

No. 21-3091

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

ERICH SMITH; FRANK E. GARWOOD, JR.;
MARIBEL LORENZO; DR. DANIEL DONOFRIO,

Plaintiffs-Appellants,

v.

PRESIDENT UNITED STATES OF AMERICA,

Defendant-Appellee.

On Appeal from the United States District Court
for the District of New Jersey

BRIEF FOR APPELLEE

BRIAN M. BOYNTON
Acting Assistant Attorney General

RACHAEL A. HONIG
Acting United States Attorney

MARLEIGH D. DOVER
CHARLES W. SCARBOROUGH
ABBY C. WRIGHT
SARAH CARROLL
CASEN B. ROSS

*Attorneys, Appellate Staff
Civil Division, Room 7511
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
202.514.4027*

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
STATEMENT OF JURISDICTION	4
STATEMENT OF THE ISSUES.....	4
STATEMENT OF THE CASE.....	5
A. The COVID-19 Pandemic	5
B. The Development And Authorization Of COVID-19 Vaccines.....	5
C. Vaccination Requirements For Federal Employees And Contractors	8
D. Factual Background And Prior Proceedings	11
SUMMARY OF ARGUMENT.....	15
STANDARD OF REVIEW	18
ARGUMENT	19
I. The District Court Lacks Jurisdiction Over Plaintiffs’ Claims.....	19
A. Plaintiffs’ Claims Are Not Ripe.....	19
B. The Federal-Employee Plaintiffs’ Claims Are Precluded By The Civil Service Reform Act.	26
C. Plaintiffs Cannot Obtain Injunctive Relief Against The President, The Sole Defendant Named In The Operative Complaint.	31
II. The District Court Did Not Abuse Its Discretion In Denying Injunctive Relief.....	34
A. Plaintiffs Are Unlikely To Succeed On The Merits.....	35
B. Plaintiffs Have Not Established Irreparable Injury.....	45

C. The Public Interest And The Balance Of Harms Favor The
Government.....48

CONCLUSION 51

COMBINED CERTIFICATIONS

TABLE OF AUTHORITIES

Cases:	Page(s)
<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967).....	20, 21
<i>Adams v. Freedom Forge Corp.</i> , 204 F.3d 475 (3d Cir. 2000)	47
<i>Altschuld v. Raimondo</i> , No. 21-cv-2779, slip op. (D.D.C. Nov. 8, 2021), ECF No. 23	45-46, 49
<i>American Fed’n of Gov’t Emps. v. Secretary of Air Force</i> , 716 F.3d 633 (D.C. Cir. 2013)	29
<i>America’s Frontline Doctors v. Wilcox</i> , No. 21-1243, 2021 WL 4546923 (C.D. Cal. July 30, 2021)	49
<i>Bauer v. Summey</i> , No. 21-CV-2952, 2021 WL 4900922 (D.S.C. Oct. 21, 2021)	37
<i>Beberman v. U.S. Dep’t of State</i> , 675 F. App’x 131 (3d Cir. 2017)	32-33, 47
<i>Blake v. Papadakos</i> , 953 F.2d 68 (3d Cir. 1992)	19
<i>BST Holdings, LLC v. OSHA</i> , 17 F.4th 604 (5th Cir. 2021)	44
<i>Cafeteria & Rest. Workers Union v. McElroy</i> , 367 U.S. 886 (1961).....	41
<i>Campbell Soup Co. v. ConAgra, Inc.</i> , 977 F.2d 86 (3d Cir. 1992)	45, 46
<i>Church v. Biden</i> , No. 21-2815, 2021 WL 5179215 (D.D.C. Nov. 8, 2021)	16, 24, 26, 45, 49
<i>Clapper v. Amnesty Int’l, USA</i> , 568 U.S. 398 (2013)	23

Combs v. Homer-Center Sch. Dist.,
540 F.3d 231 (3d Cir. 2008) 39

Comite’ De Apoyo A Los Trabajadores Agricolas v. Perez,
774 F.3d 173 (3d Cir. 2014) 21

