines. First Lieutenant Soto has never exhibited or demonstrated any behavior, and no factors exist, that give rise to an objective basis for the Department of the Navy or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. First Lieutenant Soto is amenable to continuing to serving with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, First Lieutenant Soto remains fully capable of performing the essential functions and duties of his job without compromising the safety or readiness of the U.S. Armed Forces and the reasonable accommodation he has requested does not pose an undue hardship on the Department of the Navy, Department of Defense, or United States Armed Forces. Despite this, on October 10, 2021, First Lieutenant Soto's request for a religious exemption was denied. As a result, First Lieutenant Soto has suffered, and continues to suffer irreparable harm as his fundamental rights have been deprived, or at a minimum, are imminently guaranteed to be deprived, resulting in severe adverse employment action being taken against him including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Secretary Austin's August 24, DoD Order.

79. Following the issuance of Secretary Austin's Vaccine Mandate, Corporal Hall submitted to the Department of the Navy a request for religious exemption from the Vaccine Mandate as an accommodation of his sincerely held beliefs. Corporal Hall articulated that he has exercised and continues to exercise sincerely held religious beliefs that compel her to abstain from receiving any of the currently available COVID-19 vaccines. Corporal Hall has never exhibited or

demonstrated any behavior, and no factors exist, that give rise to an objective basis for the Department of the Navy or any entity within the federal government to question either the nature or the sincerity of her religious beliefs, observances, or practices. Corporal Hall is amenable to continuing to serving with the reasonable accommodations in place and within which she has worked for nearly two years since the outset of the pandemic without incident. With such accommodations, Corporal Hall remains fully capable of performing the essential functions and duties of his job without compromising the safety or readiness of the U.S. Armed Forces and the reasonable accommodation he has requested does not pose an undue hardship on the Department of the Navy, Department of Defense, or United States Armed Forces. Despite this, on September 29, 2021, Corporal Hall's request for a religious exemption was denied. As a result, Corporal Hall has suffered, and continues to suffer irreparable harm as his fundamental rights have been deprived, or at a minimum, are imminently guaranteed to be deprived, resulting in severe adverse employment action being taken against him including without limitation, reprimand, loss of benefits, loss of promotional opportunity, termination of employment, and other life-altering disciplinary measures for exercising and seeking accommodation of his sincerely held religious beliefs prohibiting him from complying with Secretary Austin's August 24, DoD Order.

D. PLAINTIFFS' SINCERELY HELD RELIGIOUS BELIEFS

80. As stated above, all Plaintiffs have sincerely held religious beliefs, as rooted in Scripture, that preclude them from complying with the Vaccine Mandate because of the connections between the available COVID-19 vaccines and the cell lines of aborted fetuses, whether in the vaccines' origination, production, development, testing, or other inputs. Plaintiffs also have sincerely held religious beliefs, rooted in Scripture, that their bodies are temples of the Holy Spirit and that they cannot place anything into their Temples without confirmation and

conviction from the Holy Spirit.

- 81. A fundamental component of Plaintiffs' sincerely held religious beliefs is that all life is sacred, from the moment of conception to natural death, and that abortion is the murder of an innocent life and a grave sin against God.
- 82. Plaintiffs' sincerely held religious beliefs are rooted in Scripture's teachings that "[a]ll Scripture is given by inspiration of God, and is profitable for doctrine, for reproof, for correction, [and] for instruction in righteousness." 2 Timothy 3:16 (KJV).
- 83. Because of that sincerely held religious belief, Plaintiffs believe that they must conform their lives, including their decisions relating to medical care, to the commands and teaching of Scripture.
- 84. Plaintiffs have sincerely held religious beliefs that God forms children in the womb and knows them prior to birth, and that because of this, life is sacred from the moment of conception to natural death. See Psalm 139:13–14 (ESV) ("For you formed my inward parts; you knitted me together in my mother's womb. I praise you, for I am fearfully and wonderfully made."); Psalm 139:16 (ESV) ("Your eyes saw my unformed substance; in your book were written, every one of them, the days that were formed for me, when as yet there was none of them"); Isaiah 44:2 (ESV) ("Thus says the LORD who made you, who formed you from the womb"); Isaiah 44:24 (ESV) ("Thus says the LORD, your Redeemer, who formed you from the womb: 'I am the Lord, who made all things ""); Isaiah 49:1b (ESV) ("The LORD called me from the womb, from the body of my mother he named my name."); Isaiah 49:5 (ESV) ("And now the LORD says, he who formed me from the womb to be his servant"); Jeremiah 1:5 (ESV) ("Before I formed you in the womb I knew you, and before you were born I consecrated you; I appointed you a prophet to the nations."").

- 85. Plaintiffs also have sincerely held religious beliefs that every child's life is sacred because each is made in the image of God. See Genesis 1:26–27 (ESV) ("Then God said, 'Let us make man in our image, after our likeness So God created man in his own image, in the image of God he created him; male and female he created them." (Footnote omitted)).
- 86. Plaintiffs have sincerely held religious beliefs that because life is sacred from the moment of conception, the killing of that innocent life is the murder of an innocent human in violation of Scripture. See, e.g., Exodus 20:13 (ESV) ("You shall not murder."); Exodus 21:22–23 (ESV) (imposing death penalty for killing of an unborn child); Exodus 23:7 (ESV) ("[D]o not kill the innocent and righteous"); Genesis 9:6 (ESV) ("Whoever sheds the blood of man, by man shall his blood be shed, for God made man in his own image."); Deuteronomy 27:25 (ESV) ("Cursed be anyone who takes a bribe to shed innocent blood." (Internal quotation marks omitted)); Proverbs 6:16–17 (ESV) ("There are six things that the LORD hates, seven that are an abomination to him: . . . hands that shed innocent blood").
- 87. Abortion is the modern-day sacrifice of children made in the image of God. Plaintiffs do not want to be part of such an "abomination." They do not want indirectly or directly to be in any way associated with abortion. To do so is abhorrent, loathsome, detestable, abominable to God. In short, to require these employees to inject a substance into their bodies that has any association (no matter how near or remote to abortion) is a sin against their Creator, their Lord, and their Savior.
- 88. Plaintiffs also believe in the fundamental Christian teaching of therapeutic proportionality, which is an assessment of whether the benefits of a medical intervention outweigh the undesirable side-effects and burdens in light of the integral good of the person, including, psychological, and spiritual bodily goods.

- 89. It can also extend to the good of others and the common good, which likewise entail spiritual and moral dimensions and are not reducible to public health.
- 90. The judgment of therapeutic proportionality must be made by the person who is the potential recipient of the intervention in the concrete circumstances, not by public health authorities or by other individuals who might judge differently in their own situations.
- 91. Plaintiffs' religious beliefs compel them to not condone, support, justify, or benefit (directly or indirectly) from the taking of innocent human life via abortion, and that to do so is sinning against God.
- 92. Plaintiffs' sincerely held religious beliefs preclude them from accepting any one of the three currently available COVID-19 vaccines derived from, produced or manufactured by, tested on, developed with, or otherwise connected to aborted fetal cell lines.

E. PFIZER'S COMIRNARY® & PFIZER-BIONTECH VACCINES

- 93. On August 23, 2021, the FDA approved Pfizer's COMIRNATY® (COVID-19 vaccine, mRNA) ("COMIRNATY"), which is legally distinguishable from the Pfizer-BioNTech vaccine ("BioNTech") as evidenced by the FDA's COMIRNATY vaccine approval announcement published on August 23, 2021.
- 94. The FDA approval letter only states that COMIRNATY is FDA-approved; Pfizer-BioNTech, is not, nor has it ever been approved by the FDA.
- 95. It could not be clearer that BioNTech is not FDA-approved and therefore, the vaccine remains subject to the EUA provisions of the federal Food, Drug, and Cosmetic Act ("FDCA").
- 96. As a result, a mass misinformation campaign has construed the two legally distinct vaccines to be considered by the public at-large as a single "Pfizer vaccine" this is not correct.

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97. The two Pfizer vaccines are legally distinct and include differences. For example, the two vaccines have different number of ingredients: COMIRNATY has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients.

Table 2. Composition of COMIRNATY Multiple Do	ose Vial	
Ingredients	Quantity after Dilution (per vial)	Function
SARS-CoV-2 spike glycoprotein mRNA (UNII: 5085ZFP6SJ)	225 µg	Active Ingredient
(b) (4) [4-hydroxybutyl)azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate) (UNII: (b) (4)	3.23 mg	Lipid component
(b) (4) [2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide] (UNII (b) (4)	0.4 mg	Lipid component
DSPC [1,2-distearoyl-sn-glycero-3-phosphocholine] (UNII: 043IPI2M0K)	0.7 mg	Lipid component
Cholesterol (UNII: 97C5T2UQ7J)	1.4 mg	Lipid component
Potassium chloride (UNII: 660YQ98I10)	0.07 mg	Excipient
Monobasic potassium phosphate (UNII: 4J9FJ0HL51)	0.07 mg	Excipient
Sodium Chloride	2.7 mg	Excipient
(UNII: 451W47IQ8X)		
Dibasic sodium phosphate dihydrate (UNII: GR686LBA74)	0.49 mg	Excipient
Sucrose (UNII: C151H8M554)	46.0 mg	Excipient
(b) (4) (UNII: (b) (4)	0.450 mL	Excipient

- 98. As you can see in the below graph, 0.45mg of the 2.25mg (20%) of ingredients contained in a COMIRNATY vial has been sanitized.
- 99. The approval announcement posted on the FDA's website reads, "On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as COMIRNATY, for the prevention of COVID-19 disease in individuals 16 years of age and older." ¹⁶
- 100. While Pfizer's COMIRNATY approval letter states that its two vaccines share the same formulation, the FDA concedes that "the products are <u>legally distinct</u> with *certain* differences . . ." *Id.* (emphasis added).

¹⁶ See supra, fn XXX

- 101. To date, no entity has revealed, nor have Plaintiffs been able to obtain, any evidence indicating what those "certain differences" may be. Despite this, the FDA asserts that the two formulations can be used interchangeably.
- 102. For example, in the FDA's fact sheet¹⁷ for recipients and caregivers, for example, it reads, "The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series."
- 103. In a press release¹⁸ announcing Pfizer's collaboration with Brazil's Eurofarma to manufacture COVID-19 vaccine doses, Pfizer wrote, "COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech" and "Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA." The press release continued, stating, "This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) . . .". *Id*.
- 104. Then, in a September 6, 2021 press release¹⁹ announcing a submittal to a request by the European Medicines Agency (EMA) to update its Conditional Marketing Authorization (CMA) for a booster dose, BioNTech–Pfizer's co-partner in the production of the Pfizer-BioNTech COVID-19 vaccine–clearly states, "The Pfizer-BioNTech COVID-19 vaccine has not been

¹⁷ The Food and Drug Administration, *Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* (Aug. 23, 2021), available at: https://www.fda.gov/media/144414/download.

¹⁸ Pfizer, *Pfizer and BioNTech Announce Collaboration with Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America* (Aug. 26, 2021), available at: <a href="https://www.pfizer.com/news/press-release/press-

¹⁹ Press Release, *Pfizer and BioNTech Submit a Variation to EMA with the Data in Support of a Booster Dose of COMIRNATY*®, BIONTECH (Sept. 6, 2021), available at: https://investors.biontech.de/node/10581/pdf.

approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) . . .". *Id*.

105. The product's labeling is even indicative that the vaccines are distinguishable. In a letter addressed to Pfizer, the FDA stated, "The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for 'Emergency Use Authorization."²⁰





106. Mindful of this new marketing change, the FDA included specific language in its August 23 letter to Pfizer distinguishing the two vaccines, stating "the licensed vaccine (COMIRNATY) has the same formulation as the EUA-authorized vaccine (Pfizer-BioNTech) and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns." *Id.* This is not true.

²⁰ Food and Drug Administration, Pfizer-BioNTech COVID-19 EUA LOA reissued August 23, 2021, (Aug. 23, 2021), available at: https://www.fda.gov/media/150386/download

107. According to the CDC, "the FDA approved the licensure of COMIRNATY (COVID-19 Vaccine, mRNA), made by Pfizer for BioNTech." The *FDA did not approve* the Pfizer-BioNTech vaccine. Despite full knowledge that the BioNTech vaccine is not FDA-approved, the CDC nevertheless stated that, because "[t]he FDA-approved Pfizer-BioNTech product COMIRNATY and the FDA-authorized Pfizer-BioNTech COVID-19 vaccine have the same formulation[,] [the two vaccines] can be used interchangeably to provide the COVID-19 vaccination series . . .". As a result, the CDC has advised:

[V]accination providers can use doses distributed under EUA [(e.g., the non-FDA approved Pfizer-BioNTech vaccine)] to administer the vaccination series as if the doses were the licensed vaccine.²²

- 108. The CDC is wrong. The EUA statute, 21 U.S.C. § 360bbb-3, explicitly states that anyone to whom an EUA product is administered **must be informed of the option to accept or to refuse it**, as well as alternatives to the product and the risks and benefits of receiving it.
- 109. The CDC's erroneous assertion that "vaccination providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine" fails to appreciate perhaps the most consequential difference between COMIRNATY and Pfizer-BioNTech: their current availability.
- 110. The FDA's COMIRNATY approval letter facially states, the CDC: (1) explicitly distinguishes the COMIRNATY and BioNTech vaccines; (2) expressly distinguishes that COMIRNATY is approved and BioNTech is not FDA-approved but under EUA; (3) asserts that COMIRNATY and BioNTech have the same "formulation"; (4) alleges that BioNTech can be used interchangeably with COMIRNATY despite "certain differences" existing between the two

²¹ Centers for Disease Control and Prevention, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, (last visited Sept. 15, 2021), available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

different vaccines; and then with abject audacity, advises that "[a]lthough COMIRNATY is approved . . . there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of [the BioNTech] EUA.".

- In unequivocal terms, the FDA has made it expressly clear: "There is no adequate, approved, and available alternative **to the emergency use** of [the BioNTech] COVID-19 Vaccine to prevent COVID-19."
- 112. The only vaccine that has received FDA approval is COMIRNATY, yet COMIRNATY is unavailable. No FDA-approved COVID-19 vaccine is available.

F. IRRESPECTIVE OF FDA APPROVAL, NONE OF THE CURRENTLY AVAILABLE COVID-19 VACCINES COULD EXIST BUT-FOR THE USE OF ABORTED FETAL CELL TISSUE

- 113. Use of tissue procured from aborted fetuses is not new. It has been adjudicated that bioprocurement companies have, in fact, sold fetal tissue in violation of federal law.
- 114. On July 15, 2015, the United States House of Representatives Energy and Commerce Committee and House Judiciary Committee opened investigations into illegal fetal tissue procurement practices.²³ On August 14, 2015, the House Oversight and Government Reform Committee initiated a third investigation.²⁴ On October 7, 2015, and as a means to consolidate the three House investigations into one, the House created a Select Investigative Panel within the Energy and Commerce Committee.²⁵ The Senate Judiciary Committee also initiated its own investigation, which it conducted contemporaneously and independent of the consolidated House

Press Release, House Energy and Commerce Committee, Energy and Commerce Committee Launches Investigation Following "Abhorrent" Planned Parenthood Video (Jul. 15, 2015) *see also* Press Release, House Judiciary Committee, Chairman Goodlatte Announces House judiciary Committee Investigation into Horrific Abortion Practices (Jul. 15, 2015).

²⁴Letter from Jason Chaffetz, Chariman, Committee on Oversight and Government Reform, *et al.*, to Cecile Richards, President, Planned Parenthood Federation of America, Inc. (Aug. 14, 2015).

²⁵Wesley Lowery & Mike DeBonis, *Boehner: There will be no government shutdown; select committee will probe Planned Parenthood*, WASHINGTON POST (Sep. 27, 2015), available at: https://wapo.st/2QxxdDR.

investigation.²⁶

115. The two Congressional investigations concluded in December 2016²⁷ after both, the House and Senate independently concluded that many actors within the abortion industry had committed systemic violations of the law.²⁸ Due to these findings, the House Select Investigative Panel and Senate Judiciary Committee issued numerous criminal and regulatory referrals to federal, state, and local law enforcement entities, including for several abortion providers and fetal tissue procurement companies.

116. In October 2016, the Orange County, California, District Attorney initiated a civil prosecution against DV Biologics and DaVinci Biosciences for illegally re-selling fetal tissue the companies obtained from Planned Parenthood of Orange and San Bernardino Counties ("PP-Orange").²⁹ The successful prosecution resulted in a stipulated judgment in which both companies admitted to selling fetal body parts obtained from PP-Orange for profit. The parties also agreed to pay \$7.8 million for violating state and federal laws.³⁰

117. In December 2016, the Texas Health and Human Services Division ("Texas HHS") issued a Final Notice of Termination to Planned Parenthood Gulf Coast ("PP-Gulf Coast") based in Houston that terminated its enrollment in the Texas Medicaid program. According to Texas HHS, the termination was based on two factors: (1) footage of CMP's visit to the PP-Gulf Coast clinic revealing that PP-Houston would modify procedures in order to sell tissue; and (2) the U.S.

²⁶ *Id*.

²⁷ Id

²⁸ Select Investigative Panel of the Energy & Commerce Committee, FINAL REPORT (Dec. 30, 2016); *see also* Majority Staff Of S. Comm. On The Judiciary, 114TH CONG., Human Fetal Tissue Research: Context and Controversy, S. Doc. No. 114-27 (2d Sess. 2016).

²⁹ See Complaint, The People of the State of California v. DV Biologics, LLC, Orange Cnty. No. 30-2016-00880665-CU-BT-CJC (Cal. Super., Oct. 11, 2016).

³⁰ See Judgment, The People of the State of California v. DV Biologics, LLC, Orange Cnty. No. 30-2016-00880665-CU-BT-CJC (Cal. Super., Dec. 19, 2017).

House investigation's conclusion that PP-Houston had repeatedly lied to it.³¹

118. In January 2017, the Attorney General of Arizona initiated a civil prosecution against abortion provider, Jackrabbit Family Medicine, P.C. ("Camelback Family Planning") for illegally transferring fetal tissue to StemExpress, LLC, a California-based bioprocurement company.³² The prosecution was successful, and the Arizona Attorney General determined that the consent formed used by StemExpress were deficient because:

The consent forms did not state certain facts regarding StemExpress's business. . . . The consent forms [] did not state that, under the agreement [Camelback Family Planning] had entered into with StemExpress in addition to supplying the collection tubes and paying the costs of shipping the samples to StemExpress, StemExpress would pay [Camelback Family Planning] set amounts from \$75–250 for each blood and tissue sample provided. 33

- 119. As part of the settlement, Camelback Family Planning was required to return all payments received it received from StemExpress and agree it would refrain from selling fetal tissue in the future.³⁴ Camelback Family Planning ultimately returned the money it received from StemExpress in exchange for *inter alia* fetal tissues.³⁵
- 120. Fetal tissue has a long history of being procured and sold and it is not subject to dispute that HEK-293 and PER.C6 fetal cell lines were used in the development and testing of the three (3) available COVID-19 vaccines.
- 121. As reported by the North Dakota Department of Health, in its handout literature for those considering one of the COVID-19 vaccines, "[t]he non-replicating viral vector vaccine

³¹ Letter from Stuart W. Bowen, Jr., Inspector General, Texas Health & Human Services Commission, to Planned Parenthood Gulf Coast, et al. (Dec. 20, 2016).

³² See Complaint, State of Arizona v. Jackrabbit Family Medicine, P.C., Maricopa Cnty. No. CV2017-000863 (Ariz. Super., Jan. 19, 2017).

³³ See Assurance of Discontinuance, State of Arizona v. Jackrabbit Family Medicine, P.C., Maricopa Cnty. No. CV2017-000863 (Ariz. Super., Jan. 19, 2017).

³⁴ *Id*.

³⁵ *Id*.

produced by Johnson & Johnson did require the use of fetal cell cultures, specifically PER.C6, in order to produce and manufacture the vaccine."³⁶

- 122. The Louisiana Department of Health likewise confirms that the Johnson & Johnson COVID-19 vaccine used the PER.C6 fetal cell line, which "is a retinal cell line that was isolated from a terminated fetus in 1985."³⁷
- 123. Scientists at the American Association for the Advancement of Science have likewise published research showing that the Johnson & Johnson vaccine used aborted fetal cell lines in the development and production phases of the vaccine.³⁸
- 124. The same is true of the Moderna and Pfizer-BioNTech mRNA vaccines. The Louisiana Department of Health's publications again confirm that aborted fetal cells lines were used in the "proof of concept" phase of the development of their mRNA vaccines.³⁹
- 125. The North Dakota Department of Health likewise confirms: "Early in the development of mRNA vaccine technology, fetal cells were used for 'proof of concept' (to demonstrate how a cell could take up mRNA and produce the SARS- CoV-2 spike protein) or to characterize the SARS-CoV-2 spike protein."⁴⁰
- 126. The Chief Scientific Officer and Senior Director of Worldwide Research for Pfizer have also been reported to demonstrate that its COVID-19 vaccine is derived from aborted fetal

³⁶ See North Dakota Health, COVID-19 Vaccines & Fetal Cell Lines (Apr. 20, 2021), available at: https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19 Vaccine Fetal Cell Handout.pdf.

³⁷ La. Dep't of Public Health, You Have Questions, We Have Answers: COVID-19 Vaccine FAQ (Dec. 21, 2020), available at: https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You Have Qs COVID19 Vaccine FAQ.pdf, emphasis added).

³⁸ Meredith Wadman, Vaccines that use human fetal cells draw fire, Science (June 12, 2020), available at: https://science.sciencemag.org/content/368/6496/1170.full.

³⁹ See La. Dep't of Public Health, supra fn. 29.

⁴⁰ N.D. Health, *supra* fn. 28 (emphasis added).

cells and have made statements that they wanted to keep that information from the public.⁴¹

127. Specifically, Vanessa Gelman, Pfizer Senior Director of Worldwide Research: "From the perspective of corporate affairs, we want to avoid having the information on fetal cells floating out there...The risk of communicating this right now outweighs any potential benefit we could see, particularly with general members of the public who may take this information and use

it in ways we may not want out there. We have not received any questions from policy makers or

media on this issue in the last few weeks, so we want to avoid raising this if possible." Id.

128. And, Philip Dormitzer, Pfizer's Chief Scientific Officer is reported as saying that he wanted to keep the information secret because of the objections that pro-life individuals, such as Plaintiffs in this action, would have: "HEK293T cells, used for the IVE assay, are ultimately derived from an aborted fetus. On the other hand, the Vatican doctrinal committee has confirmed that they consider it acceptable for Pro-Life believers to be immunized. Pfizer's official statement

129. Because all three of the currently available COVID-19 vaccines are developed and produced from, tested with, researched on, or otherwise connected with the aborted fetal cell lines HEK-293 and PER.C6, Plaintiffs' sincerely held religious beliefs compel them to abstain from obtaining or injecting any of these products into their body, regardless of the perceived benefit or

couches the answer well and is what should be provided in response to an outside inquiry." Id.

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rationale.

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⁴¹ See PFIZER LEAKS: Whistleblower Goes On Record, Reveals Internal Emails from Chief Scientific Officer & Senior Director of Worldwide Research Discussing COVID Vaccine ... 'We Want to Avoid Having the Information on the Fetal Cells Floating Out There', ProjectVeritas (Oct. 6, 2021), available at: https://www.projectveritas.com/news/pfizer-leaks-whistleblower-goes-on-record-reveals-internal-emails-from-chief/.

G. PLAINTIFFS' AMENABILITY TO LESS RESTRICTIVE ALTERNATIVES THAT COMPORT WITH THEIR RELIGIOUS BELIEFS & ACHIEVE THE SAME GOAL SOUGHT TO BE ACHIEVED BY VACCINATION

- 130. Plaintiffs have offered, and are ready, willing, and able to comply with all reasonable health and safety requirements to facilitate their religious exemption and accommodation from the Vaccine Mandate.
- 131. Plaintiffs have, and continue to, engage in a variety of mitigation strategies to stem, if not entirety prevent, the spread of COVID-19, which is the very objective of the Vaccine Mandate. While engaged in these accommodating mitigation strategies, Plaintiffs dutifully fulfilled their employment obligations to, at minimum, a satisfactory standard.
- the beginning of her employment, has worked exclusively from home and has only ever visited a physical federal office location on two occasions—once, to get a battery in her government-provided computer replaced, and then a second time to replace the entire computer itself. Mr. Czerwinski, who works from home the majority of the time, frequently washes his hands and wears a mask while socially distancing whenever on-site work is required. The number of reasonable accommodations that do not impose an undue hardship and are less restrictive than the blanket Vaccine Mandate could be articulated at nauseum. Despite this, Plaintiffs continue to remain open to reasonable accommodations in lieu of being forced to choose which fundamental right is most important to them: (1) freely exercising their religion; (2) pursuing the careers of their choosing; or (3) succumb to the unwanted injection of a medication, such as a vaccine, into their nonconsenting bodies.
- 133. The accommodations which have been ongoing for nearly two years are certainly reasonable under the accumulating scientific evidence. Indeed, a preliminary study has shown that

in the case of a breakthrough infection, the Delta variant is able to grow in the noses of vaccinated people just as if they were not vaccinated at all. The virus that grows is just as infectious as that in unvaccinated people, meaning vaccinated people can transmit the virus and infect others.⁴²

H. DEPT. OF DEFENSE MISREPRESENTATIONS, FALSIFICATION OF MEDICAL RECORDS, & BLANKET DENIALS OF RELIGIOUS EXEMPTION REQUESTS

- 134. On August 23, 2021, the FDA admitted that "[a]lthough COMIRNATY is approved ... there is not sufficient approved vaccine available for distribution . . .". 43
- 135. Despite this, on August 27, 2021, Captain Rylan Commins received an email⁴⁴ in which Marine Lieutenant Alys Jordan, a HMLA-267 Flight Surgeon at Camp Pendleton, advised "[t]he orders are in for the Comirnaty vaccine and we should have them by early next week."
- 136. On October 15, 2021, Major Edwin Paz requested information from the DiLorenzo Clinic as to whether the clinic had any of the FDA-approved COMIRNATY available. The email indicates that the Director of the DiLorenzo Clinic, Dr. Seto, stated: "Pfizer has not made any Comirnaty. There is no expected date when we will receive Comirnaty." ⁴⁵ This was also corroborated, DoD OIG COVID-19 Coordinator, Plaintiff Lesley Church, who has been informed by DoD officials that the Pentagon does not have COMIRNATY and does not know when COMIRNATY will be available.
 - 137. It is indisputable: The United States Department of Defense does not, nor has it

⁴² Sanjay Mishra, Evidence mounts that people with breakthrough infections can spread Delta easily, National Geographic (Aug. 20, 2021), available at: https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily (emphasis added); *see also* Statement from CDC Director Rochelle P. Walensky, MD, MPH Statement from CDC on Today's MMWR (July 30, 2021), available at: https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html (noting "the Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people.").

⁴³ Centers for Disease Control and Prevention, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, (last visited Sept. 15, 2021), available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

⁴⁴ Email to Rylan Commins, U.S. Marine Corps (Aug. 27, 2021, 4:02PM) (on file with author); see Exhibit 6.

⁴⁵ Email to Major Edward Paz, U.S. Marine Corps (Oct. 15, 2021, 10:49 AM) (on file with author); see Exhibit 7.

ever had, one or more FDA-approved doses of COMIRNATY – the only COVID-19 vaccine that has received approval from the FDA. Despite this, (1) the FDA indicating just 96 hours earlier that COMIRNATY was unavailable, DoD personnel advised active-duty servicemembers that Camp Pendleton was expected to receive COMIRNATY "early [the following] week."; (2) DoD personnel orally misinformed active-duty that the vaccine being administered was the "same fluid" yet COMIRNATY and Pfizer-BioNTech do not even have the same number of ingredients; and (3) perhaps most egregious of all, **the DoD has falsified active-duty personnel's medical records**.

138. Jacob Workman, a Chief Warrant Officer One in the Missouri National Guard has testified that his immunization records within the TRICARE medical portal reflect that he was inoculated on October 8, 2021:⁴⁶

Jacob WorkmanCONFIDENTIALPage 2 of 4

IMMUNIZATION HISTORY			
Date Range: All	Sorted By: Vaccine (Ascending)		
Filter: None Applied			

Immunization	COVID-19 Pfizer (COMIRNATY)		
Date Given	08 Oct 2021	Next Due Date	29 Oct 2021
Dosage	0.3 ml	Series	
Provider	Unknown, Provider	Facility	
Manufacturer Name	Pfizer, Inc	Lot Number	FF8839

139. Finally, notwithstanding the above, the U.S. Marine Corps, under the jurisdiction of Secretary of Defense Austin and President Biden, has begun processing 1st Lt. Soto and Cpl. Hall for administrative separation and subjected them to adverse administrative disciplinary action pursuant to the Marine Administrative Message (MARDAMIN) issued on October 23, 2021.

⁴⁶ Immunization History, Medical Records of Jacob Workman, TRICARE MED. PORT., (Oct. 8, 2021); see Exhibit 8.

140. Cpl. Hall submitted his religious exemption request on August 28, 2021, but it was unlawfully denied by the Marines Corps on September 29, 2021.⁴⁷ Likewise, First Lieutenant Soto submitted his religious exemption request on September 22, 2021, but it was unlawfully denied by the Marines Corps on October 10, 2021.⁴⁸

141. Notably, the language used by the Department of the Navy is identical, inapplicable, and/or irrelevant. The "copy and paste" language written of the denial letters written by Deputy Commandant for Manpower and Reserve Affairs, David A Ottington, states *inter alia* that he: (1) "carefully considered" the requests for an immunization waiver; and that he (2) "considered your requests dated [DATE], the command endorsements and exhibits attached to it, advice from the Director, Health Services Headquarters, U.S. Marine Corps, and the recommendation of the Religious Accommodation Review Board . . ." and that he "consulted with legal counsel."

142. As a preliminary concern, the date Deputy Commandant Ottington claims Cpl. Hall submitted his exemption request is incorrect. Cpl. Hall submitted his request on August 28, 2021; not August 25, 2021. This is hardly careful consideration. Rather, the copy & paste verbatim language vitiates the notion that at least Cpl. Hall's religious exemption request was not "carefully considered."

143. To the extent one letter is not carefully considered, 1st Lt. Soto likewise has reason to believe his letter, too, was not carefully considered. And whereas the only two (2) means by which Defendants can deprive Plaintiffs of their fundamental right to the free exercise of religion is if the belief is not "sincerely held" or accommodating one's religion poses an "undue hardship"

⁴⁷ Cpl. Hall Denial Letter, Req. for Religious Accom., DEPT. OF THE NAVY (Sept. 29, 2021); see Exhibit 9.

⁴⁸ 1st Lt. Soto Denial Letter, Req. for Religious Accom. DEPT. OF THE NAVY (Oct. 10, 2021); see Exhibit 10.

⁴⁹ See infra, fn.'s 48-49; see also Exhibits 9-10.

on Defendants, this material discrepancy is hardly an ancillary matter.

144. Of course, it is impossible to determine whether one's religious belief is "sincerely held" absent review on an individualized case-by-case basis; thus, the relevancy as to the blanket form denial letter is of the highest importance when dealing with a fundamental right at stake. 1st Lt. Soto and Corporal Hall have been unconstitutionally deprived of their First Amendment rights because Defendants cannot establish their religious beliefs are not sincerely held.

145. As to the "undue hardship" justification, it is spectacularly cavalier to assert that "there is no less-restrictive way of accommodating [Plaintiffs'] request[s] that ensures military readiness and the preservation of the health of the force." First, vaccinated individuals have infected thousands of vaccinated individuals. Yet according to the CDC, out of 120.2 million COVID-19 cases in the United States, there is not a single case in which a person has re-contracted COVID-19 and transmitted it to another person. In fact, just 10 days ago, San Diego County reported a total of 2,925 positive COVID-19 cases: 1,591 cases involving vaccinated patients and 1,334 cases involving unvaccinated patients.

146. The federal government itself disposes of any question concerning Plaintiff's FDCA claim. In a Memorandum to the President, the DOJ confirms that administration of EUA-authorized vaccines "requir[e] potential recipients to be informed of the option to accept or refuse administration of the product . . .". 54

⁵⁰ *Id*.

⁵¹ Patricia Kime, *DoD has Had 1,640 COVID 'Breakthrough' Cases Among Vaccinated Beneficiaries*, MILITARY.COM (May 21, 2021), available at: https://www.military.com/daily-news/2021/05/21/dod-has-had-1640-covid-breakthrough-cases-among-vaccinated-beneficiaries.html (last visited Oct. 24, 2021).

⁵² Case Updates, *Estimated COVID-19 Burden*, CENTERS FOR DISEASE CONTROL AND PREVENTION, (July 27, 2021), available at: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html (last visited Oct. 24, 2021).

⁵³ San Diego County, *Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report*, Health and Human Serv. Agency, (Sept. 20, 2021), *see* Exhibit 11.

⁵⁴ Dawn Johnson Memo., 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, DEPT. OF JUSTICE, (Jul. 6, 2021), see Exhibit 12.

I. OTHER COURTS HAVE ISSUED TRO'S AGAINST VACCINE MANDATES

147. Other reasonable protocols beyond the mass vaccination remain sufficient to prevent the spread of COVID-19 among employees; all of which constitute less restrictive and reasonable alternatives to the mandatory, universal mass vaccination of the entire federal workforce.

148. For example, the United States District Court for the Western District of Louisiana recently issued a TRO against a medical school for the school's failure to grant religious exemptions when other reasonable accommodations were available and mandatory vaccination was not the least restrictive means of achieving the school's interest in protecting the school's student body.⁵⁵

149. The United States District Court for the Western District of Michigan issued a TRO against a university for its failure to allow students with religious objections to vaccination to participate in athletics and other extracurricular activities when other reasonable alternatives were available as a reasonable accommodation for their religious beliefs.⁵⁶ The Sixth Circuit Court of Appeals affirmed that preliminary injunction in its order refusing to stay the preliminary injunction.⁵⁷

150. The United States District Court for the Northern District of New York and the Second Circuit Court of Appeals have both entered injunctions against enforcement of New York's COVID-19 vaccine mandate on healthcare workers that expressly excluded any religious exemption. On October 12, 2021, the Northern District of New York entered a preliminary injunction enjoining state officials from enforcing the mandate.⁵⁸ The court had previously entered

⁵⁵ Magliulo v. Edward Via Col. of Osteo. Med., No. 3:21-CV-2304, 2021 WL 36799227 (W.D. La. Aug. 17, 2021).

⁵⁶ Dahl v. Bd. of Trustees of W. Mich. Univ., No. 1:21-cv-757, 2021 WL 3891620, *2 (W.D. Mich. Aug. 31, 2021).

⁵⁷ See Dahl v. Bd. of Trustees of W. Mich. Univ., No. 21-2945, 2021 WL 4618519 (6th Cir. Oct. 7, 2021).

⁵⁸ See Dr. A. v. Hochul, No. 1:21-CV-1009, 2021 WL 4734404 (N.D.N.Y. Oct. 12, 2021).

a TRO to the same effect.⁵⁹ On September 30, in between the Northern District's TRO and preliminary injunction, the Second Circuit gave its imprimatur to the Dr. A. TRO in *We The Patriots USA, Inc. v. Hochul*, No. 21-2179, dkt. 65 (2d Cir. Sept. 30, 2021).

- 151. In *We The Patriots*, the Second Circuit issued an injunction pending appeal against New York's mandate, enjoining state officials from enforcing it "in a manner that would violate the terms of the temporary restraining order issued in *Dr. A v. Hochul.*"
- 152. Several Plaintiffs have been previously infected with COVID-19 and have serologic test results that demonstrate the natural antibodies and their immunity to COVID-19. To require these Plaintiffs to nevertheless submit to forcible vaccination is not only contrary to logic and science, but perhaps the height of what constitutes an arbitrary and capricious agency decision. Plaintiffs, however, have yet to even receive an exemption as demanded by the First Amendment.
- 153. The Task Force failed to comply with E.O. 14043 because the guidance it has issued is entirely devoid of information as to "exemptions as required by law." Specifically, the Requirement imposed on the Task Force by E.O. 14043 demands that the Task Force issue all agencies guidance on the implementation of: (1) a program to require COVID-19 vaccination for all of its federal employees; *inclusive of* (2) lawfully required exceptions to such a program.
- 154. The Guidance fails to provide agency heads with information as to: (1) what exemptions are required by law; (2) what criteria is required for federal employees, such as Plaintiffs, to obtain an exemption; (3) the process in which federal employees, such as Plaintiffs, may submit requests for an exemption; or (4) the timeframe within which agencies must respond to requests for an exemption submitted by federal employees, such as Plaintiffs.
 - 155. Due to the Task Force's failure to comply with the Executive Orders: (1) agency

⁵⁹ See 2021 WL 4189533 (N.D.N.Y. Sept. 14, 2021).

heads remain without guidance for exemption requests and as a result, continue to delay in providing Plaintiffs a mechanism to submit their requests despite the rapidly approaching November 22 deadline to be "fully vaccinated"; or (2) some agencies have promulgated their own mechanism to ask impermissible, invasive questions of those who are religious – while others do not have to provide such information – and the Task Force does so not only in direct violation of EEOC Guidance published this year, but also, in a manner that infringes upon Plaintiffs' fundamental right to the free exercise of religion.

FIRST CLAIM FOR RELIEF Violation of Free Exercise, U.S. Const. amend I.

Against All Defendants

- 156. Plaintiffs re-allege and incorporate by reference as if fully set forth herein the allegations in all preceding paragraphs.
- 157. The First Amendment's Free Exercise Clause provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." U.S. Const. amend I. Where, as here, a law targets religious practice for disparate treatment and is neither neutral nor generally applicable, that law is assessed under the Supreme Court's strict scrutiny rubric.
- 158. Defendants, acting under color of State law, have deprived and will continue to deprive Plaintiffs of their First Amendment rights.
- 159. Specifically, Defendants have instituted a Vaccine Mandate that is plainly and unconstitutionally targets religious practice for at least three reasons. *First*, in its text E.O. 14043 limits the vaccination requirement to merely Executive Branch employees of the "agencies", such as Plaintiffs, as defined by 5 U.S.C § 105 while the same vaccination requirement *does not* apply to other Executive Branch employees (*e.g.*, White House, EOP, CDC, NIH, NIAID) not being

subject to the same mandate. *Second*, the way E.O. 14043 operates in practice, including the numerous exceptions to the vaccination requirement and scheme to intentionally circumvent Plaintiffs' First Amendment protections, make clear the intent to deprive Plaintiffs of their fundamental right to freely exercise their religion. *Third*, Defendants' own words and conduct demonstrate the intent to violate Plaintiffs' First Amendment rights, in that no guidance has been issued as to what constitutes a valid religious exemption and high-level agency officials have been instructed to determine the bases – irrespective of their legality – upon which the agencies respond to religious exemption requests. The Task Force merely emphasized how important it is for the agencies to "figure[e] it out as quickly as possible . . . because [the agencies are] not going to run an accommodation in those places—and that's totally fine."

- 160. Defendants' promulgation of the Vaccine Mandate further infringes upon Plaintiffs' First Amendment right to free exercise in that it demands Plaintiffs respond to an invasive questionnaire without an objective basis giving rise to a *bona fide* doubt as to the sincerity of their closely held religious beliefs.
- 161. Defendants' have also implemented a "deadline" that is not in fact, a deadline, but a "forcing function" to induce Plaintiffs to submit religious exemption requests by an arbitrary date for the sole purpose of "collect[ing] information" about them.
- 162. Defendants have required Plaintiffs to work from home, in part or entirely, for nearly two years. Plaintiffs have done so and dutifully performed their work obligations in satisfaction of, at a minimum, expectations. Defendants have also implemented other accommodating risk mitigation strategies such as social distancing and masking with which Plaintiffs have complied and continue to comply.

- 163. The compelling interest articulated in E.O. 14043 is to "halt the spread of coronavirus disease" it is not to eradicate the disease. To that end, it is indisputable that vaccination does not achieve this end as many individuals who have been "fully vaccinated" have contracted, and continue to contract COVID-19 from vaccinated persons. To the contrary, there is no evidence that an unvaccinated individual with naturally acquired antibodies has re-contracted COVID-19 and transmitted it to another person.
- 164. Defendants can offer no evidence as to the basis upon which there is no alternative to halting the spread of COVID-19.
- 165. The offered mechanism, mass vaccination, has not worked, nor will it work, in achieving the interest it purports to satisfy.
- 166. Plaintiffs have offered numerous, less restrictive means to achieve the interest of stemming the spread of COVID-19.
- 167. Plaintiffs have faced, and continue to face, adverse employment action such as threats, harassment, and workplace hostility.
- 168. The Vaccine Mandate also seeks to stem the spread of COVID-19 for the interest of the health and safety of our federal workforce; however, if enforced, the safety and health of those who work in our federal government (and the federal government as a whole) would be harmed; not protected due to mass terminations and loss of a ready military and functioning government.
- 169. Plaintiffs seek declaratory and injunctive relief because they have no adequate remedy at law to prevent future injury caused by Defendants' violation of their First Amendment right to the free exercise of religion.

SECOND CLAIM FOR RELIEF VIOLATION OF RFRA, 42 U.S.C. § 2000bbb, et seq., Against All Defendants

- 170. Plaintiffs re-allege and incorporate all preceding paragraphs as if fully set forth herein.
- 171. The Religious Freedom Restoration Act (RFRA) provides that "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1(a).
- 172. RFRA also demands that, should the government substantially burden a person's free exercise of religion, it bears the burden of demonstrating that its burden on religious exercise furthers a compelling government interest and is the least restrictive means of achieving that compelling government interest. 42 U.S.C. § 2000bb-1(b).
- 173. RFRA plainly applies to Defendants, as they constitute a "branch, department, agency, instrumentality, and official of the United States." 42 U.S.C. § 2000bb-2(1).
- 174. Congess enacted RFRA "to provide very broad protection for religious liberty," going "far beyond what [the Supreme Court] has held is constitutionally required" under the First Amendment. *Hobby Lobby*, 573 U.S. 682, 693, 706 (2014) (emphasis added). As such, RFRA encompasses a very broad definition of "exercise of religion," which includes "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." *Hobby Lobby*, 573 U.S. at 696 (quoting 42 U.S.C. § 2000bb—5(7)(A)).
- 175. RFRA mandated that the law "be construed in favor of a broad protection of religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution." *Hobby Lobby*, 573 U.S. at 696 (quoting 42 U.S.C. § 2000cc—3(g)).

176. "RFRA operates as a kind of super statute, displacing the normal operation of other federal laws." *Bostock v. Clayton Cntv.*, 140 S. Ct. 1731, 1754 (2020).

177. Plaintiffs have sincerely held religious beliefs that Scripture is the infallible, inerrant word of the Lord Jesus Christ, and that they are to follow its teachings.

178. Plaintiffs have and exercise sincerely held religious beliefs (see *supra*, Section D) which compel them to abstain from receiving or accepting any of the currently available COVID-19 vaccines.

179. The Vaccine Mandates, on its face and as applied, target Plaintiffs' sincerely held religious beliefs by prohibiting Plaintiffs from seeking and receiving exemption and accommodation for their sincerely held religious beliefs against the COVID-19 vaccines.

THIRD CLAIM FOR RELIEF VIOLATION OF EQUAL PROTECTION For Declaratory and Injunctive Relief

- 180. Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully set forth herein.
 - 181. The Vaccine Mandates require Plaintiffs to obtain vaccination against COVID-19.
- 182. The Vaccine Mandates, either implicitly or expressly, state that exceptions will be made for those who are subject to the order but are exempt based on sincerely held religious beliefs.
- 183. While the Vaccine Mandates appear to be facially neutral and in compliance with well-established legal principles, their application and the manner in which the Vaccine Mandates are being promulgated deny Plaintiffs of Equal Protection, while other similarly situated federal employees of the Executive Branch remain exempt from the Vaccine Mandates.

- 184. The Vaccine Mandates deprive Plaintiffs, who have sincerely held religious beliefs, of their ability to freely exercise religion as their sincerely held religious beliefs prohibit compliance with the Vaccine Mandates.
- 185. Because of their closely held religious beliefs, Plaintiffs have suffered, and continue to suffer, significant stress and psychological harm caused by this impending threat to their military service or employment.
- 186. Because of their closely held religious beliefs, Plaintiffs have suffered, and continue to suffer, a deprivation of their constitutional rights because of Defendants' refusal to accommodate their sincerely held religious beliefs.
- 187. Because of their closely held religious beliefs, Plaintiffs Andrew Soto and Christopher Hall have suffered, and continue to suffer, a deprivation of their constitutional rights because of Defendant Biden and Defendant Austin's denial of their request for an accommodation for their religious beliefs.
- 188. Defendants, continue to deprive Plaintiffs of their fundamental right to free exercise and despite all Plaintiffs' beliefs being sincerely held.
- 189. Defendants, continue to deprive Plaintiffs of their fundamental right to free exercise despite having no basis to claim that providing Plaintiffs an accommodation for their sincerely held religious beliefs causes "undue hardship."
- 190. Plaintiffs, because of their sincerely held religious beliefs, are also immediately injured by the stigma created by the Vaccine Mandates. Even if some religious service members or federal employees are permitted to remain exempt from the Vaccine Mandate, they now serve in a military or under employment where the Commander-in-Chief or employer has announced that their service or work is unwanted and unwelcome, and that their religion is not respected. Any

religious service member or federal employee, that is permitted to remain in their current positions will necessarily be treated as, and experience the harms associated with, a person with second-class status.

- 191. Plaintiffs are entitled to a religious accommodations and protection on an equal basis that positions them just as other service members or federal employees without religious limitations are positioned by virtue of their COVID-19 vaccination status.
 - 192. The Vaccine Mandates single out Plaintiffs based upon their religion.
- 193. The Vaccine Mandates single out Plaintiffs based upon the status as the mechanism Defendants use satisfy its alleged objective in preserving the public health.
- 194. As a result of being singled out by Defendants, Plaintiffs have been subjected different treatment.
 - 195. The different treatment to which Plaintiffs are subjected is arbitrary.
 - 196. The different treatment to which Plaintiffs are subjected is capricious.
- 197. The Vaccine Mandates discriminate against Plaintiffs and other active-duty service members, federal employees, and federal contractors because of their religion.
- 198. The Vaccine Mandates put fundamental rights at issue and therefore, are subject to strict scrutiny.
- 199. Defendants' actions of adopting, implementing, promulgating, delegating, and enforcing the Vaccine Mandates have discriminated and continue to discriminate against Plaintiffs the basis of their religion and such actions do not survive strict scrutiny.
- 200. Defendants' actions of adopting, implementing, promulgating, delegating, and enforcing the Vaccine Mandates have discriminated and continue to discriminate against Plaintiffs

and other service members, federal employees, and federal contractors on the basis of their medical condition and such actions do not survive strict scrutiny.

201. Defendants' actions of adopting, implementing, promulgating, delegating, and enforcing the Vaccine Mandates have discriminated and continue to discriminate against Plaintiffs and other service members, federal employees, and federal contractors on the basis of invidious stereotypes, irrational fears, and moral disapproval, which are not permissible bases for differential treatment under any standard of review.

202. Plaintiffs seek declaratory and injunctive relief because they have no adequate remedy at law to prevent future injury caused by Defendants' violation of their Fifth Amendment rights to equal protection.

FOURTH CLAIM FOR RELIEF VIOLATION OF THE FDCA, 21 U.S.C. § 360bbb-3, et seq. For Declaratory and Injunctive Relief

- 203. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.
- 204. Federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until FDA has approved the drug or product as safe and effective for its intended uses. *See, e.g.*, Food, Drug, and Cosmetic Act ("FDCA") §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C. § 262(a). A vaccine is *both* a drug and a biological product. *See* FDCA § 201(g), 21 U.S.C. § 321(g); 42 U.S.C. § 262(i)(1); FDCA § 564(a)(4)(C) (defining "product" to mean "a drug, device, or biological product"). However, an exception exists whereas the FDCA authorizes the FDA to issue EUAs for medical products (e.g., non-FDA-approved vaccines such as Pfizer-BioNTech) under certain emergency circumstances. 21 U.S.C. § 360bbb-3,

- 205. Once a product receives an EUA, the product may be introduced into interstate commerce and administered to individuals despite the medical product not yet having received full-FDA approval. Such administration is only permitted "[t]o the extent practicable" given the emergency circumstances, and "as the [agency] finds necessary or appropriate to protect the public health." As a result, "[a]ppropriate" conditions are imposed on each EUA the FDA issues. *Id.* § 564(e)(1)(A).
- 206. Perhaps the most critical condition imposed is ensuring all recipients have given "informed consent" prior to receiving the non-FDA-approved medical product. Under FDCA § 564(e)(1)(A)(ii)(III), recipients of a EUA-authorized medical products must "[be] informed" of inter alia "the option to accept or refuse administration of the product." *Id*.
- 207. The FDCA also requires medical products that have not been fully approved by the FDA-such as the Pfizer-BioNTech vaccine—satisfy certain conditions "to ensure that individuals to whom the product is administered are informed . . . 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)(ii).
- 208. Since December 2020, the FDA has issued an EUA for the BioNTech vaccine. As part of the BioNTech EUA, the FDA imposed a condition stating that all recipients must have the "option to accept or refuse" the non-FDA-approved vaccine. To effectuate this, the EUA requires all recipients to receive a Fact Sheet ("BioNTech Fact Sheet") stating: "It is your choice to receive or not receive [the vaccine]."
- 209. Concerning the military, Congress enacted 10 U.S.C. § 1107a as a specific condition that expressly refers to the "option to accept or refuse" the medical product; the same

condition requirement that applies to the public at-large and non-military personnel set forth in FDCA § 564(e)(1)(A)(ii)(III). See Pub. L. No. 108-136, sec. 1603(b)(1), § 1107a, 117 Stat. at 1690.

- 210. When an EUA product is administered to members of the armed forces, "the condition described in section 564(e)(1)(A)(ii)(III)", (e.g., the "option to accept or refuse"), **is** required pursuant to § 564(e)(1)(A), (2)(A). FDCA § 564 et seq.
- 211. On July 6, 2021, Acting Assistant Attorney General Dawn Johnsen ("DOJ") submitted a Memorandum Opinion to the Deputy Counsel for the President in response to the question: "Whether the 'option to accept or refuse' condition in section 564 prohibits entities from imposing such vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs."
- 212. The DOJ concluded that "FDCA § 564(e)(1)(A)(ii)(III) [requires] . . . potential vaccine recipients be "informed" of . . . "the option to accept or refuse administration of the product." *Id.* at 6–7. The DOJ's conclusion is also corroborated by both, the FDA and Pfizer. Specifically, Pfizer's EUA Letter, Pfizer's Fact Sheet, and the FDA's Fact Sheet, all state "that recipients 'have a choice to receive or not receive' the vaccine."
- 213. Because the only FDA-approved vaccine is COMIRNATY, and in light of the fact that COMIRNATY is unavailable, the only vaccines that can conceivably be administered are non-FDA-approved vaccines only available under EUA; therefore, because such vaccines are not fully-FDA-approved, and based upon the requirements of FDCA § 564(e) *et seq.*, the DOJ's Memorandum Opinion, Pfizer's EUA Letter, Pfizer's Fact Sheet, and the FDA's Fact Sheet, it is not subject to dispute that **any recipient of the non-FDA-approved Pfizer-BioNTech vaccine**

made available exclusively under an EUA must receive the option to accept or refuse administration of the product."