Cruzan ex rel. Cruzan v. Director, Mo. Dep’t of Health,
497 U.S. 261 (1990) 38

Deborah Heart & Lung Ctr. v. Virtua Health, Inc.,
833 F.3d 399 (3d Cir. 2016) 34, 41

DiLuigi v. Kafkalias,
584 F.2d 22 (3d Cir. 1978) 42

Dixon v. De Blasio,
No. 21-CV-5090, 2021 WL 4750187 (E.D.N.Y. Oct. 12, 2021) 37

Doe ex rel. Doe v. Boyertown Area Sch. Dist.,
897 F.3d 518 (3d Cir. 2018) 18

Doe v. Zucker,
520 F. Supp. 3d 217 (N.D.N.Y. 2021) 37

Elgin v. Department of the Treasury,
567 U.S. 1 (2012) 16, 27, 28, 29, 30

Engquist v. Oregon Dep’t of Agric.,
553 U.S. 591 (2008) 41

Flast v. Cohen,
392 U.S. 83 (1968) 20

Fleming v. Spencer,
718 F. App’x 185 (4th Cir. 2018) 26

Foley v. Biden,
No. 21-cv-1098, slip op. (N.D. Tex. Oct. 6, 2021), ECF No. 18 32

Franklin v. Massachusetts,
505 U.S. 788 (1992) 16, 31, 32

Garcia v. United States,
680 F.2d 29 (5th Cir. 1982) 50

Greater Phila. Chamber of Commerce v. City of Philadelphia,
 949 F.3d 116 (3d Cir. 2020) 17, 35

Harris v. University of Mass., Lowell,
 No. 21-cv-11244, 2021 WL 3848012 (D. Mass. Aug. 27, 2021) 42

Holland v. Rosen,
 895 F.3d 272 (3d Cir. 2018) 39

Instant Air Freight Co. v. C.F. Air Freight, Inc.,
 882 F.2d 797 (3d Cir. 1989) 45

Jacobson v. Florida Sec’y of State,
 974 F.3d 1236 (11th Cir. 2020) 34

Jacobson v. Massachusetts,
 197 U.S. 11 (1905) 13, 17, 36, 39, 40, 42-43

Johnson v. Brown,
 No. 21-CV-1494, 2021 WL 4846060 (D. Or. Oct. 18, 2021) 37

Klaassen v. Trustees of Ind. Univ.,
 7 F.4th 592 (7th Cir. 2021)17, 36, 37, 39, 40, 42

Klaassen v. Trustees of Ind. Univ.,
 No. 21A15 (U.S. Aug. 12, 2021)36

Maniscalco v. New York City Dep’t of Educ.,
 No. 21-CV-5055, 2021 WL 4344267 (E.D.N.Y. Sept. 23, 2021),
aff’d, No. 21-2343, 2021 WL 4814767 (2d Cir. Oct. 15, 2021) 36

Maniscalco v. New York City Dep’t of Educ.,
 No. 21A50 (U.S. Oct. 1, 2021).....36

McCray v. Biden,
 No. 21-2882, 2021 WL 5823801 (D.D.C. Dec. 7, 2021) 16, 24, 28, 32

Mississippi v. Johnson,
 71 U.S. (4 Wall.) 475 (1866).....30

Morton v. Beyer,
 822 F.2d 364 (3d Cir. 1987) 47-48

Munaf v. Geren,
 553 U.S. 674 (2008) 19

National Aeronautics & Space Admin. v. Nelson,
 562 U.S. 134 (2011) 41

National Park Hosp. Ass’n v. Department of Interior,
 538 U.S. 803 (2003) 25

National Treasury Emps. Union v. Horner,
 854 F.2d 490 (D.C. Cir. 1988) 42

National Treasury Emps. Union v. Nixon,
 492 F.2d 587 (D.C. Cir. 1974) 32

National Wildlife Fed’n v. United States,
 626 F.2d 917 (D.C. Cir. 1980) 32

Navy Seal 1 v. Biden,
 No. 21-cv-2429, 2021 WL 5448970 (M.D. Fla. Nov. 22, 2021) 32