- 214. The EUA is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704. Further, the EUA was a decision from which rights or obligations were determined and from which legal consequences (e.g., vitiating Plaintiffs' statutorily provided "option to accept or refuse administration of the product", FDCA § 564(e)(1)(A)(ii)(III)) flowed.
 - 215. Plaintiffs have no adequate or available administrative remedy.
 - 216. In the alternative, any effort to obtain an administrative remedy would be futile.
 - 217. Plaintiff has no adequate remedy at law.
- 218. As a direct and proximate result of Defendants' actions, Plaintiffs have suffered, and will continue to suffer, irreparable harm and their rights will be continued to be violated absent the injunctive relief requested.
- 219. As a direct and proximate result of E.O. 14042, the Federal Contractor Plaintiffs and respective Federal Contractor Class and Subclass Members have suffered, and will continue to suffer, irreparable harm and their rights will be continued to be violated absent the injunctive relief requested.
- 220. As a direct and proximate result of E.O. 14043, the Federal Employee Plaintiffs and respective Federal Employee Class and Subclass Members have suffered, and will continue to suffer, irreparable harm and their rights will be continued to be violated absent the injunctive relief requested.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, respectfully pray for relief as follows:

- A. That the Court issue a temporary restraining order restraining and enjoining Defendants and their officers, agents, employees, and attorneys, and all other persons in active concert or participation with them, from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Vaccine Mandate such that:
 - i. Defendants will immediately comply with the EUA Provisions of the FDCA so that each individual has the "option to accept or refuse" administration of all currently available COVID-19 vaccines as currently there is no FDAapproved COVID-19 vaccine is available to the population;
 - Defendants will immediately cease in their refusal to consider, evaluate, or accept Plaintiffs' requests for exemption and accommodation for their sincerely held religious beliefs;
 - iii. Defendants' will immediately grant Plaintiffs' requests for religious exemption from the Vaccine Mandate to accommodate their sincerely held religious beliefs;
 - iv. Defendants will immediately cease any actions arising from or connected to the Department of Defense, as to both, the civilian *and* servicemember Plaintiffs' religious exemption and accommodation requests, including current and ongoing punishment and threatening to dishonorably discharge, court martial, and impose other life-altering disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

- B. That the Court issue a preliminary injunction pending trial, and a permanent injunction upon judgment, restraining and enjoining Defendants and their officers, agents, employees, and attorneys, and all other persons in active concert or participation with them, from enforcing, threatening to enforce, attempting to enforce, or otherwise requiring compliance with the Vaccine Mandates such that:
 - i. Defendants will immediately comply with the Emergency Use

 Authorization Statute so that each individual has the "option to accept or
 refuse" administration of the COVID-19 vaccines as there is currently no

 FDA approved COVID-19 vaccine available to the population;
 - Defendants will immediately cease in their refusal to consider, evaluate, or accept Plaintiffs' requests for exemption and accommodation for their sincerely held religious beliefs;
 - iii. Defendants' will immediately grant Plaintiffs' requests for religious exemption and accommodation from the Vaccine Mandate; and
 - iv. Defendants will immediately cease any actions arising from or connected to the Department of Defense, as to both, the civilian *and* servicemember Plaintiffs' religious exemption and accommodation requests, including current and ongoing punishment and threatening to dishonorably discharge, court martial, and impose other life-altering disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs; and
 - iv. Defendants will immediately cease any actions arising from or connected to the military servicemember Plaintiffs' religious exemption and

accommodation requests, including current and ongoing punishment and threatening to dishonorably discharge, court martial, and impose other life-altering disciplinary actions on Plaintiffs for failure to accept a COVID-19 vaccine that violates their sincerely held religious beliefs;

- C. That this Court render a declaratory judgment declaring that the Vaccine Mandate, both on its face and as applied by Defendants, is illegal and unlawful in that it purports to remove federal civil rights and constitutional protections from federal employees and military servicemembers and further declare
 - i. the Vaccine Mandate violates the EUA Provisions of the FDCA by imposing a mandatory COVID-19 vaccination condition upon Plaintiffs' employment and ability to remain free from adverse employment while depriving Plaintiffs of their statutorily provided "option to accept or refuse" all EUA products;
 - ii. the Vaccine Mandate, without sufficient provision for exemption or accommodation for sincerely held religious beliefs, violates the First Amendment to the United States Constitution by imposing a substantial burden on Plaintiffs' sincerely held religious beliefs;
 - iii. the Vaccine Mandate, without sufficient provision for exemption or accommodation for sincerely held religious beliefs, violates the federal Religious Freedom Restoration Act by imposing a substantial burden on Plaintiffs' sincerely held religious beliefs;

- D. That this Court adjudge, decree, and declare the rights and other legal obligations and relations within the subject matter here in controversy so that such declaration shall have the full force and effect of final judgment;
- E. That this Court retain jurisdiction over for purposes of issuing Order;
- F. That this Court grant such other and further relief as the Court deems equitable and just under the circumstances.

Dated: October 24, 2021.

Respectfully submitted,

By: /S/ MICHAEL A. YODER
Michael A. Yoder [1600519]
THE LAW OFFICE OF MICHAEL A. YODER, PLLC 2300 Wilson Blvd., Suite 700
Arlington, VA 22202
Tel: (571) 234-5594

Fax: (571) 327-5554 michael@yoderesq.com

Counsel for Plaintiffs

VERIFICATION

I, MICHAEL A. YODER, am over the age of eighteen years and counsel for all Plaintiffs

in this action. The statements and allegations included in the foregoing Verified Complaint are

based upon reports and information known to me, provided to me by Plaintiffs, and/or furnished

to me and that I declare under penalty of perjury that everything represented herein is true to the

best of my knowledge, information and belief.

Dated: October 24, 2021

/s/ Michael A. Yoder

MICHAEL A. YODER

Counsel for Plaintiffs

VERIFICATION

I, STEVEN D. CHURCH, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Steven Church

STEVEN D. CHURCH

(Original Signature retained by Counsel)

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VERIFICATION

I, LESLEY CHURCH, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Lesley Church

LESLEY CHURCH

(Original Signature retained by Counsel)

VERIFICATION

I, GRACE BROWN, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Grace Brown

GRACE BROWN

(Original Signature retained by Counsel)

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VERIFICATION

I, ALMA GONZALEZ, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Alma Gonzalez

ALMA GONZALEZ

(Original Signature retained by Counsel)

VERIFICATION

I, DYNIKA BARNWELL, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Dynika Barnwell

DYNIKA BARNWELL

(Original Signature retained by Counsel)

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VERIFICATION

I, DOUGLAS CZERWINSKI, am over the age of eighteen years and a Plaintiff in this

action. The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Douglas Czerwinski

DOUGLAS CZERWINSKI

(Original Signature retained by Counsel)

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VERIFICATION

I, JASON COFFEY, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Jason Coffey

JASON COFFEY

(Original Signature retained by Counsel)

VERIFICATION

I, JOSHUA SCHMIDT, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Joshua Schmidt

JOSHUA SCHMIDT

(Original Signature retained by Counsel)

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VERIFICATION

I, MELINA ROYER, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Melina Royer

MELINA ROYER

(Original Signature retained by Counsel)

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VERIFICATION

I, TAMIKA WALLS, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Tamika Walls

TAMIKA WALLS

(Original Signature retained by Counsel)

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VERIFICATION

I, JAIME ESPITIA, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Jaime Espitia

JAIME ESPITIA

(Original Signature retained by Counsel)

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VERIFICATION

I, SOMER STEPHENS, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Somer Stephens

SOMER STEPHENS

(Original Signature retained by Counsel)

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VERIFICATION

I, ALEX BERNE, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Alex Berne

ALEX BERNE

(Original Signature retained by Counsel)

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VERIFICATION

I, ALAN CAMP, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Alan Camp

ALAN CAMP

(Original Signature retained by Counsel)

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VERIFICATION

I, STEPHANIE PERROTTA, am over the age of eighteen years and a Plaintiff in this

action. The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Stephanie Perrotta

STEPHANIE PERROTTA

(Original Signature retained by Counsel)

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VERIFICATION

I, CHRISTOPHER AXTELL, am over the age of eighteen years and a Plaintiff in this

action. The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Christopher Axtell

CHRISTOPHER AXTELL

(Original Signature retained by Counsel)

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VERIFICATION

I, KRISTOFOR HALLFRISCH, am over the age of eighteen years and a Plaintiff in this

action. The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Kristofor Hallfrisch

KRISTOFOR HALLFRISCH

(Original Signature retained by Counsel)

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VERIFICATION

I, DOROTHY MORGAN, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Dorothy Morgan

DOROTHY MORGAN

(Original Signature retained by Counsel)

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VERIFICATION

I, ANDREW SOTO, am over the age of eighteen years and a Plaintiff in this action. The

statements and allegations that pertain to me or which I make in this VERIFIED COMPLAINT

are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called

upon to testify to their truthfulness, I would and could do so competently. I declare under penalty

of perjury, under the laws of the United States, that the foregoing statements are true and correct

to the best of my knowledge.

Dated: October 24, 2021

/s/ Andrew Soto

ANDREW SOTO

(Original Signature retained by Counsel)

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VERIFICATION

I, CHRISTOPHER HALL, am over the age of eighteen years and a Plaintiff in this action.

The statements and allegations that pertain to me or which I make in this VERIFIED

COMPLAINT are true and correct, and based upon my personal knowledge (unless otherwise

indicated). If called upon to testify to their truthfulness, I would and could do so competently. I

declare under penalty of perjury, under the laws of the United States, that the foregoing statements

are true and correct to the best of my knowledge.

Dated: October 24, 2021

/s/ Christopher Hall

CHRISTOPHER HALL

(Original Signature retained by Counsel)

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)										
I. (a) PLAINTIFFS				DEFENDANTS *all in their official capacities						
Steven Church, Lesley Church, Alma Gonzalez, Dynika Barnwell, Douglas Czerwinski, Jason Coffey, Joshua Schmidt, Melina Royer, Tamika Walls, Jaime Espitia, Somer Stephens, Alex Berne, Alan Camp, Stephanie Perrotta, Christopher Axtell, Grace Brown, Kristofor Hallfrisch, Dorothy Morgan, Andrew Soto, and Christopher Hall			alls, errotta,	Joseph R. Biden, Lloyd J. Austin III, Antony J. Blinken, Janet Yellen, Merrick B. Garland, Thomas J. Vilsack, Gina M. Raimondo, Martin J. Walsh, Xavier Becerra, Marcia L. Fudge, Peter Buttigieg, Jennifer N. Granholm, Miguel Cardona, Denis McDonough, Alejandro Mayorkas, Clarence W. Nelson II, Kilolo Kihakazi, and Robin Carnahan						
(b) COUNTY OF RESIDENCE (EXC		ISTED PLAINTIFF LAINTIFF CASES)		COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED				/ED		
(c) ATTORNEYS (FIRM NA	ME, ADDRES	S, AND TELEPHONE NUMBER	.)	ATTORNEYS (IF KNOWN)						
Michael A. Yoder, Esq. The Law Office of Michael A 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201 Tel: (571) 235-5594										
II. BASIS OF JURISI (PLACE AN X IN ONE B								S (PLACE AN x IN ONE ERSITY CASES ONLY		
1 U.S. Government Plaintiff	O 3 Fe	deral Question S. Government Not a Party)		this State	PTF O 1	DFT 1	Incorpor	rated or Principal Place	PTF O 4	O 4
2 U.S. Government Defendant	(Ir	versity dicate Citizenship of	Citizen of	Another State	2	O 2	Incorpor	rated and Principal Place	O 5	O 5
	Pa	rties in item III)	Citizen or Foreign C	Subject of a ountry	O 3	O 3	Foreign 1		O 6	O 6
		IV. CASE ASSIC								
(Place an X i	n one categ	ory, A-N, that best repre	sents you	· Cause of A	ction and	one in a	corresp	onding Nature of Su	it)	
O A. Antitrust		Personal Injury/ Ialpractice	0	C. Admi Revie		Ageno	cy	O D. Tempor Order/Pi Injunctio	relimina	
	310 Airplane 315 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Medical Malpractice 365 Product Liability 367 Health Care/Pharmaceutical Personal Injury Product Liability 368 Asbestos Product Liability		ity Oth	Social Security 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g)) Other Statutes 891 Agricultural Acts 893 Environmental Matters 890 Other Statutory Actions (If Administrative Agency is Involved)		Any nature of suit from any category may be selected for this category of case assignment. *(If Antitrust, then A governs)*				
O E. General Civ	il (Other)	OR		_	ro Se Gei		<i>livil</i>			
Real Property 210 Land Condemnation 220 Foreclosure 423 Withdrawal 28 U 423 Wi		SC 157 ther s Conditions	8 8 8	I Tax Suits 70 Taxes (U defendar 71 IRS-Thir 7609 ture/Penalt 25 Drug Re Propert 90 Other Statutes 75 False Cl 76 Qui Tan 3729(a)) 00 State Re	S plaint nt) rd Party y lated Se y 21 USC aims Acc n (31 USc apportion	26 USC izure of C 881 t	465 Other Imn 470 Racketeer & Corrupt 480 Consumer 485 Telephone Protection 490 Cable/Sate 850 Securities/e Exchange 896 Arbitration 899 Administra Act/Review Agency De 950 Constitutio	Influence Organiza Credit Consumo Act (TCPA ellite TV Commodi tive Proc y or Appe cision	d ation er A) ties/ cedure al of	
			f 4	30 Banks & 50 Commer 60 Deporta 62 Naturali	cce/ICC tion zation	U	Statutes 890 Other Stat (if not adm review or I	inistrativ	e agency	

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O G. Habeas Corpus/ 2255	O H. Employment Discrimination	O I. FOIA/Privacy Act	O J. Student Loan	
530 Habeas Corpus – General 510 Motion/Vacate Sentence 463 Habeas Corpus – Alien Detainee	442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation)	895 Freedom of Information Act 890 Other Statutory Actions (if Privacy Act)	152 Recovery of Defaulted Student Loan (excluding veterans)	
	(If pro se, select this deck)	*(If pro se, select this deck)*		
K. Labor/ERISA (non-employment) 710 Fair Labor Standards Act 720 Labor/Mgmt. Relations 740 Labor Railway Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Empl. Ret. Inc. Security Act	L. Other Civil Rights (non-employment) 441 Voting (if not Voting Rights Act) 443 Housing/Accommodations 440 Other Civil Rights 445 Americans w/Disabilities – Employment 446 Americans w/Disabilities – Other 448 Education	M. Contract 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholder's Suits 190 Other Contracts 195 Contract Product Liability 196 Franchise	N. Three-Judge Court 441 Civil Rights – Voting (if Voting Rights Act)	
V. ORIGIN				
O 1 Original Proceeding Proceeding Court O 3 Remanded from Appellate Court Court C 5 Transferred from another district (specify) 6 Multi-district District Judge from Mag. Direct File Judge				
VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.) First Amendment, Fifth Amendment, 42 U.S.C. §§ 2000bb to 2000bb-1, et seq., 21 U.S.C. § 360bbb-3				
VII. REQUESTED IN COMPLAINT	A CONTRACTOR OF D. C.D. C.D. C.D.	s Injunctive Relief RY DEMAND: Check Y YES	ES only if demanded in complaint	
VIII. RELATED CASE(S) IF ANY	(See instruction) YES	NO X If yes, p	lease complete related case form	
DATE: October 24, 2021	SIGNATURE OF ATTORNEY OF REC	CORD/S/ MICHAEL	. A. YODER	

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

- I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.
- III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the <u>primary</u> cause of action found in your complaint. You may select only <u>one</u> category. You <u>must</u> also select <u>one</u> corresponding nature of suit found under the category of the case.
- VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

UNITED STATES DISTRICT COURT

for the
District of Columbia

	District o	of Columbia
)
STEVEN CHURCH, et al.		,))
Plaintiff(s)		Ć
v.		Civil Action No.
		ý
JOSEPH R. BIDEN, et al.))
Defendant(s))
Defenuin(s)		,
	SUMMONS IN	A CIVIL ACTION
To: (Defendant's name and address)	JOSEPH R. BIDEN President of the Uni 1600 Pennsylvania 1st Floor, West Wir Washington, D.C. 2	ited States Ave NW
A lawsuit has been filed ag	gainst you.	
are the United States or a United St. P. 12 (a)(2) or (3) — you must serv	tates agency, or an office ve on the plaintiff an ansire. The answer or motio Michael A. Yoder, I	Michael A. Yoder, PLLC Suite 700
If you fail to respond, judg You also must file your answer or		entered against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		
		Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (name	ne of individual and title, if an	ıy)		
was red	ceived by me on (date)		·		
	☐ I personally served	the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons a		ence or usual place of abode with (name)		
			a person of suitable age and discretion who res		re,
	on (date)	, and mailed a	copy to the individual's last known address; or		
		ons on (name of individual)			, who is
	designated by law to a	accept service of process	s on behalf of (name of organization)		
			on (date)	; or	
	☐ I returned the summons unexecuted because			; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penalty	of perjury that this info	ormation is true.		
Date:		_			
			Server's signature		
		_	Printed name and title		
		_	Server's address		

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the District of Columbia

	District of C	olumbia
STEVEN CHURCH, et al. Plaintiff(s) v.)))))	Civil Action No.
JOSEPH R. BIDEN, et al. Defendant(s))	
	SUMMO	NS IN A CIVIL ACTION
To: (Defendant's name and address)	LLOYD J. AUSTIN III as Secretary of the Dep 1000 Defense Pentagor Washington, D.C. 2030	n, Room 3E880
A lawsuit has been filed aga	ainst you.	
are the United States or a United States P. 12 (a)(2) or (3) — you must serve	ates agency, or an officer or e on the plaintiff an answer	hael A. Yoder, PLLC te 700
If you fail to respond, judgr You also must file your answer or n	<u> </u>	red against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		Signature of Clerk or Deputy Clerk
		Signature of Clerk of Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was rec	This summons for (na. ceived by me on (date)	me of individual and title, if any	· .		
	☐ I personally served	I the summons on the indi-	<u> </u>	; or	
	☐ I left the summons		on (date) nce or usual place of abode with (name) a person of suitable age and discretion w	·	···
	on (date)		opy to the individual's last known addre		.e,
		ons on (name of individual) accept service of process	on behalf of (name of organization)		, who is
			on (date)	; or	
	☐ I returned the sum	mons unexecuted because	-		; or
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total	1 of \$	·
	I declare under penalt	y of perjury that this infor	mation is true.		
Date:		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the District of Columbia

	District of C	Columbia
)	
)	
STEVEN CHURCH, et al.)	
Plaintiff(s))	
v.)	Civil Action No.
)	
JOSEPH R. BIDEN, et al.)	
Defendant(s))	
	SUMMONS IN A	A CIVIL ACTION
To: (Defendant's name and address)	ANTONY J. BLINKE capacity as Secretary of The Executive Office, 600 19th Street NW Washington, D.C. 2052	of State Suite 5.600
A lawsuit has been filed ag	gainst you.	
are the United States or a United S P. 12 (a)(2) or (3) — you must ser	tates agency, or an officer of we on the plaintiff an answer	hael A. Yoder, PLLC ite 700
	Armigion, virginia 222	201
If you fail to respond, judg You also must file your answer or	•	ered against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		
	-	Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (nan	ne of individual and title, if any)			
was re	ceived by me on (date)	·			
	☐ I personally served	the summons on the individual	at (place)		
			on (date)		
	☐ I left the summons	at the individual's residence or	usual place of abode with (name)		
		, a perso	on of suitable age and discretion who res	sides the	ere,
	on (date)	, and mailed a copy to	the individual's last known address; or		
	☐ I served the summo	ons on (name of individual)			, who is
	designated by law to a	accept service of process on bel	nalf of (name of organization)		
			on (date)	; or	
	☐ I returned the sumn	nons unexecuted because			; or
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penalty	y of perjury that this information	n is true.		
Date:					
			Server's signature		
			Printed name and title		
			Server's address		

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the District of Columbia

	District o	i Columbia
))
STEVEN CHURCH, et al.		,))
Plaintiff(s)		
v.		Civil Action No.
		,)
)
JOSEPH R. BIDEN, et al.))
Defendant(s))
	SUMMONS IN	N A CIVIL ACTION
To: (Defendant's name and address)	JANET YELLEN, in capacity as Secretary 1500 Pennsylvania A Room 2134 Washington, D.C. 20	y of Treasury Avenue NW
A lawsuit has been filed ag	gainst you.	
are the United States or a United S P. 12 (a)(2) or (3) — you must ser	tates agency, or an office ve on the plaintiff an answer. The answer or motion Michael A. Yoder, E	Nichael A. Yoder, PLLC Suite 700
If you fail to respond, judg You also must file your answer or		ntered against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		
	-	Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was rec	This summons for (no ceived by me on (date)	ume of individual and title, if an	· -			
	☐ I personally served	d the summons on the indi	·-	; or		
	☐ I left the summons		nce or usual place of abode with (name)	·	·a	
	on (date) , and mailed a copy to the individual's last known address; or					
		nons on (name of individual) accept service of process	on behalf of (name of organization)		, who is	
			on (date)	; or		
	☐ I returned the sum	mons unexecuted because			; or	
	☐ Other (<i>specify</i>):					
	My fees are \$	for travel and \$	for services, for a tota	al of \$		
	I declare under penal	ty of perjury that this info	rmation is true.			
Date:		_	Server's signature			
		_	Printed name and title	2		
		_	Server's address			

	District of C	Columbia
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)	
STEVEN CHURCH, et al.)	
Plaintiff(s))	
V.)	Civil Action No.
)	
JOSEPH R. BIDEN, et al.)	
Defendant(s))	
Defendani(s)	,	
	SUMMONS IN A	A CIVIL ACTION
To: (Defendant's name and address)	MERRICK B. GARLA official capacity as Att the United States 950 Pennsylvania Ave Washington, D.C. 205	nue NW
A lawsuit has been filed aga	ainst you.	
are the United States or a United States P. 12 (a)(2) or (3) — you must serve	ates agency, or an officer of e on the plaintiff an answer	not counting the day you received it) — or 60 days if you remployee of the United States described in Fed. R. Civ. r to the attached complaint or a motion under Rule 12 of nust be served on the plaintiff or plaintiff's attorney,
	The Law Office of Mic	
	2300 Wilson Blvd., Su Arlington, Virginia 222	
	Timigion, Virginia 222	201
If you fail to respond, judgr You also must file your answer or n	•	ered against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		
		Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was re	This summons for (na ceived by me on (date)	ame of individual and title, if ar	· · · -		
was ic	•	d the summons on the ind			
		d the summons on the ma	on (date)	; or	
	☐ I left the summon		ence or usual place of abode with (name)		
	on (Irra)		, a person of suitable age and discretion who re		re,
	-		copy to the individual's last known address; or	ľ	
		nons on (name of individual)	1 1 10 0		, who is
	designated by law to	accept service of process	s on behalf of (name of organization)		
				; or	
	☐ I returned the sum	nmons unexecuted because	e		; or
	☐ Other (<i>specify</i>):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
Date.		_	Server's signature		
		_	Printed name and title		
		:-	Server's address		

	District of C	Columbia
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)	
STEVEN CHURCH, et al.)	
Plaintiff(s))	
V.)	Civil Action No.
)	
JOSEPH R. BIDEN, et al.)	
Defendant(s))	
Defendani(s)	,	
	SUMMONS I	N A CIVIL ACTION
To: (Defendant's name and address)	DEBRA ANN HAAL capacity as Secretary of 1849 C Street NW Washington, D.C. 202	of the Interior
A lawsuit has been filed aga	ainst you.	
are the United States or a United States P. 12 (a)(2) or (3) — you must serve the Federal Rules of Civil Procedure	ates agency, or an officer of e on the plaintiff an answe	(not counting the day you received it) — or 60 days if you or employee of the United States described in Fed. R. Civ. It to the attached complaint or a motion under Rule 12 of must be served on the plaintiff or plaintiff's attorney,
whose name and address are:	Michael A. Yoder, Esq	Į.
	The Law Office of Mic	
	2300 Wilson Blvd., Su Arlington, Virginia 222	
	Timigron, Virginia 22	
If you fail to respond, judgr You also must file your answer or n		ered against you for the relief demanded in the complaint.
		CLERK OF COURT
_		
Date:		Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)			
was rec	ceived by me on (date)		<u> </u>			
	☐ I personally served	d the summons on the ind	ividual at (place)			
			on (date)	; or		
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)			
		,	a person of suitable age and discretion who res	ides there,		
	on (date), and mailed a copy to the individual's last known address; or					
	☐ I served the summ	ons on (name of individual)		, who is		
	designated by law to	accept service of process	on behalf of (name of organization)			
			on (date)	; or		
	☐ I returned the sum	mons unexecuted because	e	; or		
	☐ Other (specify):					
	My fees are \$	for travel and \$	for services, for a total of \$			
	I declare under penal	ty of perjury that this info	ormation is true.			
Date:						
		_	Server's signature			
		_	Printed name and title			
		_	Server's address			

	District of Col	umbia		
)			
)			
STEVEN CHURCH, et al.)			
Plaintiff(s))			
V.)	Civil Action No.		
)			
JOSEPH R. BIDEN, et al.)			
Defendant(s))			
	SUMMONS IN A	A CIVIL ACTION		
To: (Defendant's name and address)	THOMAS J. VILSACK, capacity as Secretary of A 1400 Independence Aven Washington, D.C. 20250	Agriculture		
A lawsuit has been filed ag	gainst you.			
are the United States or a United S P. 12 (a)(2) or (3) — you must serv	tates agency, or an officer or enve on the plaintiff an answer to	counting the day you received it) — or 60 days if you imployee of the United States described in Fed. R. Civ. the attached complaint or a motion under Rule 12 of the served on the plaintiff or plaintiff's attorney, el A. Yoder, PLLC		
	2300 Wilson Blvd., Suite 700			
	Arlington, Virginia 22201			
If you fail to respond, judg You also must file your answer or		d against you for the relief demanded in the complaint.		
		CLERK OF COURT		
Date:	_			
		Signature of Clerk or Deputy Clerk		

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (nan	ne of individual and title, if any)			
was re	ceived by me on (date)	·			
	☐ I personally served	the summons on the individual	at (place)		
			on (date)		
	☐ I left the summons	at the individual's residence or	usual place of abode with (name)		
		, a perso	on of suitable age and discretion who res	sides the	ere,
	on (date)	, and mailed a copy to	the individual's last known address; or		
	☐ I served the summo	ons on (name of individual)			, who is
	designated by law to a	accept service of process on bel	nalf of (name of organization)		
			on (date)	; or	
	☐ I returned the sumn	nons unexecuted because			; or
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penalty	y of perjury that this information	n is true.		
Date:					
			Server's signature		
			Printed name and title		
			Server's address		

	District of C	Columbia
)))	
STEVEN CHURCH, et al.)	
Plaintiff(s))	
V.)))	Civil Action No.
JOSEPH R. BIDEN, et al.)	
Defendant(s)		
	SUMMONS II	N A CIVIL ACTION
To: (Defendant's name and address)	GINA M. RAIMONDO capacity as Secretary of 1401 Constitution Ave Washington, D.C. 202	of Commerce NW
A lawsuit has been filed aga	ainst you.	
are the United States or a United Sta P. 12 (a)(2) or (3) — you must serv	ates agency, or an officer of e on the plaintiff an answer	not counting the day you received it) — or 60 days if you remployee of the United States described in Fed. R. Civ. to the attached complaint or a motion under Rule 12 of nust be served on the plaintiff or plaintiff's attorney,
	The Law Office of Mic	hael A. Yoder, PLLC
	2300 Wilson Blvd., Sui	
	Arlington, Virginia 222	201
If you fail to respond, judgr You also must file your answer or n		ered against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:		
		Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)			
was rec	ceived by me on (date)		<u> </u>			
	☐ I personally served	d the summons on the ind	ividual at (place)			
			on (date)	; or		
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)			
		,	a person of suitable age and discretion who res	ides there,		
	on (date), and mailed a copy to the individual's last known address; or					
	☐ I served the summ	ons on (name of individual)		, who is		
	designated by law to	accept service of process	on behalf of (name of organization)			
			on (date)	; or		
	☐ I returned the sum	mons unexecuted because	e	; or		
	☐ Other (specify):					
	My fees are \$	for travel and \$	for services, for a total of \$			
	I declare under penal	ty of perjury that this info	ormation is true.			
Date:						
		_	Server's signature			
		_	Printed name and title			
		_	Server's address			

	District of Columbia	
STEVEN CHURCH, et al. Plaintiff(s) v. JOSEPH R. BIDEN, et al. Defendant(s))))) ()) () () () () () () () () ()	
Dejenaani(s)	,	
	SUMMONS IN A CIVIL ACTION	
To: (Defendant's name and address)	MARTIN J. WALSH, in his official capacity as Secretary of Labor 200 Constitution Avenue NW Washington, D.C. 20210	
A lawsuit has been filed aga	ainst you.	
are the United States or a United States P. 12 (a)(2) or (3) — you must serve	e of this summons on you (not counting the day you received it)— tes agency, or an officer or employee of the United States describe e on the plaintiff an answer to the attached complaint or a motion u e. The answer or motion must be served on the plaintiff or plaintiff Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201	ed in Fed. R. Civ. nder Rule 12 of
If you fail to respond, judgm You also must file your answer or m	nent by default will be entered against you for the relief demanded notion with the court.	in the complaint.
	CLERK OF COURT	
Date:		
	Signature of Clerk or Dept	uty Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was ra	This summons for (nan ceived by me on (date)				
was ic	•	·			
	☐ I personally served	the summons on the individual			
			on (date)	; or	
	☐ I left the summons	at the individual's residence or	usual place of abode with (name)		
		, a perso	on of suitable age and discretion who re	sides the	ere,
	on (date)	, and mailed a copy to	the individual's last known address; or		
	☐ I served the summo	ons on (name of individual)			, who is
	designated by law to a	accept service of process on beh	alf of (name of organization)		
			on (date)	; or	
	☐ I returned the sumn	nons unexecuted because			; or
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penalty	y of perjury that this information	n is true.		
Date:					
			Server's signature		
			Printed name and title		
			Server's address		

	District of Columbia
)
STEVEN CHURCH, et al.))
Plaintiff(s)	
V.	Civil Action No.
)
)
JOSEPH R. BIDEN, et al.	
Defendant(s)	
	SUMMONS IN A CIVIL ACTION
To: (Defendant's name and address)	XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services 200 Independence Avenue SW Washington, D.C. 20201
A lawsuit has been filed ag	ainst you.
are the United States or a United S P. 12 (a)(2) or (3) — you must serv	e of this summons on you (not counting the day you received it) — or 60 days if you ates agency, or an officer or employee of the United States described in Fed. R. Civ. to on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the the answer or motion must be served on the plaintiff or plaintiff's attorney, Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201
If you fail to respond, judg You also must file your answer or	ment by default will be entered against you for the relief demanded in the complaint. motion with the court.
	CLERK OF COURT
Date:	
	Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was re	This summons for (na ceived by me on (date)	ame of individual and title, if ar	· · · -		
was ic	•	d the summons on the ind			
	on (date) ; or				
	☐ I left the summons at the individual's residence or usual place of abode with (name)				
	on (Irra)		, a person of suitable age and discretion who re		re,
	-		copy to the individual's last known address; or	ľ	
		nons on (name of individual)	1 1 10 0		, who is
	designated by law to	accept service of process	s on behalf of (name of organization)		
				; or	
	☐ I returned the sum	nmons unexecuted because	e		; or
	☐ Other (<i>specify</i>):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
Date.		_	Server's signature		
		_	Printed name and title		
		:-	Server's address		

District of Columbia				
)			
)			
STEVEN CHURCH, et al.)			
Plaintiff(s))			
V.)	Civil Action No.		
)			
JOSEPH R. BIDEN, et al.)			
Defendant(s))			
(//////////	,			
	SUMMONS IN A	A CIVIL ACTION		
To: (Defendant's name and address) MARCIA L. FUDGE, in her official capacity as Secretary of Housing and Urban Development 451 7th Street SW Washington, DC 20410				
A lawsuit has been filed ag	gainst you.			
are the United States or a United St. P. 12 (a)(2) or (3) — you must serv	tates agency, or an officer of we on the plaintiff an answe	chael A. Yoder, PLLC ite 700		
If you fail to respond, judg You also must file your answer or		ered against you for the relief demanded in the complaint.		
		CLERK OF COURT		
Date:				
		Signature of Clerk or Deputy Clerk		

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was red	ceived by me on (date)		·		
	☐ I personally serve	ed the summons on the ind	lividual at (place)		
			on (date)	; or	
	☐ I left the summons at the individual's residence or usual place of abode with (name)				
		,	a person of suitable age and discretion who resi	des there,	
	on (date)	, and mailed a	copy to the individual's last known address; or		
	☐ I served the summons on (name of individual) , w				
	designated by law to	accept service of process	s on behalf of (name of organization)		
			on (date)	; or	
	☐ I returned the sum	nmons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	lty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

for the

	District of Co	olumbia
STEVEN CHURCH, et al. Plaintiff(s) v. JOSEPH R. BIDEN, et al.))))))))	Civil Action No.
Defendant(s))	
	SUMMONS IN A	CIVIL ACTION
To: (Defendant's name and address)	PETER BUTTIGIEG, i capacity as Secretary of 1200 New Jersey Aven Washington, DC 20590	Transportation ue SE
A lawsuit has been filed ag	gainst you.	
are the United States or a United St P. 12 (a)(2) or (3) — you must serv	tates agency, or an officer or we on the plaintiff an answer	te 700
If you fail to respond, judg You also must file your answer or	•	red against you for the relief demanded in the complaint.
		CLERK OF COURT
Date:	-	Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who res	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	on (date) ; or				
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

	District of	Columbia	
)		
)		
STEVEN CHURCH, et al.)		
Plaintiff(s))		
V.)	Civil Action No.	
)		
JOSEPH R. BIDEN, et al.)		
Defendant(s))		
	SUMMONS IN A	A CIVIL ACTION	
To: (Defendant's name and address) JENNIFER M. GRANHOLM, in her official capacity as Secretary of Energy 1000 Independence Avenue SW Washington, D.C. 20585			
A lawsuit has been filed ag	ainst you.		
are the United States or a United St P. 12 (a)(2) or (3) — you must serv	ates agency, or an officer of re on the plaintiff an answer. The answer or motion of Michael A. Yoder, Eso The Law Office of Michael States	chael A. Yoder, PLLC	
	2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201		
If you fail to respond, judg You also must file your answer or i		tered against you for the relief demanded in the complaint.	
		CLERK OF COURT	
Date:			
		Signature of Clerk or Deputy Clerk	

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who res	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	on (date) ; or				
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

	District of Co	lumbia		
)			
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STEVEN CHURCH, et al.)			
Plaintiff(s)				
v.)	Civil Action No.		
)			
JOSEPH R. BIDEN, et al.)			
Defendant(s))			
	SUMMONS IN A (CIVIL ACTION		
To: (Defendant's name and address) MIGUEL CARDONA, in his official capacity as Secretary of Education 400 Maryland Avenue SW Washington, DC 20202				
A lawsuit has been filed ag	gainst you.			
are the United States or a United St. P. 12 (a)(2) or (3) — you must serv	tates agency, or an officer or early on the plaintiff an answer to re. The answer or motion must be Michael A. Yoder, Esq. The Law Office of Michael A.			
	2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201			
	Allington, virginia 2220	1		
If you fail to respond, judg You also must file your answer or		ed against you for the relief demanded in the complaint.		
		CLERK OF COURT		
Date:				
		Signature of Clerk or Deputy Clerk		

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who res	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	on (date) ; or				
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

District of Columbia				
STEVEN CHURCH, et al. Plaintiff(s) v.))))) (ivil Action No.))			
JOSEPH R. BIDEN, et al.)			
Defendant(s)				
	SUMMONS IN A CIVIL ACTION			
To: (Defendant's name and address)	DENIS McDONOUGH, in his official capacity as Secretary of Veteran Affairs 810 Vermont Ave NW Washington, D.C. 20420			
A lawsuit has been filed ag	gainst you.			
are the United States or a United S P. 12 (a)(2) or (3) — you must serv	ce of this summons on you (not counting the day you received it) — or 60 days if you tates agency, or an officer or employee of the United States described in Fed. R. Civ. we on the plaintiff an answer to the attached complaint or a motion under Rule 12 of re. The answer or motion must be served on the plaintiff or plaintiff's attorney, Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201			
If you fail to respond, judg You also must file your answer or	gment by default will be entered against you for the relief demanded in the complaint. motion with the court.			
	CLERK OF COURT			
Date:	Signature of Clerk or Deputy Clerk			
	Signature of Clerk of Deputy Clerk			

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who res	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	on (date) ; or				
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

District of Columbia				
STEVEN CHURCH, et al.)))			
Plaintiff(s))			
v.)))	Civil Action No.		
JOSEPH R. BIDEN, et al.)			
Defendant(s)				
	SUMMONS I	IN A CIVIL ACTION		
To: (Defendant's name and address)	ALEJANDRO MAYOR capacity as Secretary of 2707 Martin Luther Kir Washington, D.C. 2052	f Homeland Security ng Jr. Avenue SE		
A lawsuit has been filed aga	ainst you.			
are the United States or a United States P. 12 (a)(2) or (3) — you must serve	ates agency, or an officer or e on the plaintiff an answer	not counting the day you received it) — or 60 days if you employee of the United States described in Fed. R. Civ. to the attached complaint or a motion under Rule 12 of ust be served on the plaintiff or plaintiff's attorney,		
	The Law Office of Mich	nael A. Yoder PLLC		
	2300 Wilson Blvd., Suit			
	Arlington, Virginia 222	01		
If you fail to respond, judgr You also must file your answer or n	•	red against you for the relief demanded in the complaint.		
		CLERK OF COURT		
Date:				
		Signature of Clerk or Deputy Clerk		

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who resi	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	_		on (date)	; or	
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

District of Columbia				
STEVEN CHURCH, et al. Plaintiff(s) v. JOSEPH R. BIDEN, et al. Defendant(s))) ()) () () () () () () () () () () (
	SUMMONS IN A CIVIL ACTION			
To: (Defendant's name and address)	CLARENCE W. NELSON II, in his official capacity as Administrator of the National Aeronautics and Space Administration 300 E Street SW Washington, D.C. 20546			
A lawsuit has been filed aga	inst you.			
Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201				
If you fail to respond, judgr You also must file your answer or n	ent by default will be entered against you for the relief demanded in the complaint. otion with the court.			
	CLERK OF COURT			
Date:	Signature of Clerk or Deputy Clerk			
	Signature of Clerk of Deputy Clerk			

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who resi	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	_		on (date)	; or	
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

District of Columbia				
STEVEN CHURCH, et al. Plaintiff(s) v. JOSEPH R. BIDEN, et al. Defendant(s)))))) (Civil Action No.))))))))			
	SUMMONS IN A CIVIL ACTION			
 Γο: (Defendant's name and address) KILOLO KIJAKAZI, in her official capacity as Acting Commissioner of the Social Security Administration Office of General Counsel, Room 617 6401 Security Boulevard Baltimore, MD 21235 				
A lawsuit has been filed aga	inst you.			
Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201				
If you fail to respond, judgn You also must file your answer or m	nent by default will be entered against you for the relief demanded in the complaint. notion with the court.			
	CLERK OF COURT			
Date:				
	Signature of Clerk or Deputy Clerk			

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

	This summons for (no	ame of individual and title, if an	ny)		
was rec	ceived by me on (date)		<u> </u>		
	☐ I personally served	d the summons on the ind	ividual at (place)		
			on (date)	; or	
	☐ I left the summons	s at the individual's reside	ence or usual place of abode with (name)		
		,	a person of suitable age and discretion who resi	ides there,	
	on (date), and mailed a copy to the individual's last known address; or				
	☐ I served the summ	ons on (name of individual)		, who is	
	designated by law to	accept service of process	on behalf of (name of organization)		
	_		on (date)	; or	
	☐ I returned the sum	mons unexecuted because	e	; or	
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
	I declare under penal	ty of perjury that this info	ormation is true.		
Date:					
		_	Server's signature		
		_	Printed name and title		
		_	Server's address		

District of Columbia				
STEVEN CHURCH, et al. Plaintiff(s) v.)))) () () () () () () () () () () ()			
JOSEPH R. BIDEN, et al. Defendant(s)				
	SUMMONS IN A CIVIL ACTION			
To: (Defendant's name and address)	ROBIN CARNAHAN, in her official capacity as Administrator of General Services Administration 1800 F Street NW Washington, DC 20405			
A lawsuit has been filed ag	gainst you.			
Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Michael A. Yoder, Esq. The Law Office of Michael A. Yoder, PLLC 2300 Wilson Blvd., Suite 700 Arlington, Virginia 22201				
If you fail to respond, judg You also must file your answer or	ment by default will be entered against you for the relief demanded in the complaint. motion with the court.			
	CLERK OF COURT			
Date:				
	Signature of Clerk or Deputy Clerk			

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

was ra	This summons for (nan ceived by me on (date)				
was ic	•	·			
	☐ I personally served	the summons on the individual			
			on (date)	; or	
	☐ I left the summons	at the individual's residence or	usual place of abode with (name)		
		, a perso	on of suitable age and discretion who re	sides the	ere,
	on (date)	, and mailed a copy to	the individual's last known address; or		
	☐ I served the summo	ons on (name of individual)			, who is
	designated by law to a	accept service of process on beh	alf of (name of organization)		
			on (date)	; or	
	☐ I returned the sumn	nons unexecuted because			; or
	☐ Other (specify):				
	My fees are \$	for travel and \$	for services, for a total of \$		
I declare under penalty of perjury that this information is true.					
Date:					
			Server's signature		
			Printed name and title		
			Server's address		

EXHIBIT 1

Executive Order 13991

Presidential Documents

Executive Order 13991 of January 20, 2021

Protecting the Federal Workforce and Requiring Mask-Wearing

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 7902(c) of title 5, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID–19) by relying on the best available data and science-based public health measures. Such measures include wearing masks when around others, physical distancing, and other related precautions recommended by the Centers for Disease Control and Prevention (CDC). Put simply, masks and other public health measures reduce the spread of the disease, particularly when communities make widespread use of such measures, and thus save lives.

Accordingly, to protect the Federal workforce and individuals interacting with the Federal workforce, and to ensure the continuity of Government services and activities, on-duty or on-site Federal employees, on-site Federal contractors, and other individuals in Federal buildings and on Federal lands should all wear masks, maintain physical distance, and adhere to other public health measures, as provided in CDC guidelines.

- **Sec. 2.** Immediate Action Regarding Federal Employees, Contractors, Buildings, and Lands. (a) The heads of executive departments and agencies (agencies) shall immediately take action, as appropriate and consistent with applicable law, to require compliance with CDC guidelines with respect to wearing masks, maintaining physical distance, and other public health measures by: on-duty or on-site Federal employees; on-site Federal contractors; and all persons in Federal buildings or on Federal lands.
- (b) The Director of the Office of Management and Budget (OMB), the Director of the Office of Personnel Management (OPM), and the Administrator of General Services, in coordination with the President's Management Council and the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), shall promptly issue guidance to assist heads of agencies with implementation of this section.
- (c) Heads of agencies shall promptly consult, as appropriate, with State, local, Tribal, and territorial government officials, Federal employees, Federal employee unions, Federal contractors, and any other interested parties concerning the implementation of this section.
- (d) Heads of agencies may make categorical or case-by-case exceptions in implementing subsection (a) of this section to the extent that doing so is necessary or required by law, and consistent with applicable law. If heads of agencies make such exceptions, they shall require appropriate alternative safeguards, such as additional physical distancing measures, additional testing, or reconfiguration of workspace, consistent with applicable law. Heads of agencies shall document all exceptions in writing.
- (e) Heads of agencies shall review their existing authorities and, to the extent permitted by law and subject to the availability of appropriations and resources, seek to provide masks to individuals in Federal buildings when needed.
- (f) The COVID-19 Response Coordinator shall coordinate the implementation of this section. Heads of the agencies listed in 31 U.S.C. 901(b) shall

- update the COVID–19 Response Coordinator on their progress in implementing this section, including any categorical exceptions established under subsection (d) of this section, within 7 days of the date of this order and regularly thereafter. Heads of agencies are encouraged to bring to the attention of the COVID–19 Response Coordinator any questions regarding the scope or implementation of this section.
- **Sec. 3**. Encouraging Masking Across America. (a) The Secretary of Health and Human Services (HHS), including through the Director of CDC, shall engage, as appropriate, with State, local, Tribal, and territorial officials, as well as business, union, academic, and other community leaders, regarding mask-wearing and other public health measures, with the goal of maximizing public compliance with, and addressing any obstacles to, mask-wearing and other public health best practices identified by CDC.
- (b) The COVID-19 Response Coordinator, in coordination with the Secretary of HHS, the Secretary of Homeland Security, and the heads of other relevant agencies, shall promptly identify and inform agencies of options to incentivize, support, and encourage widespread mask-wearing consistent with CDC guidelines and applicable law.
- Sec. 4. Safer Federal Workforce Task Force.
- (a) *Establishment*. There is hereby established the Safer Federal Workforce Task Force (Task Force).
 - (b) Membership. The Task Force shall consist of the following members:
 - (i) the Director of OPM, who shall serve as Co-Chair;
 - (ii) the Administrator of General Services, who shall serve as Co-Chair;
 - (iii) the COVID-19 Response Coordinator, who shall serve as Co-Chair;
 - (iv) the Director of OMB;
 - (v) the Director of the Federal Protective Service;
 - (vi) the Director of the United States Secret Service;
 - (vii) the Administrator of the Federal Emergency Management Agency; (viii) the Director of CDC; and
 - (ix) the heads of such other agencies as the Co-Chairs may individually or jointly invite to participate.
- (c) Organization. A member of the Task Force may designate, to perform the Task Force functions of the member, a senior-level official who is a full-time officer or employee of the member's agency. At the direction of the Co-Chairs, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees, as appropriate.
- (d) Administration. The General Services Administration shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations. The Co-Chairs shall convene regular meetings of the Task Force, determine its agenda, and direct its work.
- (e) Mission. The Task Force shall provide ongoing guidance to heads of agencies on the operation of the Federal Government, the safety of its employees, and the continuity of Government functions during the COVID—19 pandemic. Such guidance shall be based on public health best practices as determined by CDC and other public health experts, and shall address, at a minimum, the following subjects as they relate to the Federal workforce:
 - (i) testing methodologies and protocols;
 - (ii) case investigation and contact tracing;
 - (iii) requirements of and limitations on physical distancing, including recommended occupancy and density standards;
 - (iv) equipment needs and requirements, including personal protective equipment;
 - (v) air filtration;

- (vi) enhanced environmental disinfection and cleaning;
- (vii) safe commuting and telework options;
- (viii) enhanced technological infrastructure to support telework;
- (ix) vaccine prioritization, distribution, and administration;
- (x) approaches for coordinating with State, local, Tribal, and territorial health officials, as well as business, union, academic, and other community leaders:
- (xi) any management infrastructure needed by agencies to implement public health guidance; and
- (xii) circumstances under which exemptions might appropriately be made to agency policies in accordance with CDC guidelines, such as for mission-critical purposes.
- (f) Agency Cooperation. The head of each agency listed in 31 U.S.C. 901(b) shall, consistent with applicable law, promptly provide the Task Force a report on COVID-19 safety protocols, safety plans, or guidance regarding the operation of the agency and the safety of its employees, and any other information that the head of the agency deems relevant to the Task Force's work.
- **Sec. 5.** Federal Employee Testing. The Secretary of HHS, through the Director of CDC, shall promptly develop and submit to the COVID–19 Response Coordinator a testing plan for the Federal workforce. This plan shall be based on community transmission metrics and address the populations to be tested, testing types, frequency of testing, positive case protocols, and coordination with local public health authorities for contact tracing.
- **Sec. 6.** Research and Development. The Director of the Office of Science and Technology Policy, in consultation with the Secretary of HHS (through the National Science and Technology Council), the Director of OMB, the Director of CDC, the Director of the National Institutes of Health, the Director of the National Science Foundation, and the heads of any other appropriate agencies, shall assess the availability of Federal research grants to study best practices for implementing, and innovations to better implement, effective mask-wearing and physical distancing policies, with respect to both the Federal workforce and the general public.
- **Sec. 7**. *Scope*. (a) For purposes of this order:
 - (i) "Federal employees" and "Federal contractors" mean employees (including members of the Armed Forces and members of the National Guard in Federal service) and contractors (including such contractors' employees) working for the executive branch;
 - (ii) "Federal buildings" means buildings, or office space within buildings, owned, rented, or leased by the executive branch of which a substantial portion of occupants are Federal employees or Federal contractors; and
 - (iii) "Federal lands" means lands under executive branch control.
- (b) The Director of OPM and the Administrator of General Services shall seek to consult, in coordination with the heads of any other relevant agencies and the COVID–19 Response Coordinator, with the Sergeants at Arms of the Senate and the House of Representatives and the Director of the Administrative Office of the United States Courts (or such other persons designated by the Majority and Minority Leaders of the Senate, the Speaker and Minority Leader of the House, or the Chief Justice of the United States, respectively), to promote mask-wearing, physical distancing, and adherence to other public health measures within the legislative and judicial branches, and shall provide requested technical assistance as needed to facilitate compliance with CDC guidelines.
- **Sec. 8**. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:
 - (i) the authority granted by law to an executive department or agency, or the head thereof; or

- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) Independent agencies are strongly encouraged to comply with the requirements of this order.
- (d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

R. Bedar. Ji

THE WHITE HOUSE, January 20, 2021.

[FR Doc. 2021–01766 Filed 1–22–21; 11:15 am] Billing code 3295–F1–P

Order, Dept. of Defense, dated Aug. 24, 2021



SECRETARY OF DEFENSE 1000 DEFENSE PENTAGON WASHINGTON, DC 20301-1000

AUG 2 4 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP COMMANDERS OF THE COMBATANT COMMANDS DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and



Readiness may provide additional guidance to implement and comply with FDA requirements or Centers for Disease Control and Prevention recommendations.

The Secretaries of the Military Departments should impose ambitious timelines for implementation. Military Departments will report regularly on vaccination completion using established systems for other mandatory vaccine reporting.

Our vaccination of the Force will save lives. Thank you for your focus on this critical mission.

ARAPIRETE

2

Executive Order 14043

Presidential Documents

Executive Order 14043 of September 9, 2021

Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 3302, and 7301 of title 5, United States Code, it is hereby ordered as follows:

Section 1. Policy. It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID–19), including the B.1.617.2 (Delta) variant, by relying on the best available data and science-based public health measures. The Delta variant, currently the predominant variant of the virus in the United States, is highly contagious and has led to a rapid rise in cases and hospitalizations. The nationwide public health emergency, first declared by the Secretary of Health and Human Services on January 31, 2020, remains in effect, as does the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) declared pursuant to the National Emergencies Act in Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak). The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services has determined that the best way to slow the spread of COVID–19 and to prevent infection by the Delta variant or other variants is to be vaccinated.

COVID-19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID-19 vaccines, the Pfizer-BioNTech COVID-19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID-19 Vaccine and the Janssen COVID-19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

The health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service. I have determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service requires immediate action to protect the Federal workforce and individuals interacting with the Federal workforce. It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID–19 to their co-workers and members of the public. The CDC has found that the best way to do so is to be vaccinated.