Newdow v. Roberts,
 603 F.3d 1002 (D.C. Cir. 2010)31

Norris v. Stanley,
 No. 21-CV-756, 2021 WL 4738827 (W.D. Mich. Oct. 8, 2021) 37

Oburn v. Shapp,
 521 F.2d 142 (3d Cir. 1975) 47

Philadelphia Fed’n of Teachers v. Ridge,
 150 F.3d 319 (3d Cir. 1998) 21, 24, 25, 26

Plains All Am. Pipeline L.P. v. Cook,
 866 F.3d 534 (3d Cir. 2017) 19

Planned Parenthood of Cent. N.J. v. Farmer,
 220 F.3d 127 (3d Cir. 2000) 20

Prince v. Massachusetts,
 321 U.S. 158 (1944) 36-37

Raines v. Byrd,
 521 U.S. 811 (1997) 20

Reilly v. City of Harrisburg,
858 F.3d 173 (3d Cir. 2017) 35, 45, 48

Rodden v. Fauci,
No. 21-cv-317, 2021 WL 5545234 (S.D. Tex. Nov. 27, 2021) 24, 32, 46

Rodriguez-Vélez v. Pierluisi-Urrutia,
No. 21-1366, 2021 WL 5072017 (D.P.R. Nov. 1, 2021) 37

Roman Catholic Diocese of Brooklyn v. Cuomo,
141 S. Ct. 63 (2020) (per curiam) 39-40, 45, 49

Rydie v. Biden,
No. 21-2696, 2021 WL 5416545 (D. Md. Nov. 19, 2021) .. 28, 32, 37, 42, 45, 48, 49

Sampson v. Murray,
415 U.S. 61 & n.68 (1974) 18, 47, 47

Sarullo v. U.S. Postal Serv.,
352 F.3d 789 (3d Cir. 2003) 16, 28, 29

Semper v. Gomez,
747 F.3d 229 (3d Cir. 2014) 16, 27, 28-29, 30

South Bay United Pentecostal Church v. Newsom,
140 S. Ct. 1613 (2020) 40

Swan v. Clinton,
100 F.3d 973 (D.C. Cir. 1996) 31, 32

Texas v. United States,
523 U.S. 296 (1998) 25-26

Tigges v. Northam,
473 F. Supp. 3d 559 (E.D. Va. 2020) 49

Toilet Goods Ass’n v. Gardner,
387 U.S. 158 (1967) 25

Trump v. Hawaii,
138 S. Ct. 2392 (2018) 39

Trump v. New York,
141 S. Ct. 530 (2020) 15, 16, 20, 23

United States v. Fausto,
484 U.S. 439 (1988) 18, 26, 27

Valdez v. Grisham,
No. 21-CV-783, 2021 WL 4145746 (D.N.M. Sept. 13, 2021) 37

Washington v. Glucksberg,
521 U.S. 702 (1997)..... 37, 38

We the Patriots USA, Inc. v. Hochul,
17 F.4th 266 (2d Cir. 2021).....35-36, 37, 40, 42

Workman v. Mingo Cty. Bd. of Educ.,
419 F. App’x 348 (4th Cir. 2011) 40

Wyatt, Virgin Islands, Inc. v. Virgin Islands ex rel. Virgin Islands Dep’t of Labor,
385 F.3d 801 (3d Cir. 2004) 20

Wyoming Outdoor Council v. U.S. Forest Serv.,
165 F.3d 43, 50 (D.C. Cir. 1999).....26

Zucht v. King,
260 U.S. 174 (1922) 37

Statutes:

Civil Service Reform Act of 1978,
Pub. L. No. 95-454, 92 Stat. 1111 3

5 U.S.C. § 1212(a)(2) 27

5 U.S.C. § 1214(a)(1)(A) 27

5 U.S.C. § 1214(a)(3) 27

5 U.S.C. § 2301(b)(2) 27

5 U.S.C. § 2302 27

5 U.S.C. § 2302(a) 27

5 U.S.C. § 2302(b)(1)-(13) 27

5 U.S.C. § 3301 41

5 U.S.C. § 3302 41

5 U.S.C. § 7301 41

5 U.S.C. § 7512 26, 28

5 U.S.C. § 7513(d) 26

5 U.S.C. § 7703(b)(1) 26

21 U.S.C. § 360bbb-3 6
 28 U.S.C. § 1292(a)(1) 4
 28 U.S.C. § 2201 4
 28 U.S.C. § 2202 4
 42 U.S.C. § 262(a)(1) 6
 42 U.S.C. § 262(i)(1) 6