The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce. Agencies have also taken important actions, including in some cases requiring COVID–19 vaccination for members of their workforce.

Accordingly, building on these actions, and in light of the public health guidance regarding the most effective and necessary defenses against COVID—19, I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID—19 vaccination for all Federal employees, subject to such exceptions as required by law.

- **Sec. 2**. Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees. Each agency shall implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law. The Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order.
- Sec. 3. Definitions. For the purposes of this order:
- (a) The term "agency" means an Executive agency as defined in 5 U.S.C. 105 (excluding the Government Accountability Office).
- (b) The term "employee" means an employee as defined in 5 U.S.C. 2105 (including an employee paid from nonappropriated funds as referenced in 5 U.S.C. 2105(c)).
- **Sec. 4**. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:
 - (i) the authority granted by law to an executive department or agency, or the head thereof; or
 - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
- (d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

R. Beden. J.

THE WHITE HOUSE, September 9, 2021.

[FR Doc. 2021–19927 Filed 9–13–21; 8:45 am] Billing code 3295–F1–P

Task Force Guidance, dated Sept. 13, 2021

Safer Federal Workforce Task Force

COVID-19 Workplace Safety: Agency Model Safety Principles

Last Updated September 13, 2021 (Previously Updated July 29, 2021)

Recent Updates

- Federal Executive Branch employees must be fully vaccinated, except in limited circumstances
 where an employee is legally entitled to a reasonable accommodation. Agencies must work
 expeditiously so that their employees are fully vaccinated as quickly as possible and by no later
 than November 22, 2021.
- With the government-wide adoption and implementation of these vaccination requirements, agencies are no longer required to establish a screening testing program for employees or onsite contractor employees who are not fully vaccinated, although they may do so.
- The President has <u>announced</u> that Federal contractor employees will be required to be vaccinated. Prior to being contractually required to be vaccinated, onsite contractor employees who are not fully vaccinated and are not part of an agency testing program must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building.

Purpose

The purpose of this document is to provide model safety principles for executive departments and agencies (hereafter, "agency" and collectively, "agencies") for their COVID-19 workplace safety plans. In Executive Order No. 13991, President Biden established the Safer Federal Workforce Task Force to oversee the development and implementation of agency COVID-19 workplace safety plans across the Federal Government. In his Executive Order on *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees* and his Executive Order on *Ensuring Adequate COVID Safety Protocols for Federal Contractors*, President Biden directed the Task Force to issue guidance on implementation of the requirements in those Orders.

Agencies should incorporate these model safety principles into their existing COVID-19 workplace safety plans.

Agencies with onsite contractor employees should address how the protocols below are applied to those individuals to promote Federal workplace safety in the context of COVID-19.

Overview of Model Principles

The Federal Government is committed to addressing essential work requirements consistent with best public health practices. The Administration's paramount concern is the health and safety of all Federal employees, onsite contractor employees, and individuals interacting with the Federal workforce.

The principles presented here are aligned with the latest guidance from the Centers for Disease Control and Prevention (CDC) for employers and for fully vaccinated people and the Occupational Safety and Health Administration (OSHA) on protecting workers, based on evolving understanding of the pandemic. These principles will be reassessed over time, as conditions warrant and as CDC guidelines are updated.

Where a locality has imposed additional pandemic-related requirements more protective than those set forth in these model safety principles, those requirements should be followed in Federal buildings and on Federal land in that locality.

Goal

The health and safety of the Federal workforce is the Administration's highest priority.

Health and Safety

Vaccination

To ensure the safety of the Federal workforce, Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. Agencies must work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021.

When a Federal employee is required to be vaccinated, the time the employee spends obtaining any COVID-19 vaccination (including travel time) is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. Employees may not be credited with administrative leave for time spent getting a vaccination. If, due to unforeseen circumstances, the employee is unable to obtain the vaccine during basic tour of duty hours the normal overtime hours of work rules apply.

Employees will receive paid time off to address any side effects. Employees will also receive paid time off to accompany a family member being vaccinated. For this purpose, a "family member" is an individual who meets the definition of that term in OPM's leave regulations (see 5 CFR 630.201).

Some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status. Given the different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated, agencies need to ask about the vaccination status of visitors to Federal buildings and onsite contractor employees who are not yet contractually required to be vaccinated. Individuals must attest to the truthfulness of the response they provide. When an individual discloses that they are not fully vaccinated or declines to provide information on their vaccination status, agencies should treat that individual as not fully vaccinated for purposes of implementing safety measures, including with respect to mask wearing and physical distancing.

Onsite contractor employees who are not yet contractually required to be vaccinated and who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building—as noted below, if a contractor employee is regularly tested pursuant to an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Visitors to Federal buildings who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building. See the section below on Meetings, Events, and Conferences

for how visitor requirements apply to in-person participants in meetings, events, and conferences hosted by agencies.

These requirements related to the provision of information about vaccination and provision of proof of a recent negative COVID-19 test do not apply to members of the public entering a Federal building or Federal land to obtain a public service or benefit. If they are not fully vaccinated, these visitors must comply with all relevant CDC guidance, including wearing a mask and physically distancing from other people.

Levels of Community Transmission

For purposes of this guidance, when determining levels of community transmission in a given area, agencies should reference the CDC COVID-19 Data Tracker County View. Agencies can use discretion in determining the counties relevant to the determination of the level of community transmission in a given area for a given Federal facility. For example, agencies may consider the county in which an agency facility is located as well as the transmission levels of surrounding local counties from which employees commute to the facility.

Telework and Remote Work

Agencies should utilize telework and remote work consistent with the principles set forth in OMB Memorandum M-21-25 and agency plans for reentry and post-reentry.

COVID-19 Coordination Team

Each agency should maintain its COVID-19 Coordination Team, as detailed in OMB Memorandum M-21-15. This team should, at a minimum, include a representative from: each component agency (if applicable); the appropriate human resources office(s); occupational safety and health experts; executive leadership; legal counsel; and a public health expert. If such a public health expert does not exist at the agency, the Safer Federal Workforce Task Force will designate someone. The team should meet regularly to review compliance with agency COVID-19 workplace safety plans and protocols, consider potential revisions to agency COVID-19 workplace safety plans and protocols pursuant to guidance from the Safer Federal Workforce Task Force and current CDC guidelines, and evaluate any other operational needs related to COVID-19 workplace safety. The team should coordinate all decisions with Facility Security Committees, as appropriate. For privately owned facilities leased by the Federal Government, the team must coordinate with the General Services Administration (GSA), where appropriate, and the lessor's designated representative.

Face Masks and Physical Distancing

Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. In addition, some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status.

Individuals who are not fully vaccinated must wear a mask regardless of community transmission level. In areas of high or substantial transmission, fully vaccinated people must wear a mask in public indoor settings, except for limited exceptions discussed in this section.

In areas of low or moderate transmission, in most settings, fully vaccinated people generally do not need to wear a mask or physically distance in Federal buildings or on Federal land, except where required by Federal, State, local, Tribal, or territorial laws, rules, or regulations. Fully vaccinated individuals might choose to wear a mask regardless of the level of transmission for a variety of reasons. Nothing in CDC guidance precludes an employee from wearing a mask, if the employee so chooses. CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, should be followed, as applicable.

Individuals who are not fully vaccinated or who decline to provide their vaccination status—or who are in an area of substantial or high transmission—must wear a mask that covers their nose and mouth, and that is in accordance with current CDC guidance. CDC recommends the following: disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source), masks with two or three layers, and masks with inner filter pockets. Agencies should not allow novelty or non-protective masks, masks with ventilation valves, or face shields as a substitute for masks.

In addition to properly wearing a mask, individuals who are not fully vaccinated or who decline to provide information about their vaccination status must maintain distance. To the extent practicable, individuals who are not fully vaccinated or who decline to provide information about their vaccination status should maintain a distance of at least six feet from others at all times, consistent with CDC guidelines, including in offices, conference rooms, and all other communal and work spaces.

For individuals who are required to wear a mask:

- Appropriate masks should be worn consistently and correctly (over mouth and nose).
- Appropriate masks should be worn in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- In general, people do not need to wear masks when outdoors. However, consistent with CDC guidance, those who are not fully vaccinated should wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated.
- Agencies may provide for exceptions consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining distancing in accordance with CDC guidelines.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Masks do not provide the same level of protection as respirators and should not replace personal protective equipment required or recommended at the workplace.

Testing

Agencies may establish a program to test Federal employees who are not fully vaccinated for COVID-19. Agencies may also test contractor employees working onsite who are not fully vaccinated as part of a

testing program—if contractor employees are tested as part of an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Agencies must have a process in place for employee diagnostic testing after a workplace exposure.

Contact Tracing

The agency's COVID-19 Coordination Team will collaborate with and support the contact tracing programs of local health departments to help identify, track, and manage contacts of COVID-19 cases.

The team will engage in coordination with facilities staff to implement infection control and workplace safety efforts once informed of a known or suspected case of COVID-19 (due either to specific symptoms or a positive test).

The team should ensure that the agency makes disclosures to local public health officials, as required or necessary, to provide for the health and safety of Federal employees, contractor employees, and the general public, in accordance with local public health mandates. If COVID-19 cases occur within a specific building or work setting, it will be the responsibility of that agency's COVID-19 Coordination Team (or a field office or agency component designee) to determine—in consultation with local public health officials—appropriate next steps. Agencies should be transparent in communicating related information to the workforce, as relevant and appropriate; disclosures must be consistent with Federal, State, and local privacy and confidentiality laws and regulations.

Travel

Federal employees should adhere strictly to CDC guidelines before, during, and after travel.

For Federal employees who are fully vaccinated, there are no Government-wide restrictions on travel (although agency travel policies still apply).

For the limited number of Federal employees who are not fully vaccinated, agencies should generally observe the following guidance, unless it is contrary to a reasonable accommodation to which an employee is legally entitled. Official domestic travel should be limited to only necessary mission-critical trips. International travel should also be avoided, if at all possible, unless it is mission critical (e.g., military deployments, COVID-19 response deployments or activities, diplomats traveling, high-level international negotiations that cannot occur remotely). Heads of agencies should issue specific guidance to account for the particulars of their agency's mission.

Meetings, Events, and Conferences

Should an agency intend to host an in-person meeting, conference, or event that will be attended by more than 50 participants—regardless of whether participants include members of the public—the agency must first seek the approval of its agency head, in consultation with the agency's COVID-19 Coordination Team.

In-person attendees at any meetings, conferences, and events hosted by an agency, regardless of size, must be asked to provide information about vaccination status. In requesting this information, agencies should comply with any applicable Federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act. In-person attendees who are not fully vaccinated or decline to provide

information about their vaccination status must provide proof of a negative COVID-19 test completed no later than the previous 3 days and comply with masking and physical distancing requirements for individuals who are not fully vaccinated consistent with the requirements for visitors in the Face Masks and Physical Distancing section above. In-person attendees in areas of high or substantial transmission must wear a mask in public indoor settings regardless of vaccination status.

Symptom Monitoring

If Federal employees, onsite contractors, or visitors have symptoms consistent with COVID-19, they should not enter a Federal workplace.

Federal employees and contractor employees working on site should regularly complete virtual or inperson health checks (ask about symptoms, close contact with someone with SARS-CoV-2 infection, and SARS-CoV-2 testing and diagnosis status). The agency will use this information to assess the individual's risk level and to determine whether the individual should be allowed entry to the workplace. Visitors may be asked to complete symptom screening before entering a Federal facility. In developing these tools, agencies may adapt the one developed by CDC.

Any individual, regardless of vaccination status, who develops any symptoms consistent with COVID-19 during the workday must immediately isolate, wear a mask (if the individual is not already doing so and one is available), notify their supervisor, and promptly leave the workplace. Agencies should have processes in place to provide advice and support to supervisors on any related reporting or human resources requirements.

Quarantine, Isolation, and Steps for Fully Vaccinated Individuals Following Exposure to Someone with Suspected or Confirmed COVID-19

Any individual with a suspected or confirmed case of COVID-19 will be advised to isolate, pursuant to CDC guidelines, and in compliance with State, local, and Tribal laws and regulations. Personnel who are not fully vaccinated and who have had a close contact with someone who has tested positive for COVID-19 should follow CDC and State, local, and Tribal guidance for guarantine.

Individuals who have been fully vaccinated and have had close contact with someone with suspected or confirmed COVID-19 should get tested 3-5 days after exposure, even if they do not have symptoms. They should also wear a mask indoors in public for 14 days following exposure or until their test result is negative. If their test result is positive, they should isolate for 10 days.

Confidentiality and Privacy

All medical information collected from individuals, including vaccination information, test results, and any other information obtained as a result of testing and symptom monitoring, will be treated in accordance with applicable laws and policies on confidentiality and privacy, and will be accessible only to those with a need to know. Agencies should consult their Senior Agency Officials for Privacy on matters related to the handling of personally identifiable information and identify a point of contact for all questions relating to personal medical information.

Workplace Operations

Occupancy

Agencies may establish occupancy limits for specific workplaces as a means of facilitating physical distancing. Note that by reducing the number of people in a space, occupancy limits also increase the heating, ventilation, and air conditioning delivery of outdoor air per person.

Environmental Cleaning

Agencies should ensure regular cleaning of common use, high-touch, and high-density spaces, such as lobbies, restrooms, elevators, and stairwells. Office space that is in regular use is to be cleaned regularly, and in accordance with CDC guidelines. Wipes and other Environmental Protection Agency-approved disinfectants will be made available for use by individuals to wipe down workstations and related personal property. Physical barriers, such as plexiglass shields, may be installed, where appropriate.

In the event of a suspected or confirmed case of COVID-19 in the workplace, agencies should ensure enhanced environmental cleaning of the spaces that the individual occupied or accessed in accordance with CDC and, where applicable, GSA guidance, which provides as follows:

- If fewer than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, clean and disinfect the space.
- If more than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, cleaning is enough. You may choose to also disinfect depending on certain conditions or everyday practices required by your facility.
- If more than 3 days have passed since the person who is sick or diagnosed with COVID-19 has been in the space, no additional cleaning (beyond regular cleaning practices) is needed.

If enhanced cleaning is required, wait as long as possible (at least several hours) before cleaning and disinfecting. Extended wait periods allow increased opportunity for viral deactivation to occur naturally, while also allowing time for aerosols to settle, prior to surface disinfection.

The agency's COVID-19 Coordination Team will determine the appropriate scope of workplace closures needed—in some cases, it may be a suite or individual offices or part of a floor, in other cases, it may include an entire building.

Hygiene

Hand sanitizer stations are to be available at the building entrance and throughout workspaces. Hand sanitizers should contain at least 60% alcohol and be manufactured in accordance with the requirements of the U.S. Food and Drug Administration (FDA). Ingredients should be listed on a "Drug Facts" label. Agencies should ensure the hand sanitizer is not on the FDA's do not use list.

Ventilation and Air Filtration

Modifications to ventilation systems should be considered in accordance with CDC guidance, especially as building population density increases. To the maximum extent feasible, indoor ventilation will be optimized to increase the proportion of outdoor air and improve filtration. Deployment of portable higherficiency particulate air (HEPA) cleaners should be considered for higher-risk spaces (e.g., health clinics).

Collective Bargaining Obligations

Consistent with President Biden's policy to support collective bargaining, agencies are reminded to satisfy applicable collective bargaining obligations under 5 U.S.C. Chapter 71 when implementing workplace safety plans, including on a post-implementation basis where necessary. Agencies are also strongly encouraged to communicate regularly with employee representatives on workplace safety matters.

Task Force Video Footage, .mp4 file

USB overnighted to Clerk of Court

Affidavit of Authentication, Capt. Rylan Commins

re: Email, Lt. Alys Jordan, dated Aug. 27, 2021

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

STEVEN CHURCH, et al.

Plaintiffs,

v.

JOSEPH R. BIDEN, et al.

Defendants.

Civil Action No.: 1:21-cv-xxxx (XXX)

AFFIDAVIT OF CAPTAIN RYLAN COMMINS AUTHENTICATING ELECTRONIC CORRESOPNDENCE

I, CAPTAIN RYLAN COMMINS, declare as follows:

- 1. I am an am an active-duty member of the United States Marines Corps and the actual and intended recipient of the correspondence attached hereto as Exhibit 1. I am providing this declaration based on my own personal knowledge and if called as a witness, I could and would testify competently as to all statements included herein.
- 2. The subject of this communication pertains to whether the 22 Area Branch Medical Clinic at Camp Pendleton had yet to receive COMIRNATY as it is the only FDA-approved COVID-19 vaccine available in the United States.
- 3. Lieutenant Alys Jordan, a HLMDA-267 Flight Surgeon at Camp Pendleton, advised "The orders are in for the Comirnaty vaccine and we should have them by early next week."
- 4. As the recipient of the correspondence attached hereto, I am familiar and knowledgeable with this document and all contents included therein.

Case 1:21-cv-02815-CKK Document 1-26 Filed 10/24/21 Page 3 of 5

5. I certify that the attached .pdf-formatted correspondence accurately reflects the true

communications that took place and that no alterations as to its true contents have been made

physically, digitally, or otherwise, notwithstanding highlighting placed over the salient portion of

the communication and the sanitization of sensitive information.

6. I have not deleted, modified, or otherwise altered the original version in text o

meaning, and have maintained the original electronic copy of this communication, including any

related data thereto.

I DECLARE UNDER PENALTY OF PERJURY THAT THE STATEMENTS IN THIS DECLARATION ARE TRUE AND ACCURATE TO THE BEST OF MY KNOWLEDGE,

INFORMATION AND BELIEF.

Executed this 21st day of October, 2021.

/s/ Rylan Commins

CAPTAIN RYLAN COMMINS
United States Marine Corps

(Original Signature retained by Counsel)

2

Email Correspondence, dated Aug. 27, 2021

Commins Capt Rylan R

()rom:

Sent: To:

Friday, August 27, 2021 4:02 PM

Commins Capt Rylan R

Subject:

FYI

FYI

Good morning Gentlemen,

An update on the mass vaccination plan. If the Maradmin comes anytime between now and Tuesday 31AUG, we can expect a 3-day SHOTEX to commence on 01SEPT. If the order comes after that, we can expect a 3-day SHOTEX to commence on 08SEPT. I will send updates as they come.

The orders are in for the Comirnaty vaccine and we should have them by early next week. Please let me know if you have any questions.

Very respectfully,

LT Alys Jordan HMLA-267 Flight Surgeon Camp Pendleton, CA

Affidavit of Authentication, Maj. Edwin Paz

re: DiLorenzo Clinic Email, dated Oct. 15, 2021

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

STEVEN CHURCH, et al.

Plaintiffs,

v.

JOSEPH R. BIDEN, et al.

Defendants.

Civil Action No.: 1:21-cv-xxxx (XXX)

AFFIDAVIT OF AUTHENTICATION

I, MAJOR EDWIN PAZ, declare as follows:

- 1. I am an active-duty member of the United States Marines Corps and the author of the correspondence attached hereto as <u>Exhibit 1</u>. I am providing this declaration based on my own personal knowledge and if called as a witness, I could and would testify competently as to all statements included herein.
- 2. I am the author and sender of the TRICARE medical portal communication attached hereto that was transmitted on October 14-15, 2021.
- 3. The subject of this communication pertains to an inquiry as to whether the DiLorenzo clinic had in stock any vials of an FDA-approved COVID-19 vaccine.
- 4. I sent this communication through the TRICARE medical portal to the office of my primary care provider, Charles Cho, D.O.
- 5. It is a routine and customary practice that members of Dr. Cho's medical staff, such as registered nurses, respond to messages submitted to Dr. Cho's office through the TRICARE medical portal.

Case 1:21-cv-02815-CKK Document 1-27 Filed 10/24/21 Page 3 of 8

6. As the sender of these communications and the intended and actual recipient of the

responses to these communications, I am familiar and knowledgeable with this document and all

contents included therein.

7. I certify that the attached .pdf-formatted correspondence accurately reflects the true

communications that took place and that no alterations or modifications have been made, whether

physically, digitally, or otherwise.

8. I have not deleted, modified, or otherwise altered the original version of this

correspondence, including any related data thereto.

I DECLARE UNDER PENALTY OF PERJURY THAT THE STATEMENTS IN THIS DECLARATION ARE TRUE AND ACCURATE TO THE BEST OF MY KNOWLEDGE, INFORMATION AND BELIEF.

Executed this 21st day of October, 2021.

/s/ Edwin Paz

MAJOR EDWIN PAZ

United States Marine Corps

(Original Signature retained by Counsel)

TRICARE ® Medical Portal Communications

From: Mr. Jose Moore 10/15/2021 10:49:44 AM

For: Dr. Charles Cho DO at NCR-DiLorenzo -PC-Tricare Health Clinic

To: Mr. Edwin Paz

10/15/21, 5:12 PM

RE: RE: Comirnaty Vaccine Availability

Maj Paz,

Below is the response I received from Dr. Seto, the medical director of the DiLorenzo Clinic:

Mr. Moore,

Good morning, thank you for your email. Per the memo attached, "On September 13, 2021, the National Library of Medicine within the National Institutes of Health (NIH), reported, "[a]t present, Pfizer does not plan to produce any product with these new [Comirnaty National Drug Codes] and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution."

Therefore, Pfizer has not made any Comirnaty.

There is no expected date when we will receive Comirnaty.

Dr. Seto

210913 Pfizer Received FDA BLA License for its COVID-19 Vaccine - no new product or labels.pdf

download

MESSAGE THREAD Collapse all

From: Mr. Jose Moore Oct 15, 2021

Maj Paz,

Below is the response I received from Dr. Seto, the medical director of the DiLorenzo Clinic:

Mr. Moore,

Good morning, thank you for your email. Per the memo attached, "On September 13, 2021, the National Library of Medicine within the National Institutes of Health (NIH), reported, "[a]t present, Pfizer does not plan to produce any product with these new [Comirnaty National Drug Codes] and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution."

Therefore, Pfizer has not made any Comirnaty.

There is no expected date when we will receive Comirnaty.

Dr. Seto

From: Mr. Jose Moore Oct 15, 2021

Good Morning Maj Paz,

I have sent your message to clinic management and they should be contacting you on here soon.

Jose Moore, RN

From: Mr. Edwin Paz Oct 14, 2021

Hello,

I would like to know if the DiLorenzo Clinic has the FDA licensed Commirnaty labeled vials in stock. If yes, can you please provide a copy of the included safety booklet that contains vaccine ingredients.

If not, when will the Commirnaty labeled vials be available?

10/15/21, 5:12 PM Case 1:21-cv-0281516ArkHo Orline Salome Meslaging Provided & Palical - Massay 6 Centre

See attached US Senator letter for additional reference before providing a response.

Thank you!

United States Senate

WASHINGTON, DC 20510

October 12, 2021

ATTACHMENT INCLUDED IN ORIGINAL CORREPSONDENCE DATED OCTOBER 14, 2021

The Honorable Joseph R. Biden President The White House Washington, D.C. 20500

The Honorable Lloyd J. Austin III Secretary of Defense U.S. Department of Defense 1000 Defense Pentagon Washington, D.C. 20301

The Honorable Mark A. Milley Chairman of the Joint Chiefs of Staff 9999 Joint Staff Pentagon Washington, D.C. 20318

Dear President Biden, Secretary Austin and General Milley:

Multiple sources have alleged that the Department of Defense's (DoD) mandatory COVID-19 vaccinations may not be in accordance with Secretary of Defense Austin's August 24, 2021 memorandum (vaccine mandate) stating "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."

On August 23, 2021, the FDA stated, "[a]lthough 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 [Emergency Use Authorization] EUA." On September 13, 2021, the National Library of Medicine within the National Institutes of Health (NIH), reported, "[a]t present, Pfizer does not plan to produce any product with these new [Comirnaty National Drug Codes] and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution." Again on September 22, 2021, the FDA stated, "there is not sufficient approved vaccine [Comirnaty] available for distribution to this population

¹ Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF).

² Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021, archived copy available at

https://web.archive.org/web/20210823142034/https://www.fda.gov/media/150386/download (See footnote 9).

³ Announcement, U.S. National Library of Medicine, Pfizer received FDA BLA license for its COVID-19 vaccine (Sept. 13, 2021), available at https://dailymed.nlm.nih.gov/dailymed/dailymed-announcements-details.cfm?date=2021-09-13.

October 12, 2021 Page 2

[individuals 16 years of age and older] in its entirety at the time of reissuance of this EUA."⁴ Absent a sufficient supply of the only approved COVID-19 vaccine, Comirnaty, it is not clear how DoD is complying with Secretary Austin's assertion that mandatory vaccination will only occur with the fully-licensed vaccine.⁵

In order to understand the extent to which DoD service members subject to mandatory COVID-19 vaccination may have not received fully-approved vaccines as prescribed by Secretary Austin's vaccine mandate, I request the following information:

- 1. How many vaccinations have been administered since Secretary Austin's vaccine mandate?
- 2. Please provide the number of voluntary and mandated vaccinations administered to DoD service members using each vaccine by month:
 - a. Moderna EUA;
 - b. Johnson and Johnson (Janssen) EUA;
 - c. Pfizer-BioNTech EUA; and
 - d. Comirnaty FDA approved.
- 3. Please provide all orders issued to DoD personnel regarding DoD's vaccine mandate.
- 4. Please provide all guidelines issued to DoD personnel regarding DoD's vaccine mandate.
- 5. Please provide all documents and communications regarding DoD's vaccine mandate, including but not limited to the development and implementation of the vaccine mandate.

Thank you for your attention to this urgent matter. Please respond no later than October 26, 2021.

Sincerely,

Ron Johnson U.S. Senator

⁴ Letter to Amit Patel, BioNTech Manufacturing GmbH, from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 6, Sept. 22, 2021, available at https://www.fda.gov/media/150386/download (See footnote 12).

⁵ Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF).

Affidavit of Authentication, Jacob Workman

re: Immunization Records, TRICARE, dated Oct. 8, 2021

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

STEVEN CHURCH, et al.

Plaintiffs,

v.

Civil Action No.: 1:21-cv-xxxx (XXX)

JOSEPH R. BIDEN, et al.

Defendants.

AFFIDAVIT OF WARRANT OFFICER ONE JACOB WORKMAN AUTHENTICATING PERSONAL MEDICAL RECORDS

I, WARRANT OFFICER ONE JACOB WORKMAN, declare as follows:

- 1. I am an active-duty member of the Missouri National Guard and submit this affidavit to authenticate my personal medical records attached hereto as Exhibit 1. I am providing this declaration based on my own personal knowledge and if called as a witness, I could and would testify competently as to all statements included herein.
- 2. I certify that I am familiar with the document attached hereto, consisting of four (4) pages, and recognize it to be a copy of my immunization records maintained on the TRICARE Patient Portal.
- 3. I certify that the attached document is a true and accurate copy of my medical records and notwithstanding the redactions that sanitize unrelated sensitive information, the attached document has not been modified or otherwise altered from its original format, whether physically, digitally, or otherwise.
- 4. I certify that my personal immunization records falsely reflect that I received the "COVID-19 Pfizer (COMIRNATY)" vaccine on October 8, 2021.

5. I certify that the COVID-19 vaccine I received on October 8, 2021 was not FDA-approved.

I DECLARE UNDER PENALTY OF PERJURY THAT THE STATEMENTS IN THIS DECLARATION ARE TRUE AND ACCURATE TO THE BEST OF MY KNOWLEDGE, INFORMATION AND BELIEF.

Executed this 21st day of October, 2021.

/s/ Jacob Workman
WO1 JACOB WORKMAN
Missouri National Guard
(Original Signature retained by Counsel)

TRICARE ® Medical Portal Immunization Record

Jacob Workman CONFIDENTIAL Page 1 of 4

Personal Health Information



Created on 19 Oct 2021 @ 1524 CDT

You are seeing portions of your own personal health data information (PHI) or your family member's immunization information as stored in the military Electronic Health Record (EHR). The PHI displayed from your EHR cannot be modified using TRICARE Online. If you have additional information not included in your EHR, note an error, or have questions regarding your PHI, please inform your Health Care team.





IMMUNIZATION HISTORY Date Range: All Sorted By: Vaccine (Ascending) Filter: None Applied

Immunization	COVID-19 Pfizer (COMIRNATY)		
Date Given	08 Oct 2021	Next Due Date	29 Oct 2021
Dosage	0.3 ml	Series	
Provider	Unknown, Provider	Facility	
Manufacturer Name	Pfizer, Inc	Lot Number	FF8839



CONFIDENTIAL Manufacturer Name Lot Number Immunization Date Given **Next Due Date** Dosage **Series** Provider **Facility** Manufacturer Name Lot Number Immunization Date Given **Next Due Date** Dosage Series Provider **Facility Manufacturer Name** Lot Number **Immunization Date Given Next Due Date** Dosage Series Facility Provider **Manufacturer Name Lot Number Immunization Date Given Next Due Date** Dosage **Series** Provider **Facility** Manufacturer Name Lot Number **Immunization Date Given Next Due Date** Dosage Series Provider **Facility Manufacturer Name** Lot Number Immunization **Date Given Next Due Date** Dosage Series Facility Provider **Manufacturer Name Lot Number Immunization Date Given Next Due Date** Dosage Series Facility Provider **Manufacturer Name** Lot Number

Page 4 of 4

CONFIDENTIAL

Immunization		
Date Given	Next Due Date	
Dosage	Series	
Provider	Facility	
Manufacturer Name	Lot Number	
Immunization		
Date Given	Next Due Date	
Dosage	Series	
Provider	Facility	
Manufacturer Name	Lot Number	
Immunization		
Date Given	Next Due Date	
Dosage	Series	
Provider	Facility	
Manufacturer Name	Lot Number	
Immunization		
Date Given	Next Due Date	
Dosage	Series	
Provider	Facility	
Manufacturer Name	Lot Number	
Immunization		
Date Given	Next Due Date	
Dosage	Series	
Provider	Facility	
Manufacturer Name	Lot Number	



Jacob Workman

Personal Data - Privacy Act 1974 (PL 93-579)
For Official Use Only (FOUO)
TRICARE Online (TOL) is a Department of Defense (DoD) computer system. Use of this site is governed by multiple DoD policies and terms summarized in the TRICARE Online Security Policy. Many of these policies are designed to protect the privacy of your personal information. We encourage you to review these policies.

EXHIBIT 9

Cpl. Christopher Hall Denial Letter

Case 1:21-cv-02815-CKK Document 1-29 Filed 10/24/21 Page 2 of 2



DEPARTMENT OF THE NAVY

HEADQUARTERS, UNITED STATES MARINE CORPS 3280 RUSSELL ROAD QUANTICO, VIRGINIA 22134-5103

> 1730 MRA

Mowaters at (703) 784-

SEP 2 9 2021

From: Deputy Commandant for Manpower and Reserve Affairs

To: Lance Corporal Christopher E. Hall 1547969592/6132 USMC

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION TO BE EXEMPT FROM THE

COVID-19 VACCINATION

1. I have carefully considered your request for an immunization waiver. Your request is denied.

- 2. In making this determination, I considered your request dated 25 August 2021, the command endorsements and exhibits attached to it, advice from the Director, Health Services, Headquarters, U.S. Marine Corps, and the recommendation of the Religious Accommodation Review Board. Additionally, I considered your right to observe the tenants of your sincerely held religious beliefs, and the government's compelling interests in mission accomplishment, including military readiness and the health and safety of the Total Force. I also considered whether an exception to the vaccination requirement is the least restrictive means of furthering the government's compelling interest. Finally, I consulted with legal counsel.
- 3. Per DoDI 1300.17, my decision must be consistent with mission accomplishment, including consideration of potential medical risks to other persons comprising the unit or organization. Immunizations are a critical component of individual and unit readiness. This compelling interest is not unique to the COVID-19 vaccination, and cannot be accomplished with the requested exception. I find that there is no less-restrictive way of accommodating your request that ensures military readiness and the preservation of the health of the force.
- 4. You have the right to appeal this decision to the Commandant of the Marine Corps. Should you decide to appeal this decision, your appeal should be in naval letter format, from you, addressed to the Commandant of the Marine Corps. Forward your appeal via your chain of command to the point of contact below, for delivery to the Commandant.

5. Point of contact on this matter is Mr. Bi 9386 or william.mcwaters@usmc.mil.

DAVED A OTTINION

Copy to: CG, 1ST MAW CO, MAG-24

CO, MALS-24

EXHIBIT 10

1st Lt. Andrew Soto Denial Letter



DEPARTMENT OF THE NAVY

HEADQUARTERS, UNITED STATES MARINE CORPS 3280 RUSSELL ROAD QUANTICO, VIRGINIA 22134-5103

> 1730 MRA

OCT 1 3 2021

From: Deputy Commandant for Manpower and Reserve Affairs
To: First Lieutenant Andrew C. Soto 1272941749/4502 USMC

Subj: REQUEST FOR RELIGIOUS ACCOMMODATION EXEMPTING 1STLT A. C. SOTO

FROM MANDATORY COVID-19 VACCINATION

- 1. I have carefully considered your request for an immunization waiver. Your request is denied.
- 2. In making this determination, I considered your request dated 22 September 2021, the command endorsements and exhibits attached to it, advice from the Director, Health Services, Headquarters, U.S. Marine Corps, and the recommendation of the Religious Accommodation Review Board. Additionally, I considered your right to observe the tenets of your sincerely held religious beliefs, and the government's compelling interests in mission accomplishment, including military readiness and the health and safety of the Total Force. I also considered whether an exception to the vaccination requirement is the least restrictive means of furthering the government's compelling interest. Finally, I consulted with legal counsel.
- 3. Per DoDI 1300.17, my decision must be consistent with mission accomplishment, including consideration of potential medical risks to other persons comprising the unit or organization. Immunizations are a critical component of individual and unit readiness. This compelling interest is not unique to the COVID-19 vaccination, and cannot be accomplished with the requested exception. I find that there is no less-restrictive way of accommodating your request that ensures military readiness and the preservation of the health of the force.
- 4. You have the right to appeal this decision to the Commandant of the Marine Corps. Should you decide to appeal this decision, your appeal should be in naval letter format, from you, addressed to the Commandant of the Marine Corps. Forward your appeal to the point of contact below, for delivery to the Commandant.
- 5. Point of contact on this matter is Mr. Bill McWaters at (703) 784-9386 or william.mcwaters@usmc.mil.

DAVID A. OTTIGNON

Copy to: CG, 2D MEF CO, 2D MIG CO, 2D INTEL BN

EXHIBIT 11

San Diego HHSA COVID-19 Statistics, Oct. 20, 2021





COVID-19 Watch

Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report

Prepared by Epidemiology and Immunization Services
Branch

www.sdepi.org

October 20, 2021

Cases

364,637

Deaths

4,163

Outbreaks

2,847

Data through 10/16/2021

Report Content Links

Page 2: Summary

Page 3: COVID-19 Infections by Vaccination Status

Page 4: COVID-19 Hospitalizations by Vaccination Status

Page 5: Daily COVID-19 Counts by Vaccination Status – Previous 3 Months

Page 6: Weekly COVID-19 Counts by Age – Previous 3 Months

Page 7: Selected Characteristics of COVID-19 Cases, Hospitalizations, and Deaths

Page 8: Age-Adjusted COVID-19 Case Rates by Race/Ethnicity

Page 9: Age-Adjusted COVID-19 Hospitalization Rates by Race/Ethnicity

Page 10: Case Rates by Zip Code of Residence

Page 11: COVID-19 Potential Exposure Settings

Community Setting Outbreaks

Page 12: <u>Number of Vaccinations Administered and Cumulative Number of Persons Fully Vaccinated</u>
Percent Fully Vaccinated by Zip Code of Residence

Page 13: COVID-19 Vaccinations by Race/Ethnicity and Health Equity

Page 14: COVID-19 Cases in Children and Outbreaks in School Settings

Page 15: COVID-19 Cases in Schools

Page 16: COVID-19 Laboratory Test Positivity Rate – Previous 12 Months

Emergency Department Data – Previous 12 Months

Page 17: COVID-19 Pandemic at a Glance

Page 18: Pandemic at a Glance: Summary of COVID-19-associated Deaths

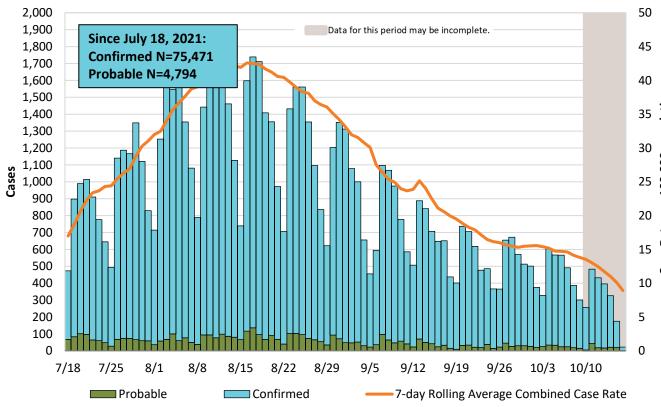






Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report Data through 10/16/2021

Figure 1. COVID-19 Confirmed and Probable Cases and 7-Day Rolling Average Case Rate by Date of Illness Onset*, San Diego County Residents, N=80,265



^{*}When onset date is unavailable, specimen collection date, date of death, or date reported is used instead.

Table 1. Summary of Cases, Deaths, and Outbreaks by Date Reported

	10/10 10/16/2021	10/2 10/0/2021	Commission
	10/10 - 10/16/2021	10/3 – 10/9/2021	Cumulative
Cases	3,624 👚	3,021	364,637
Avg Daily Cases	518 👚	432	620
Deaths	50 👚	32	4,163
Outbreaks	31	37	2,847



^{**}Probable cases are antigen positive tests received since August 1, 2020.





COVID-19 Infections by Vaccination Status

Case rate for not fully vaccinated residents is 3 times higher than fully vaccinated residents

Dates: 9/26-10/2/2021 **Not Fully Vaccinated*** Fully Vaccinated** **County Overall Case Rate Case Rate Case Rate** 24.5 14.7

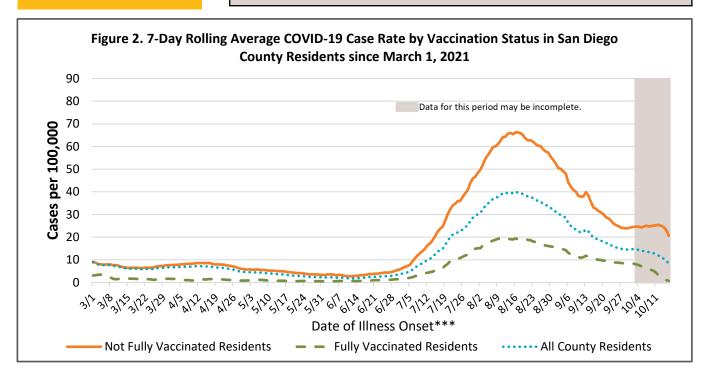


Table 2. COVID-19 Cases Among San Diego County Residents by Vaccination Status Since March 1, 2021

	Not Fully Vaccinated*	Fully Vaccinated**	Total
Cases	76,894 (76.6%)	23,429 (23.4%)	100,323
Hospitalizations	2,593 (94.4%)	154 (5.6%)	2,747
Deaths	387 (85.1%)	68 (14.9%)	455

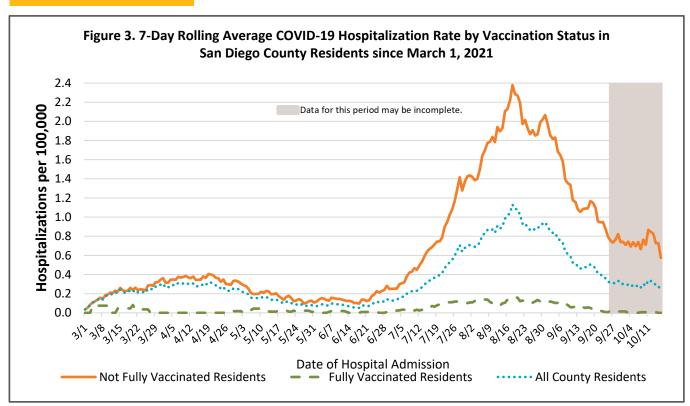
^{*}Not fully vaccinated includes individuals with one dose of the two-dose series, no doses, or unknown vaccination status. Individuals less than 12 years of age who are not yet eligible for the vaccine are also included.

^{**}Cases who first tested positive (based on specimen collection date) greater than or equal to 14 days after receiving the final dose of COVID-19 vaccine. Percentages are among total cases, hospitalizations, and deaths for the time period.

^{***}If case did not have symptoms or illness onset date is unavailable, the earliest of specimen collection date, date of death, or date reported is used instead. San Diego County Population from SANDAG 2019 Population Estimates (Prepared June 2020) = 3,351,784. The fully vaccinated population for each day is the cumulative number of county residents documented to have received the final dose of COVID-19 vaccine more than 14 days prior to that day. The not fully vaccinated population is the estimated total county population minus the fully vaccinated population.



COVID-19 Hospitalizations by Vaccination Status Dates: 9/19-9/25/2021 Hospitalization rate for not fully Fully Vaccinated ** **County Overall Not Fully Vaccinated*** vaccinated residents Hospitalization Hospitalization **Hospitalization Rate** Rate Rate is 113 times higher than fully vaccinated 0.32 0.79 0.007residents



^{*}Not fully vaccinated includes individuals with one dose of the two-dose series, no doses, or unknown vaccination status. Individuals less than 12 years of age who are not yet eligible for the vaccine are also included.

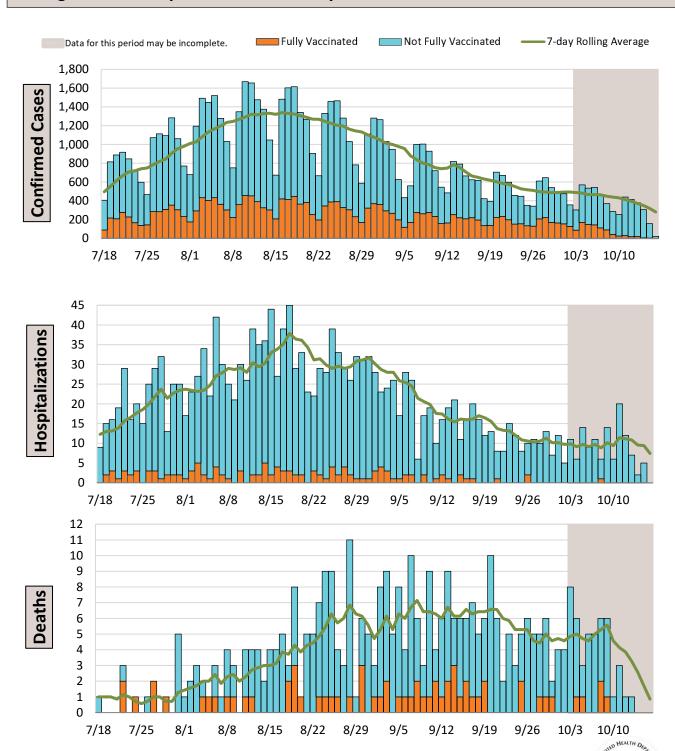


^{**}Cases who first tested positive (based on specimen collection date) greater than or equal to 14 days after receiving the final dose of COVID-19 vaccine. San Diego County Population from SANDAG 2019 Population Estimates (Prepared June 2020) = 3,351,784. The fully vaccinated population for each day is the cumulative number of county residents documented to have received the final dose of COVID-19 vaccine more than 14 days prior to that day. The not fully vaccinated population is the estimated total county population minus the fully vaccinated population.





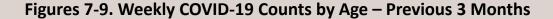
Figures 4-6. Daily COVID-19 Counts by Vaccination Status – Previous 3 Months

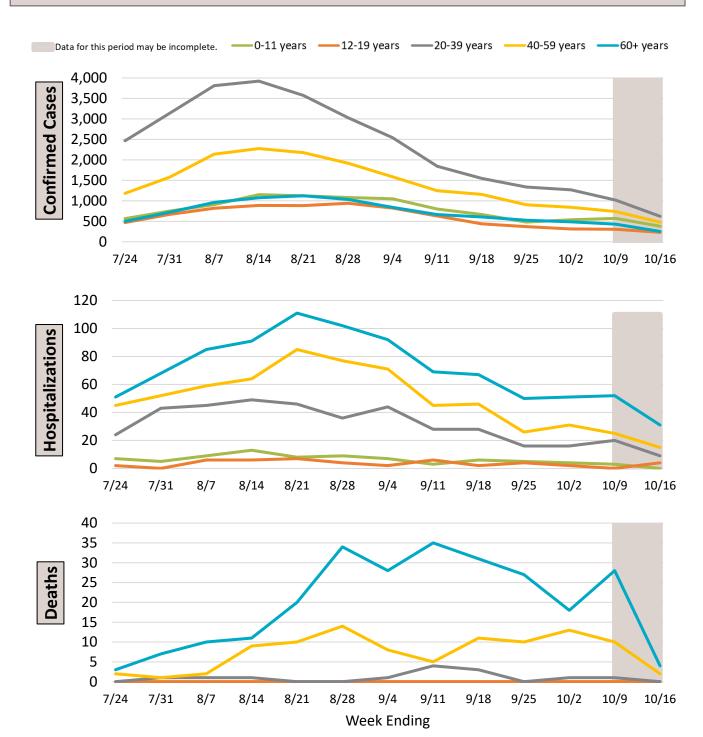


Data through 10/16/2021

Epidemiology and Immunization Services Branch www.sdepi.org (619) 692-8499















Selected Characteristics of COVID-19 Cases, Hospitalizations, and Deaths

Table 3. Confirmed Cases by Date Reported, Last Two Weeks vs. Cumulative

ses		October 3, 2021 – October 16, 2021	February 14, 2020 – October 16, 2021
ပီ	Confirmed cases	6,645	364,637
per	Median age	33 years	34 years
firm	Age range	0-100+ years	0-100+ years
Conf	Male	3,279 (50%)	176,962 (49%)
3	Female	3,317 (50%)	185,040 (51%)

Table 4. Confirmed Hospitalizations by Date of Admission, Last Two Weeks vs. Cumulative

suo		October 3, 2021 – October 16, 2021	February 14, 2020 – October 16, 2021
lizatior	Hospitalizations	161 (2%)	17,922 (5%)
	Median age	62 years	62 years
pita	Age range	0-96 years	0-100+ years
Hos	Male	89 (56%)	9,639 (54%)
	Female	70 (44%)	8,252 (46%)

Sex is unknown for 2 hospitalizations for the last two weeks and for 31 hospitalizations cumulatively.

Note: Percentage hospitalized is calculated based on the total number of cases; information may be unknown in some cases. Hospitalization counts are likely underreported and may increase as additional information is obtained.

Table 5. Confirmed Deaths by Date of Death, Last Two Weeks vs. Cumulative

		October 3, 2021 – October 16, 2021	February 14, 2020 – October 16, 2021
	Deaths	45	4,163
SI	Case Fatality Ratio	N/A*	1.1%
Deaths	Underlying Conditions**	38 (84%)	3,969 (95%)
De	Median age	67 years	76 years
	Age range	35-89 years	10-100+ years
	Male	28 (62%)	2,497 (60%)
	Female	17 (38%)	1,666 (40%)

^{*}Data are incomplete for this time period.



^{**}Refer to the graph on page 18 for more details.





Age-Adjusted COVID-19 Case Rates by Race/Ethnicity

Figure 10. Age-Adjusted Rates of Confirmed Cases by Race/Ethnicity, San Diego County Residents

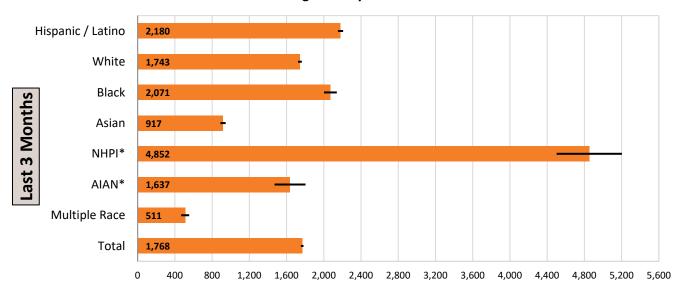
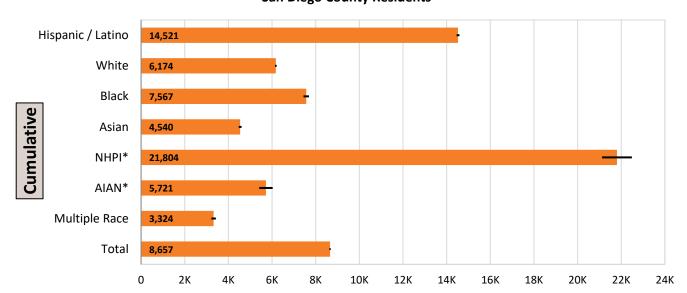


Figure 11. Age-Adjusted Rates of Confirmed Cases by Race/Ethnicity, San Diego County Residents



The black lines represent the 95% confidence intervals (error bars). Rates are not calculated for fewer than 20 events.



^{*}NHPI=Native Hawaiian/Pacific Islander, AIAN=American Indian/Alaska Native.





Age-Adjusted COVID-19 Hospitalization Rates by Race/Ethnicity

Figure 12. Age-Adjusted Rates of Hospitalizations by Race/Ethnicity, San Diego County Residents

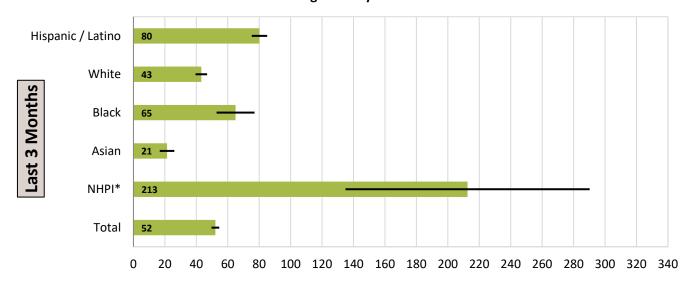
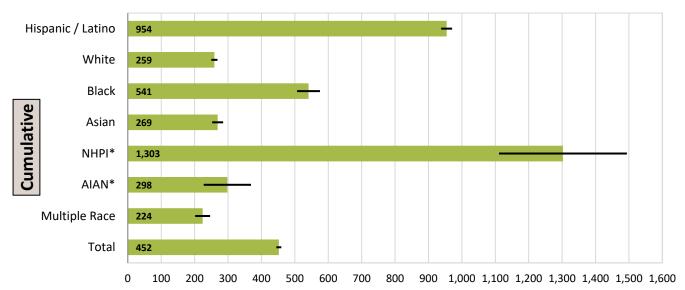


Figure 13. Age-Adjusted Rates of Hospitalizations by Race/Ethnicity, **San Diego County Residents**



The black lines represent the 95% confidence intervals (error bars).

Rates are not calculated for fewer than 20 events. Hospitalization rates were not calculated for the last three months for Multiple Race and AIAN because these categories have fewer than 20 events.



^{*}NHPI=Native Hawaiian/Pacific Islander, AIAN=American Indian/Alaska Native.