Regulations:

5 C.F.R. § 752.404 22
 Exec. Order No. 14042,
 86 Fed. Reg. 50,985 (Sept. 14, 2021) 2, 8, 9, 10, 22, 23, 40
 Exec. Order No. 14043,
 86 Fed. Reg. 50,989 (Sept. 14, 2021) 2, 8, 14, 39, 40, 41, 43

Rule:

Fed. R. Civ. P. 65(d)(2)(C) 33

Other Authorities:

Aug. 23, 2021 Letter Approving Biologics License Application from FDA
 to BioNTech Mfg. (Aug. 23, 2021), <https://go.usa.gov/xen6E>7
 Teri Dobbins Baxter, *Employer-Mandated Vaccination Policies: Different Employers,
 New Vaccines, and Hidden Risks*, 2017 Utah L. Rev. 885..... 39
 CDC:
 COVID Data Tracker, <https://go.usa.gov/xen7j>
 (last updated Dec. 9, 2021).....5
 COVID Data Tracker Weekly Review, <https://go.usa.gov/xeGmu>
 (last updated Dec. 3, 2021)..... 1, 45
 Delta Variant, <https://go.usa.gov/xen7c> (last updated Aug. 26, 2021)5

How COVID-19 Spreads, <https://go.usa.gov/xenGS>
 (last updated July 14, 2021) 5

mRNA Vaccines, <https://go.usa.gov/xenAb>
 (last updated Nov. 3, 2021) 6, 44

Viral Vector Vaccines, <https://go.usa.gov/xenAU>
 (last updated Oct. 18, 2021) 6, 44

Determination of the Acting OMB Director Regarding the Revised
 Safer Federal Workforce Task Force Guidance for Federal Contractors
 and the Revised Economy & Efficiency Analysis,
 86 Fed. Reg. 53,691 (Sept. 28, 2021) 10

Determination of the Acting OMB Director Regarding the Revised
 Safer Federal Workforce Task Force Guidance for Federal Contractors
 and the Revised Economy & Efficiency Analysis,
 86 Fed. Reg. 63,418 (Nov. 16, 2021) 10

FDA, *Comirnaty Approved Prescribing Information*, <https://go.usa.gov/xen6u>
 (last revised Aug. 2021) 8

FDA, *Comirnaty Summary Basis for Regulatory Action* (Nov. 8, 2021),
<https://go.usa.gov/xeGms> 43

85 Fed. Reg. 15,337 (Mar. 18, 2020) 5

85 Fed. Reg. 18,250 (Apr. 1, 2020) 7

HHS, *Determination that a Public Health Emergency Exists*
 (Jan. 31, 2020), <https://go.usa.gov/xenGt> 5

Nov. 19, 2021 Letter of Authorization from FDA to Pfizer Inc.,
<https://go.usa.gov/xenMa> 7, 43

Nov. 19, 2021 Letter of Authorization from FDA to ModernaTX, Inc.,
<https://go.usa.gov/xenMZ> 7, 43

Nov. 19, 2021 Letter of Authorization from FDA to Janssen Biotech, Inc.,
<https://go.usa.gov/xenMK> 7, 43

Pandemic Response Accountability Comm., *Top Challenges Facing Federal Agencies: COVID-19 Emergency Relief and Response Efforts* (June 2020), <https://go.usa.gov/xeFTb>49

Task Force:

COVID-19 Workplace Safety: Agency Model Safety Principles, <https://go.usa.gov/xe5a4> (last updated Sept. 13, 2021) 9

COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors, <https://go.usa.gov/xe5NP> (last updated Nov. 10, 2021) 10, 11, 22, 46

COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors 5, <https://go.usa.gov/xe5aB> (last updated Sept. 24, 2021)..... 10