Case 1:21-cv-02815-CKK Document 1-31 Filed 10/24/21 COVID-19 WATCH





Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report

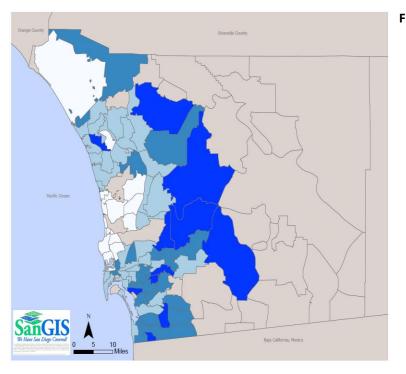
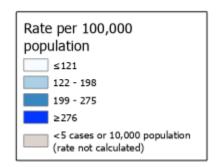


Figure 14. Confirmed Case Rate by Zip Code of Residence, 10/3/2021-10/16/2021, **San Diego County** (Countywide Rate = 198 per 100,000 Population)



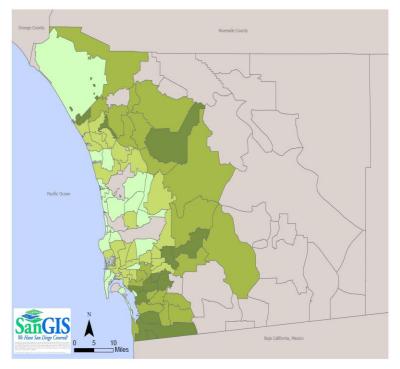
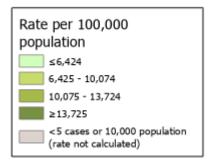


Figure 15. Cumulative Confirmed Case Rate by Zip Code of Residence, **San Diego County** (Countywide Rate = 10,879 per 100,000 Population)



Rates calculated using 2019 population estimates from the San Diego Association of Governments. Rates not calculated for counts under 5 cases or populations less than 10,000. Zip code is zip code of residence, which may not be location of exposure. Case counts and rates for each zip code are updated routinely on the County of San Diego COVID-19 website.

Data through 10/16/2021



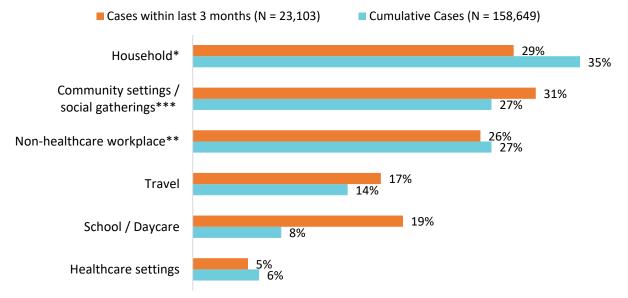






COVID-19 Potential Exposure Settings

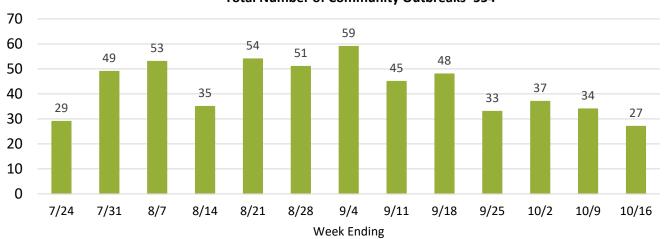
Figure 16. All Potential Exposure Settings Identified Among Confirmed Cases, **San Diego County Residents**



Potential exposure settings are places case-patients visited during their exposure period, not confirmed sources of infection. Persons may be exposed in multiple locations and types of settings, including the household, the workplace, educational settings, other community settings, and during travel. Community settings are defined as indoor or outdoor locations in which cases came within 6 feet of anyone who was not a household member for at least 15 minutes during the 2-14 days prior to symptom onset, even if the case wore a mask or facial covering.

COVID-19 Community Setting Outbreaks

Figure 17. Community Setting Outbreaks* by Date Outbreak Confirmed **Total Number of Community Outbreaks=554**



^{*}Community setting outbreaks are defined as at least three probable or confirmed COVID-19 cases within a 14-day period in people who are epidemiologically-linked in the setting, are from different households, and are not identified as close contacts of each other in any other case investigation. Examples include workplaces, adult and child daycare facilities, K-12 schools and colleges/universities, and day camps.

Data through 10/16/2021

Case 1:21-cv-02815-CKK Document 1-31 Filed 10/24/21 COVID-19 WATCH

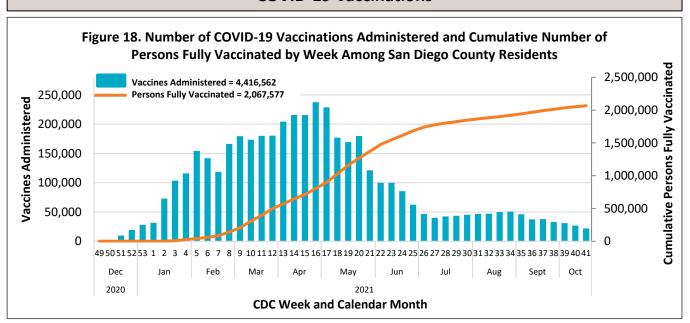


Page 13 of 20



Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report

COVID-19 Vaccinations



The bars show vaccines administered, not individuals vaccinated. The line shows the cumulative number of persons fully vaccinated per the dose and schedule regimen for the vaccine received.

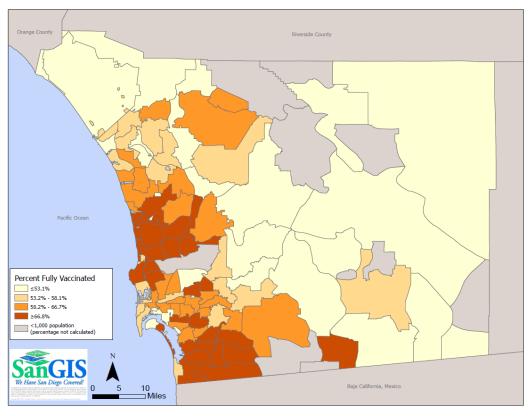


Figure 19. Percentage of the Total Population of San Diego County **Residents Who are** Fully Vaccinated, by Zip Code of Residence

Only includes vaccines that have been recorded in the San Diego Immunization Registry (SDIR). Some healthcare providers, including Veteran's Affairs, the Department of Defense, some tribal entities, and prisons do not report to SDIR. See this dashboard, updated daily, for more detailed vaccine status information for San Diego County. Data source: San Diego Immunization Registry, SANDAG 2019 Population Estimates (Prepared June 2020).

Data through 10/16/2021

Epidemiology and Immunization Services Branch www.sdepi.org

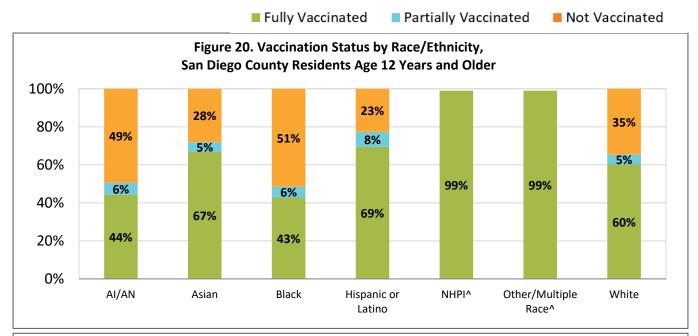
(619) 692-8499

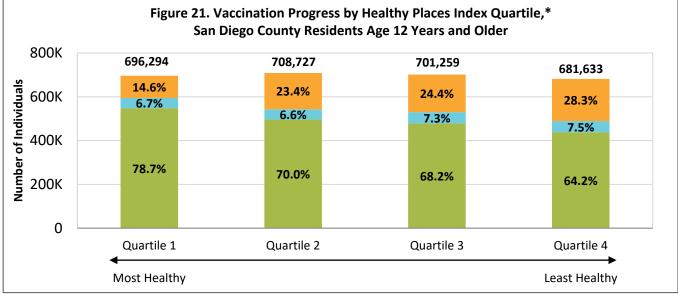






COVID-19 Vaccinations by Race/Ethnicity and Health Equity





^{*}The California Healthy Places Index

Individuals vaccinated by Veterans Affairs or Department of Defense are not included.

COVID-19 vaccine is not approved for those under age 12 at this time.

Data source: San Diego Immunization Registry, SANDAG 2019 Population Estimates (Prepared June 2020). Total population 12 years of age and older=2,833,418. Population estimate of 45,505 individuals do not reside in a census tract with a Healthy Places Index score.

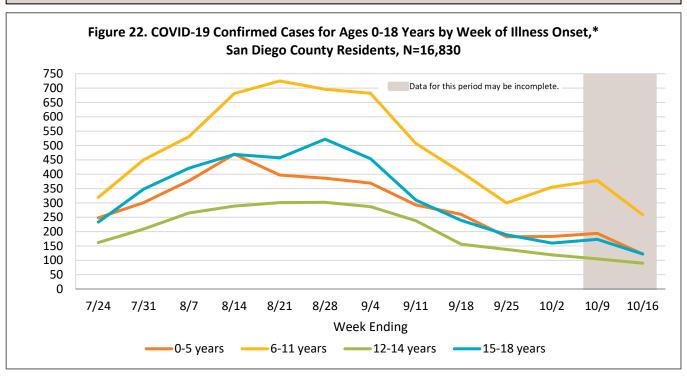
Data through 10/16/2021

[^]The percentage and rate of the population vaccinated with at least one dose of COVID-19 vaccine may approach, or exceed, 99% or 999 per 1,000 San Diego residents aged 12 years and older. The most recent race/ethnicity populations are 2019 estimates, which may underestimate the current population. When these demographics are analyzed, the population estimates may not reflect social and environmental changes of a community, possibly leading to an under- or overestimate of a population.

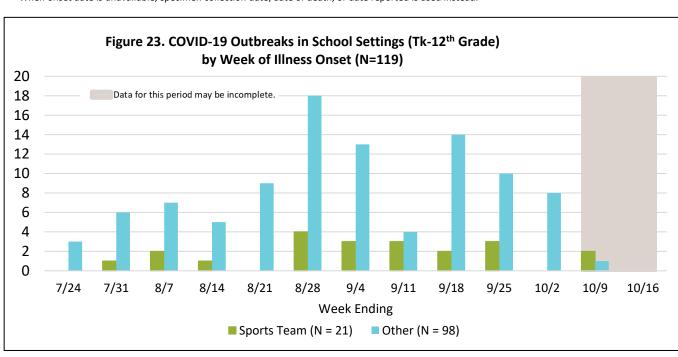




COVID-19 Cases in Children and Outbreaks in School Settings



^{*}When onset date is unavailable, specimen collection date, date of death, or date reported is used instead.



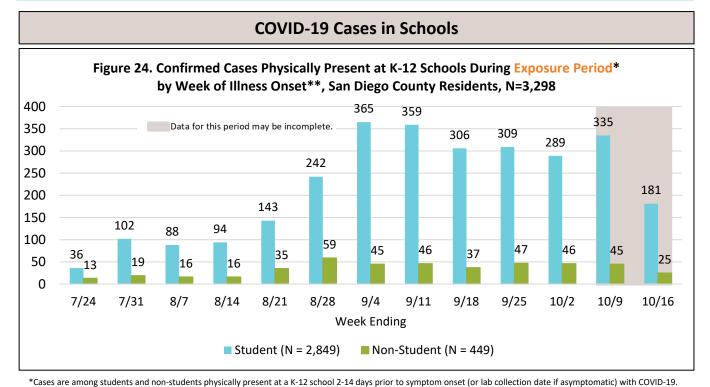


Case 1:21-cv-02815-CKK Document 1-31 Filed 10/24/21 **OVID-19 WATCH**

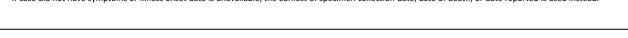


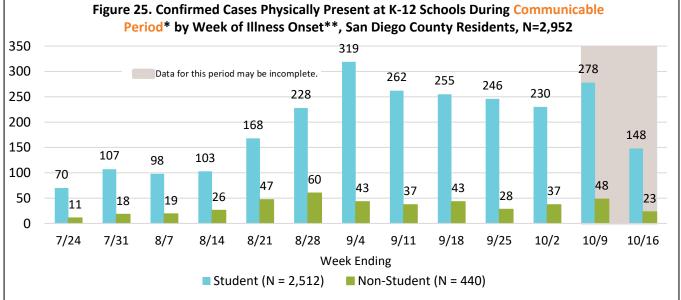


Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report



^{**}If case did not have symptoms or illness onset date is unavailable, the earliest of specimen collection date, date of death, or date reported is used instead.





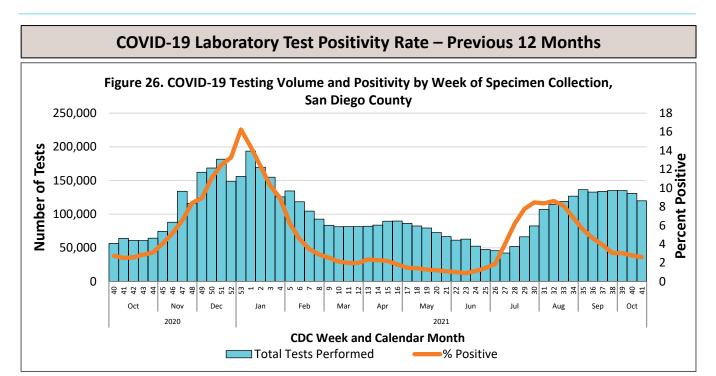
^{*}Cases are among students and non-students physically present at a K-12 school 48 hours prior to symptom onset (or lab collection date if asymptomatic) with COVID-19.

**If case did not have symptoms or illness onset date is unavailable, the earliest of specimen collection date, date of death, or date reported is used instead.

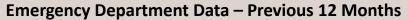


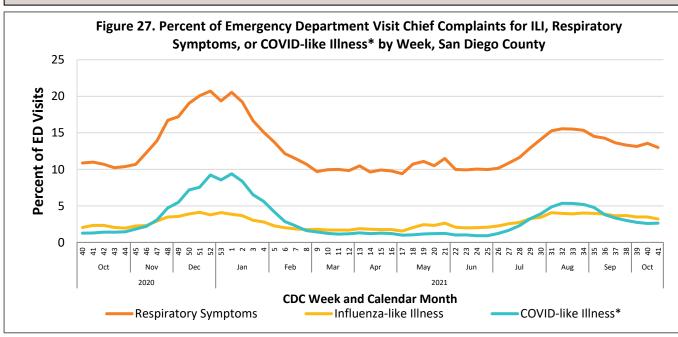






Includes PCR tests performed by COSD Public Health, hospital, and reference laboratories and reported via Electronic Laboratory Reporting (ELR) and line lists. Excludes invalid, indeterminate, and unsatisfactory results.





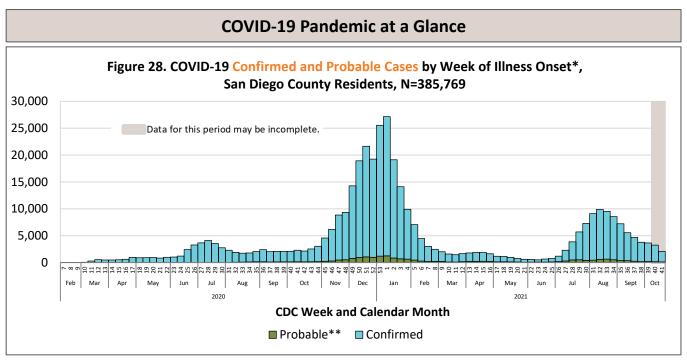
Categories are not mutually exclusive. *COVID-like Illness includes fever and cough, shortness of breath, or difficulty breathing OR coronavirus diagnostic codes.

Data through 10/16/2021

Epidemiology and Immunization Services Branch

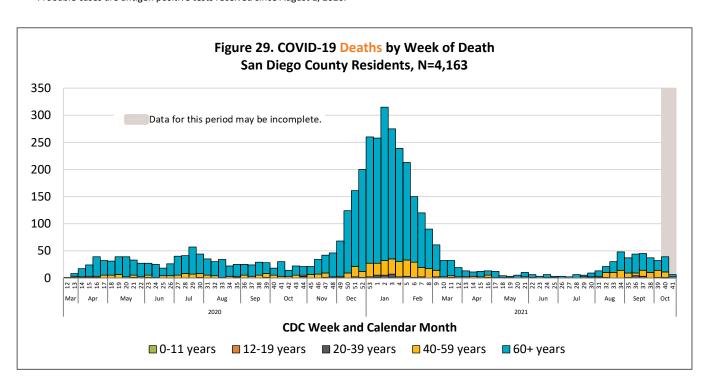






^{*}When onset date is unavailable, specimen collection date, date of death, or date reported is used instead.

^{**}Probable cases are antigen positive tests received since August 1, 2020.

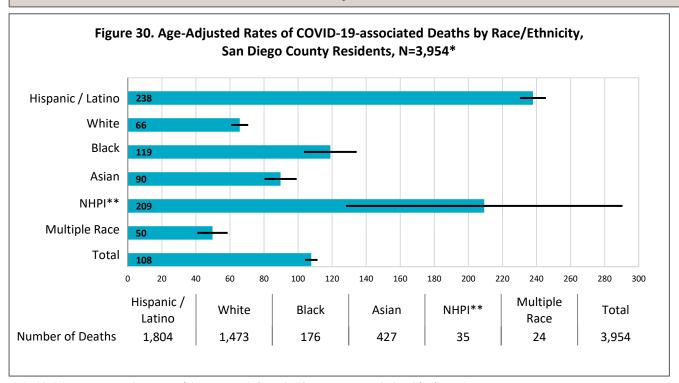






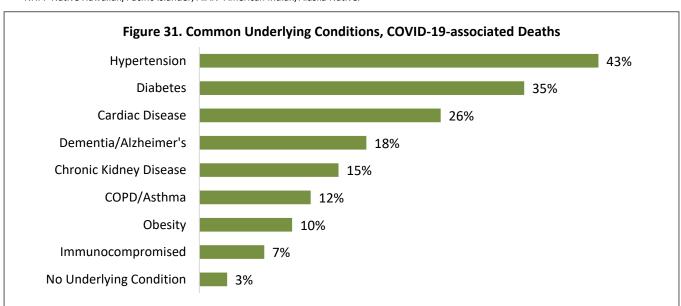


Pandemic at a Glance: Summary of COVID-19-associated Deaths



The black lines represent the 95% confidence intervals (error bars). Rates are not calculated for fewer than 20 events.

^{**}NHPI=Native Hawaiian/Pacific Islander, AIAN=American Indian/Alaska Native.



Persons may have more than one underlying condition. These data are abstracted from death certificates and available medical records and may not reflect a complete list of underlying conditions for each person.

Data through 10/16/2021

^{*}Race/ethnicity are unknown for 209 deaths.

Case 1:21-cv-02815-CKK Document 1-31 Filed 10/24/21 Page 20 of 20 COVID-19 WATCH





Weekly Coronavirus Disease 2019 (COVID-19) Surveillance Report

COVID-19 Watch Data Sources

The following sources of data are used to produce this report:

- COVID-19 case reports: Medical providers and laboratories report individual cases of PCR-confirmed and antigen-positive probable COVID-19 via fax or electronic laboratory reporting (ELR) to the County of San Diego Epidemiology Unit.
- COVID-19 deaths: The County of San Diego requests that all deaths related to COVID-19 be reported for surveillance purposes. Medical facilities may report these deaths directly to the Epidemiology Unit or they may be identified by the Office of Vital Records through death certificate registration. The Epidemiology Unit compiles the data, and only reports deaths that can be verified by a death certificate.
- Emergency Department Chief Complaint Data: Electronic emergency department data are reported to the Epidemiology Unit daily. The number of respiratory chief complaints and the number of total emergency department visits are used to calculate percentages for all respiratory-related visits and visits specific to influenza-like illness and COVID-like illness.
- COVID-19 outbreaks:
 - Skilled Nursing Facilities: at least one case of laboratory-confirmed COVID-19 in a resident.
 - Non-SNF Institution/Congregate Settings: At least three probable or confirmed COVID-19 cases within a 14-day period in epidemiologically-linked residents and/or staff.
 - o Community settings: At least three probable or confirmed COVID-19 cases within a 14-day period in people who are epidemiologically-linked in the setting, are from different households, and are not identified as close contacts of each other in any other case investigation.
- COVID-19 vaccinations: Number of vaccinations registered in the San Diego Immunization Registry (SDIR) by participating providers. Some providers, including the VA, DoD, other military, some tribal, and prisons do not report to SDIR.
- SANDAG population estimates, vintage 2019: Rates are calculated using 2019 population estimates from the San Diego Association of Governments. Rates are not calculated for counts under five cases.

The purpose of the weekly **COVID-19 Watch** is to summarize current COVID-19 surveillance in San Diego County. Data are preliminary and may change due to delayed reporting and additional information obtained during investigations.

For information on influenza in San Diego County, please see the weekly Influenza Watch surveillance report. Additional influenza data and resources and a link to subscribe to the Influenza Watch are available on the Epidemiology Unit website.



EXHIBIT 12

DOJ Memo to POTUS, re: EUA Provisions, dated July 6, 2021

(Slip Opinion)

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

Section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for a vaccine that is subject to an emergency use authorization.

July 6, 2021

MEMORANDUM OPINION FOR THE DEPUTY COUNSEL TO THE PRESIDENT

Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3, 1 authorizes the Food and Drug Administration ("FDA") to issue an "emergency use authorization" ("EUA") for a medical product, such as a vaccine, under certain emergency circumstances. This authorization permits the product to be introduced into interstate commerce and administered to individuals even when FDA has not approved the product for more general distribution pursuant to its standard review process. Section 564 directs FDA—"to the extent practicable" given the emergency circumstances and "as the [agency] finds necessary or appropriate to protect the public health"—to impose "[a]ppropriate" conditions on each EUA. FDCA § 564(e)(1)(A). Some of these conditions are designed to ensure that recipients of the product "are informed" of certain things, including "the option to accept or refuse administration of the product." *Id.* § 564(e)(1)(A)(ii)(III).

Since December 2020, FDA has granted EUAs for three vaccines to prevent coronavirus disease 2019 ("COVID-19"). In each of these authorizations, FDA imposed the "option to accept or refuse" condition by requiring the distribution to potential vaccine recipients of a Fact Sheet that states: "It is your choice to receive or not receive [the vaccine]. Should you decide not to receive it, it will not change your standard medical care." *E.g.*, FDA, Fact Sheet for Recipients and Caregivers at 5 (revised June 25, 2021), https://www.fda.gov/media/144414/download

¹ Because it is commonly referred to by its FDCA section number, and for the sake of simplicity, we will refer to this provision as section 564, rather than by its United States Code citation.

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("Pfizer Fact Sheet"). In recent months, many public and private entities have announced that they will require individuals to be vaccinated against COVID-19—for instance, in order to attend school or events in person, or to return to work or be hired into a new job. We will refer to such policies as "vaccination requirements," though we note that these policies typically are conditions on employment, education, receipt of services, and the like rather than more direct legal requirements.²

In light of these developments, you have asked whether the "option to accept or refuse" condition in section 564 prohibits entities from imposing such vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs. We conclude, consistent with FDA's interpretation, that it does not. 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.³

I.

A.

Federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until FDA has approved the drug or product as safe and effective for its intended uses. See, e.g., FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C. § 262(a). A vaccine is both a drug and a biological product. See FDCA § 201(g), 21 U.S.C. § 321(g); 42 U.S.C. § 262(i)(1). Consistent with section 564, we will generally refer to it here as a "product." See FDCA § 564(a)(4)(C) (defining "product" to mean "a drug, device, or biological product").

² For an example of the latter, see our discussion in Part II.B of a hypothetical military order to service members.

³ We do not address whether other federal, state, or local laws or regulations, such as the Americans with Disabilities Act ("ADA"), might restrict the ability of public or private entities to adopt particular vaccination policies. *See, e.g.*, Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (updated June 28, 2021), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (discussing the ADA).

Requiring the Use of a Vaccine Subject to an Emergency Use Authorization

In 2003, Congress addressed a problem raised in emergency situations where "the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents," but where, "[u]nfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents," even though "a drug, biologic, or device is highly promising in treating [such] a disease or condition." H.R. Rep. No. 108-147, pt. 1, at 2 (2003). President George W. Bush had flagged this problem in his 2003 State of the Union Address, in which he proposed Project BioShield, a legislative initiative "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague." Address Before a Joint Session of the Congress on the State of the Union (Jan. 28, 2003), 1 Pub. Papers of Pres. George W. Bush 82, 86 (2003). Among the principal components of the proposed Project BioShield legislation were provisions to enable FDA to authorize medical products for use during emergencies even before they are proven to be safe and effective under ordinary FDA review. See, e.g., H.R. 2122, 108th Cong. § 4 (2003). At that time, the only alternative to ordinary FDA approval was 21 U.S.C. § 355(i), which authorizes FDA to exempt drugs from the ordinary approval requirements where the drug is "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Such a cabined investigational new drug ("IND") exemption does not, however, allow the widespread dissemination of a drug for general public use in response to an emergency. See H.R. Rep. No. 108-147, pt. 1, at 2.

Congress enacted a version of the Project BioShield legislation's EUA provision in the National Defense Authorization Act for Fiscal Year 2004 as section 564 of the FDCA. See Pub. L. No. 108-136, § 1603(a), 117 Stat. 1392, 1684 (2003) (codified at 21 U.S.C. § 360bbb-3). Section 564 authorizes the Secretary of Health and Human Services ("HHS")—who has delegated to FDA the authorities under the statute at issue here—to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency even though the product has not yet been generally approved as safe and

⁴ The statute has been amended since, including when Congress enacted the Project BioShield Act the following year. *See* Pub. L. No. 108-276, § 4(a), 118 Stat. 835, 853 (2004).

effective for its intended use. FDCA § 564(a)(1)–(2); see also FDA, Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders at 3 n.6 (Jan. 2017) ("EUA Guidance") (noting delegation of most of the Secretary's authorities under section 564 to FDA).⁵

The most pertinent part of section 564 for purposes of your question has remained materially the same since Congress first enacted the statute in 2003. Subsection (e)(1)(A),⁶ titled "Required conditions," provides:

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable [emergency] circumstances . . . , shall, for a 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, including [certain specified conditions].

⁵ The current version of section 564(a)(1) provides in full:

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

The "declaration under subsection (b)" refers to a declaration by the Secretary "that the circumstances exist justifying" an EUA, which must be made "on the basis" of one or more types of emergencies or threats. FDCA § 564(b)(1). FDA can grant an EUA where, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available," FDA finds that "it is reasonable to believe," among other things, that "the product may be effective in diagnosing, treating, or preventing" a "serious or life-threatening disease or condition" caused by a "biological, chemical, radiological, or nuclear agent or agents" (a standard less onerous than for final approval of the product); that "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product"; and that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." FDCA § 564(c).

⁶ Subsection (e)(1) applies to a product that FDA has not approved as safe and effective for any intended use, whereas subsection (e)(2) applies to an unapproved use of an otherwise approved product. The COVID-19 vaccines fall under the former category, but the statute applies the condition at issue here to the latter category as well. *See* FDCA § 564(e)(2)(A).

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The statute then lists a number of such conditions, including "[a]p-propriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain information. FDCA § 564(e)(1)(A)(ii). This information includes the fact that FDA "has authorized the emergency use of the product," "the significant known and potential benefits and risks of such use," and "the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). Most relevant here, section 564(e)(1)(A)(ii)(III) directs FDA to impose conditions on an EUA "designed to ensure that individuals to whom the product is administered are informed . . . 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."

In the same section of the 2004 National Defense Authorization Act, Congress also enacted another provision, codified as 10 U.S.C. § 1107a, which is specific to the U.S. military and which expressly refers to the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III). Pub. L. No. 108-136, sec. 1603(b)(1), § 1107a, 117 Stat. at 1690. Subsection (a) of this law provides that when an EUA product is administered to members of the armed forces, "the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President" and "only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1).

В.

In the years after Congress enacted section 564, FDA issued dozens of EUAs in response to various public-health emergencies. *See, e.g.*, Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability, 74 Fed. Reg. 56,644 (Nov. 2, 2009) (antiviral drug to treat swine flu). The agency's use of EUAs increased dramatically with the onset of the COVID-19 pandemic in 2020. As of January 2021, the agency had issued more than 600 EUAs for products to combat COVID-19, including drugs, tests, personal protective equipment, and ventilators. *See* FDA, *FDA COVID-19 Pandemic*

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Recovery and Preparedness Plan (PREPP) Initiative: Summary Report at 6 (Jan. 2021); cf. id. at 24 (noting that FDA issued 65 EUAs prior to COVID-19). More importantly for present purposes, the agency has granted EUAs for three COVID-19 vaccines manufactured by Pfizer, Moderna, and Janssen, respectively. See Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 28,608 (May 27, 2021) (Janssen); Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 5200 (Jan. 19, 2021) (Pfizer and Moderna).

As we have explained, section 564 of the FDCA contemplates that each EUA will be subject to various conditions. For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III) in the following manner: In each letter granting the EUA, FDA established as a "condition[] of authorization" that FDA's "Fact Sheet for Recipients and Caregivers" be made available to potential vaccine recipients. See, e.g., Letter for Pfizer Inc. from RADM Denise M. Hinton, Chief Scientist, FDA at 6, 9 (updated June 25, 2021), https://www.fda.gov/media/150386/download ("Pfizer EUA Letter"). The Fact Sheet in question states (to take the Pfizer vaccine as an example): "It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care." Pfizer Fact Sheet at 5. We understand that this approach is consistent with FDA's general practice for EUAs. See EUA Guidance at 24-25 (discussing the use of fact sheets to inform recipients of EUA products "[t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product").

As access to the COVID-19 vaccines has become widespread, numerous educational institutions, employers, and other entities across the United States have announced that they will require individuals to be vaccinated against COVID-19 as a condition of employment, enrollment, participation, or some other benefit, service, relationship, or access. 7 For

⁷ See, e.g., Rukmini Callimachi, For Colleges, Vaccine Mandates Often Depend on Which Party Is in Power, N.Y. Times (May 22, 2021), https://www.nytimes.com/2021/05/22/us/college-vaccine-universities.html; Tracy Rucinski, Delta will require COVID-19

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instance, certain schools will require vaccination in order for students to attend class in person, and certain employers will require vaccination as a condition of employment.

Some have questioned whether such entities can lawfully impose such requirements in light of the fact that section 564 instructs that potential vaccine recipients are to be informed that they have the "option to accept or refuse" receipt of the vaccine. 8 In the past few months, several lawsuits have also been filed challenging various entities' vaccination requirements on the same theory. 9 The only judicial decision to have addressed this issue so far summarily rejected the challenge. See Bridges v. Houston Methodist Hosp., No. 4:21-cv-01774, 2021 WL 2399994, at *1–2 (S.D. Tex. June 12, 2021), appeal docketed, No. 21-20311 (5th Cir. June 14, 2021).

II.

A.

We conclude that section 564(e)(1)(A)(ii)(III) concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs. By its terms, the provision directs only that potential vaccine recipients be "informed" of certain information, including "the option to accept or refuse administration of the product."

vaccine for new employees, Reuters (May 14, 2021, 9:16 AM), https://www.reuters.com/world/us/delta-will-require-covid-19-vaccine-new-employees-2021-05-14/.

⁸ See, e.g., Letter for Thomas C. Galligan Jr., Interim President, Louisiana State University, from Jeff Landry, Attorney General of Louisiana (May 28, 2021); see also Advisory Committee on Immunization Practices, Summary Report at 56 (Aug. 26, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508. pdf (reporting a CDC official as saying that EUA vaccines are not allowed to be mandatory).

⁹ See, e.g., Defendant's Notice of Removal, Bridges v. Methodist Hosp., No. 4:21-cv-01774 (S.D. Tex. June 1, 2021), 2021 WL 2221293 (referencing complaint); Complaint, Neve v. Birkhead, No. 1:21-cv-00308 (M.D.N.C. Apr. 16, 2021), 2021 WL 1902937; Complaint, Cal. Educators for Med. Freedom v. L.A. Unified Sch. Dist., No. 21-cv-2388 (C.D. Cal. Mar. 17, 2021), 2021 WL 1034618; Complaint, Legaretta v. Macias, No. 2:21-cv-00179 (D.N.M. Feb. 28, 2021), 2021 WL 909707; see also Complaint, Health Freedom Defense Fund v. City of Hailey, No. 1:21-cv-00212-DCN (D. Idaho May 14, 2021), 2021 WL 1944543 (making a similar argument about a face-mask requirement).

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FDCA § 564(e)(1)(A)(ii)(III). In the sense used here, the word "inform" simply means to "give (someone) facts or information; tell." New Oxford American Dictionary 891 (3d ed. 2010); see also, e.g., Webster's Third New International Dictionary 1160 (2002) (similar). Consistent with this understanding, the conditions of authorization that FDA imposed for the COVID-19 vaccines require that potential vaccine recipients receive FDA's Fact Sheet, see, e.g., Pfizer EUA Letter at 6, 9, which states that recipients have a "choice to receive or not receive" the vaccine, see, e.g., Pfizer Fact Sheet at 5. Neither the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context. Cf. Bridges, 2021 WL 2399994, at *2 (explaining that section 564 "confers certain powers and responsibilities to the Secretary of [HHS] in an emergency" but that it "neither expands nor restricts the responsibilities of private employers"). 10

The language of another provision of section 564 reflects the limited scope of operation of section 564(e)(1)(A)(ii)(III). Section 564(l) provides that "this section [i.e., section 564] only has legal effect on a person who carries out an activity for which an authorization under this section is issued." This provision expressly forecloses any limitation on the activities of the vast majority of entities who would insist upon vaccination requirements, because most do not carry out any activity for which an EUA is issued.

To be sure, the EUA conditions effectively require parties administering the products to do so in particular ways—including that they only administer the products to individuals after providing them the informational Fact Sheets that FDA prescribes—and some of those entities,

¹⁰ Earlier-introduced versions of section 564(e)(1)(A)(ii)(III) in 2003 referred to "any option to accept or refuse administration of the product" (as opposed to "the" option), a formulation that might have even more clearly conveyed the informational nature of the condition. See, e.g., S. 15, 108th Cong. § 204 (Mar. 11, 2003) (emphasis added). We have not found any explanation for why Congress revised the provision to refer to "the option," so we ascribe little significance to the change—either for or against our reading of the statute. See Mead Corp. v. Tilley, 490 U.S. 714, 723 (1989); Trainmobile Co. v. Whirls, 331 U.S. 40, 61 (1947) ("The interpretation of statutes cannot safely be made to rest upon mute intermediate legislative maneuvers."). In 10 U.S.C. § 1107a(a), moreover, Congress used the alternative formulation "an option to accept or refuse" in referring to the condition in section 564(e)(1)(A)(ii)(III) as it relates to the armed forces. (Emphasis added.) This discrepancy counsels further against assigning interpretive weight to the change from "any" to "the" in the legislative development of section 564.

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such as universities, might also impose vaccination requirements (e.g., on their students and employees). There is no indication, however, that Congress intended to regulate such entities except with respect to the circumstances of their administration of the product itself. See, e.g., FDCA § 564(e)(1)(B)(ii) (authorizing FDA to establish "[a]ppropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use" (emphasis added)). And it would have been odd for Congress to have done so, for in that case the entities choosing to administer EUA products would be limited in their relations with third parties (e.g., students, employees) in ways that analogous entities that did not administer the products were not.

This reading of the "option to accept or refuse" condition to be informational follows not only from the plain text of the provision, but also from the surrounding requirements in section 564(e)(1)(A)(ii). See, e.g., Lagos v. United States, 138 S. Ct. 1684, 1688-89 (2018) (relying on the canon of "noscitur a sociis, the well-worn Latin phrase that tells us that statutory words are often known by the company they keep"). In addition to requiring that potential recipients be informed of "the option to accept or refuse administration of the product," the statute also requires that they be informed 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." FDCA § 564(e)(1)(A)(ii)(III). Similarly, the two other provisions in subsection (e)(1)(A)(ii) require that individuals be informed of the fact that FDA "has authorized the emergency use of the product" and of "the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." Id. § 564(e)(1)(A)(ii)(I)-(II). These provisions all appear to require only that certain factual information be conveyed to those who might use the product.

Indeed, if Congress had intended to restrict entities from imposing EUA vaccination requirements, it chose a strangely oblique way to do so, embedding the restriction in a provision that on its face requires only that individuals be provided with certain information (and grouping that requirement with other conditions that are likewise informational in nature). Congress could have created such a restriction by simply stating that persons (or certain categories of persons) may not require others to

use an EUA product. See Kloeckner v. Solis, 568 U.S. 41, 52 (2012) (rejecting a statutory interpretation positing that Congress took a "roundabout way" and an "obscure path" to reach "a simple result"); cf. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

Our reading of section 564(e)(1)(A)(ii)(III) does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have "the option to accept or refuse" the product. The legislative history of the 2003 statute does not appear to offer any clear explanation. Perhaps Congress viewed section 564(e)(1)(A)(ii)(III) as a variation on the "informed consent" requirement that applies to human subjects in "investigational drug" settings, 11 the only other context in which FDA may (in a limited fashion) authorize the introduction of unapproved drugs into interstate commerce. Or perhaps Congress included this condition to ensure that potential users of an EUA product would not misunderstand what the likely impact of declining to use that product would be.

The information conveyed pursuant to the "option" clause continues to be a true statement about a material fact of importance to potential vac-

¹¹ Section 355(i)(4) of title 21 provides that an IND exemption to the premarket approval requirement may only apply if the manufacturer or sponsor of an expert investigation requires the experts in question to certify

that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards.

Congress did not include this same "informed consent" requirement as part of the EUA provision in 2003, perhaps out of concern that it would not be practicable in emergency situations. See Project BioShield: Contracting for the Health and Security of the American Public: Hearing Before the H. Comm. on Gov't Reform, 108th Cong. 33 (Apr. 4, 2003) (statement of Mark B. McClellan, Commissioner, FDA, and Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases) ("Because urgent situations may require mass inoculations and/or drug treatments, such informed consent requirements may prove impossible to implement within the necessary time frame when trying to achieve the public health goal of protecting Americans from the imminent danger."); see also infra note 15 (explaining that the informed consent requirements contained in 21 U.S.C. § 355(i)(4) do not apply to EUA products).

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cine recipients—virtually all such persons continue to have the "option" of refusing the vaccine in the sense that there is no direct legal requirement that they receive it. See Bridges, 2021 WL 2399994, at *2 (noting that an employer's vaccination policy was not "coercive" because an employee "can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else"); Wen W. Shen, Cong. Research Serv., R46745, State and Federal Authority to Mandate COVID-19 Vaccination at 4 (Apr. 2, 2021) ("[E]xisting vaccination mandates—as they are typically structured—generally do not interfere with . . . an individual's right to refuse in that context. Rather, they impose secondary consequences—often in the form of exclusion from certain desirable activities, such as schools or employment—in the event of refusal." (footnote omitted)); Black's Law Dictionary 1121 (7th ed. 1999) (defining "option" as relevant here as "[t]he right or power to choose; something that may be chosen"); The American Heritage Dictionary of the English Language 1235 (4th ed. 2000) (similar); cf. FDCA § 564(e)(1)(A)(ii)(III) (directing that potential vaccine recipients be informed not only of "the option to accept or refuse administration of the product" but also of "the consequences, if any, of refusing administration of the product" (emphasis added)).

Importantly, however, and consistent with FDA's views, we also read section 564 as giving FDA some discretion to modify or omit "the option to accept or refuse" notification, or to supplement it with additional information, if and when circumstances change. As noted above, the statute directs FDA to establish the section 564(e)(1)(A) conditions "to the extent practicable given the applicable [emergency] circumstances" and "as the [agency] finds necessary or appropriate to protect the public health." FDCA § 564(e)(1)(A). Both of these phrases—"to the extent practicable" and "as the [agency] finds necessary or appropriate"—are generally understood to confer discretion on an agency. See, e.g., Gallegos-Hernandez v. United States, 688 F.3d 190, 195 (5th Cir. 2012) (per curiam) ("to the extent practicable"); Madison-Hughes v. Shalala, 80 F.3d 1121, 1128 (6th Cir. 1996) (collecting cases on "necessary" and "appropriate"). Moreover, the portion of section 564 that deals specifically with informational conditions provides that FDA should establish "[a]ppropriate" conditions designed to ensure that potential vaccine recipients are informed of the "option to accept or refuse" an EUA product. FDCA § 564(e)(1)(A)(ii). These qualifiers indicate that FDA's responsibility to

impose the "option to accept or refuse" condition is not absolute and that the agency has some discretion to modify or omit the condition when the agency finds the notification would not be "practicable" given the emergency circumstances, or to determine that changes to the notification are "necessary or appropriate to protect the public health." See EUA Guidance at 24 n.46 (noting circumstances in which the "option to accept or refuse" notification might not be practicable). 12 In addition, section 564 gives FDA the authority to supplement the information that is conveyed to potential vaccine recipients, including information about "the consequences, if any, of refusing administration of the product." FDCA § 564(e)(1)(A)(ii)(III); see also id. § 564(e)(1)(B) (noting that FDA has the authority to impose additional conditions as the agency "finds necessary or appropriate to protect the public health"); EUA Guidance at 22 n.40, 26–27 (noting this point). Together, then, these provisions of section 564 give FDA the authority to adapt to changing circumstances and to ensure that the information conveyed to potential users of EUA products is accurate. 13

Although many entities' vaccination requirements preserve an individual's ultimate "option" to refuse an EUA vaccine, they nevertheless impose sometimes-severe adverse consequences for exercising that option (such as not being able to enroll at a university). Under such circumstances, FDA could theoretically choose to supplement the conditions of authorization to notify potential vaccine recipients of the possibility of such consequences (or to make it even clearer that the consequences described

¹² Indeed, FDA has recently exercised its discretion not to require certain of the statutorily specified conditions with respect to the current COVID-19 pandemic. We understand that FDA has amended or plans to amend the EUAs for the COVID-19 vaccines so as not to require compliance with several of the conditions—including the "option to accept or refuse" notification—when the vaccines are exported to other countries. *See, e.g.*, Pfizer EUA Letter at 10.

¹³ Congress's use of the phrase "Required conditions" in the title of subsection (e)(1)(A) and its specification of certain conditions in the statute suggest that Congress may have presumed that FDA would generally find that the specified conditions are "necessary or appropriate" and thus impose them. As we discuss above, however, the operative text of section 564 indicates that FDA has some discretion to modify, omit, or supplement the conditions in some circumstances. See Fulton v. City of Philadelphia, 141 S. Ct. 1868, 1879 (2021) ("[A] title or heading should never be allowed to override the plain words of a text." (quoting A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 222 (2012)) (alteration in original)).

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in the Fact Sheets are limited to consequences related to medical care). As we have noted, however, section 564 does not limit the ability of entities to impose vaccination requirements, and FDA would not be required to change the Fact Sheets in order to allow them to impose such requirements. 14

* * * * *

As noted above, FDA agrees with our interpretation of section 564. On a few occasions, however, FDA has made statements that could be understood as saying that the condition described in section 564(e)(1)(A)(ii)(III) prohibits entities (particularly the U.S. military) from requiring the use of EUA products. In 2005, for instance, FDA issued an EUA that permitted the use of a vaccine for the prevention of inhalation anthrax by individuals between 18 and 65 years of age who were deemed by the Department of Defense ("DOD") to be at heightened risk of exposure due to an attack with anthrax. As a condition of that authorization, the agency required DOD to inform potential vaccine recipients "of the option to accept or refuse administration of [the vaccine]." Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005). That EUA continued:

With respect to [the] condition . . . relating to the option to accept or refuse administration of [the vaccine], the [immunization program] will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation

¹⁴ FDA further informs us that, wholly apart from FDA's own authority to change the Fact Sheet, nothing in the FDCA would prohibit an administrator of the vaccine who also has a relationship with the individuals to whom the vaccine is offered (e.g., students in a university that offers the vaccine) from supplementing the FDA Fact Sheet at the point of administration with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product (e.g., that she might not be permitted to enroll).

based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

Id.; see also id. (allowing DOD to inform recipients that "military and civilian leaders strongly recommend anthrax vaccination, but... individuals [subject to the vaccination program] may not be forced to be vaccinated" and that "the issue of mandatory vaccination will be reconsidered by [DOD] after FDA completes its administrative process."). FDA included the same information in its later extension of that EUA. See Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability, 70 Fed. Reg. 44,657, 44,659–60 (Aug. 3, 2005).

In addition, although it is less than clear, certain FDA guidance could be read as saying that section 564 confers an affirmative "option" or "opportunity" to refuse EUA products. See EUA Guidance at 24 n.46 (implying that the condition in section 564(e)(1)(A)(ii)(III)—which is subject to waiver for the armed forces under 10 U.S.C. § 1107a—protects "the option for members of the armed forces to accept or refuse administration of an EUA product"); Guidance Emergency Use Authorization of Medical Products, 2007 WL 2319112, at *15 (July 1, 2007) (stating that "[r]ecipients must have an opportunity to accept or refuse the EUA product").

These statements do not affect our conclusion. Neither the 2005 anthrax vaccine EUA nor the later FDA guidance articulated a legal interpretation of section 564(e)(1)(A)(ii)(III)'s text. And FDA appears to have insisted upon the voluntariness requirement for DOD in the anthrax vaccine EUA because of then-recent litigation in which a court enjoined DOD from implementing a mandatory vaccination program based upon a different statutory provision that is inapplicable to EUAs. See Doe v. Rumsfeld, 341 F. Supp. 2d 1 (D.D.C. 2004) (relying on 10 U.S.C. § 1107); Doe v. Rumsfeld, 297 F. Supp. 2d 119 (D.D.C. 2003) (same); see also 70 Fed. Reg. at 44,660 (requiring DOD to tell vaccine recipients the following: "On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The Court's injunction means you have the right to refuse to take the vaccine without fear of retaliation." (emphasis added)); 70 Fed. Reg.

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at 5454 (discussing litigation); see also infra note 15 (explaining that 10 U.S.C. § 1107(f) is inapplicable to EUAs).

B.

Section 564(e)(1)(A)(ii)(III) also raises a question about how to understand its cognate provision regarding the use of EUA products by the armed forces. As we noted above, in the same 2003 legislation that first created section 564, Congress also added the following provision to title 10 of the United States Code:

In the case of the administration of [an EUA] product . . . to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

10 U.S.C. § 1107a(a)(1). ¹⁵ On its own terms, this provision appears to be consistent with—and even to support—our reading of section 564, as it likewise describes the "option to accept or refuse" condition in purely informational terms. The language refers to the President's authority to

¹⁵ Section 1107(f) of title 10—an earlier-enacted provision—contains a similar, but importantly different, waiver authority. Specifically, that provision authorizes the President, "[i]n the case of the administration of an [IND] or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation," to waive "the prior consent requirement imposed under [21 U.S.C. § 355(i)(4)]." 10 U.S.C. § 1107(f)(1). That "prior consent requirement," which is imposed for purposes of the human clinical trials for which FDA authorizes "investigational" use of unapproved drugs, see 21 U.S.C. § 355(i)(4), does not apply to EUA products, which typically are more widely available, see FDCA § 564(k); EUA Guidance at 24 ("informed consent as generally required under FDA regulations is not required for administration or use of an EUA product" (footnote omitted)). Thus, the waiver provision in section 1107(f) is inapplicable to EUA products. See 10 U.S.C. § 1107(f)(2) (explaining that this waiver authority applies only in cases in which "prior consent for administration of a particular drug is required" because the Secretary of HHS determines that the drug "is subject to the [IND] requirements of [21 U.S.C. § 355(i)]"); see also id. § 1107(f)(4) (defining the relevant consent requirements as those in 21 U.S.C. § 355(i)).

waive a requirement to provide certain information, not to waive any right or affirmative "option" to refuse administration of the product itself.

On the other hand, the conference report on the legislation that created both section 564 of the FDCA and section 1107a of title 10 described the latter provision in the following way:

[This provision] would authorize the President to waive the right of service members to refuse administration of a product if the President determines, in writing, that affording service members the right to refuse the product is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.) (emphasis added). This language indicates that the conferees may have believed that section 1107a concerns some "right" of members of the armed forces to refuse the use of EUA products. And that belief may help to explain why section 1107a allows only the President to exercise the waiver authority.

Consistent with this legislative history and the vesting of the waiver authority in the President, DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a. See DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) ("In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may . . . waive the option to refuse for administration of the medical product to members of the armed forces." (emphasis added)). Moreover, we understand that DOD's position reflects the concern that service members, unlike civilian employees, could face serious criminal penalties if they refused a superior officer's order to take an EUA product. See 10 U.S.C. § 890; see also United States v. Kisala, 64 M.J. 50 (C.A.A.F. 2006) (upholding a soldier's punishment for refusing to take a vaccine). In this way, service members do not have the same "option" to refuse to comply with a vaccination requirement as other members of the public.

As noted above, it does appear that certain members of Congress thought that section 1107a concerned a prohibition against requiring service members to take an EUA product—perhaps on the view that the

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waiver authority in section 1107a paralleled the one in 10 U.S.C. § 1107(f), which does effectively prohibit the administration of an IND product in a clinical trial without first obtaining the individual's affirmative, informed *consent*. See supra note 15 (distinguishing these waiver authorities). As explained, however, that intent or expectation is not realized in the text of section 564(e)(1)(A)(ii)(III), which section 1107a expressly cross-references. Cf. Steinle v. City & Cty. of San Francisco, 919 F.3d 1154, 1164 n.11 (9th Cir. 2019) ("[T]he plain and unambiguous statutory text simply does not accomplish what the Conference Report says it was designed to accomplish."); Goldring v. Dist. of Columbia, 416 F.3d 70, 75 (D.C. Cir. 2005) ("A sentence in a conference report cannot rewrite unambiguous statutory text[.]"). We therefore conclude that section 1107a does not change our interpretation of section 564 of the FDCA.

As for DOD's concern about service members who would lack a meaningful option to refuse EUA products because of the prospect of sanction, including possibly prosecution, we note that any difference between our view and the assumption reflected in the conference report should have limited practical significance. Given that FDA has imposed the "option to accept or refuse" condition for the COVID-19 vaccines by requiring

¹⁶ It is possible the conferees assumed that the new EUA legislation would, in effect, carry over from the earlier IND provision of the FDCA, *see supra* Part I.A and note 11, the condition that a covered product may not be administered to an individual without that person's express, informed consent—a condition that applies to the military when it undertakes the sort of clinical trial with an IND that 21 U.S.C. § 355(i) governs, *see supra* note 11. Congress did not include such a consent requirement in section 564, however, perhaps because EUA products are not limited, as INDs are, to use in human clinical trials, but are instead authorized for more widespread use in the case of a declared emergency. *See supra* Part I.A and notes 11 & 15.

¹⁷ Moreover, the legislative history as a whole is not uniform on this point. The earlier House report, for instance, described the condition in purely informational terms. *See* H.R. Rep. No. 108-147, pt. 3, at 33 (2003) ("New section 564(k) [an earlier but similarly worded version of what became 10 U.S.C. § 1107a] pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are *informed* of the option to accept or refuse administration of an emergency use product, upon certain findings[.]" (emphasis added)); *see also Milner v. Dep't of the Navy*, 562 U.S. 562, 574 (2011) (noting that "[1]egislative history, for those who take it into account, is meant to clear up ambiguity, not create it," and thus, "[w]hen presented, on the one hand, with clear statutory language and, on the other, with dueling committee reports, we must choose the language").

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distribution of its Fact Sheet containing the "[i]t is your choice to receive or not receive" language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the "option" to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

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