Federal Contractors, Compliance, <https://go.usa.gov/xeVaz> (last visited Dec. 9, 2021).....23

Federal Contractors, Vaccination and Safety Protocols, <https://go.usa.gov/xeVaz> (last visited Dec. 9, 2021) (*Contractor FAQs*)..... 11, 22

Vaccinations, Enforcement of Vaccination Requirement for Federal Employees, <https://go.usa.gov/xe5aC> (last visited Dec. 9, 2021)9, 14, 21

Vaccinations, Limited Exceptions to Vaccination Requirement, <https://go.usa.gov/xe5aC> (last visited Dec. 9, 2021) 8-9

INTRODUCTION

The United States is in the midst of the most serious public health crisis in at least a century. To date, SARS-CoV-2, the virus that causes Coronavirus Disease 2019 (COVID-19), has infected more than 48 million Americans, hospitalized more than 3.4 million, and caused more than 781,000 deaths in the United States. *See* Centers for Disease Control and Prevention (CDC), *COVID Data Tracker Weekly Review*, <https://go.usa.gov/xGmu> (last updated Dec. 3, 2021) (*COVID Weekly Review*). More than a year and a half into the COVID-19 pandemic, approximately 86,000 new cases are being reported in the United States every day. *See id.* Since the pandemic's earliest days, a wide range of public health experts and government officials have agreed that the pandemic will not end until safe and effective vaccines can be broadly administered to promote widespread protection against a highly contagious virus. Three such vaccines are now widely available in the United States. Hundreds of millions of doses have been administered, and there is no question that the vaccines are safe and highly effective. Yet as of December 3, 2021, nearly 30% of adults and over 40% of the total population in the United States were not yet fully vaccinated. *See id.*

The illness and mortality caused by COVID-19 have led to serious disruptions for employers across the United States, and the federal government is no exception. In an effort to ameliorate those problems, on September 9, 2021, President Biden issued two executive orders aimed at combating the spread of COVID-19 within the

federal workforce and preventing disruptions in the provision of government services by federal contractors. *See* Exec. Order No. 14043, 86 Fed. Reg. 50,989 (Sept. 14, 2021) (federal civilian employees); Exec. Order No. 14042, 86 Fed. Reg. 50,985 (Sept. 14, 2021) (federal contractors). Executive Order 14043 directs federal agencies to require, “consistent with applicable law,” that their employees be vaccinated against COVID-19 unless a legally required exception applies. 86 Fed. Reg. at 50,990. Executive Order 14042 similarly instructs federal agencies, “to the extent permitted by law,” to ensure that certain federal contracts include a clause requiring the contractor or subcontractor to comply with COVID-19 safety protocols, which now include requiring that covered contractor employees be vaccinated against COVID-19, 86 Fed. Reg. at 50,985, again unless a legally required exception applies.

Plaintiffs—three federal employees and one employee of a federal contractor who do not wish to be vaccinated for “a range of personal reasons,” Supp. App. 118—seek to enjoin enforcement of those executive orders. Yet their claims are brought at the wrong time, in the wrong forum, and against the wrong defendant. Plaintiffs’ claims are premature: they have not been subject to any discipline for refusing vaccination, and they have not yet received responses to their requests for exceptions from the vaccination requirements. Because plaintiffs’ theories of injury are speculative, their claims are unripe. The district court thus lacks jurisdiction, and this Court should affirm the denial of preliminary relief and remand with instructions to dismiss the case. The federal-employee plaintiffs’ claims should be dismissed for

the additional reason that they have sued in the wrong forum: their claims, which relate to the terms of their federal employment, are precluded by the Civil Service Reform Act of 1978 (CSRA), Pub. L. No. 95-454, 92 Stat. 1111. And all the plaintiffs have sued the wrong defendant: plaintiffs' operative complaint seeks relief only against the President, who is not subject to declaratory and injunctive relief in his official capacity.

Although the district court erroneously believed it had jurisdiction, it correctly recognized that plaintiffs fail to satisfy any of the requirements for a preliminary injunction. *First*, plaintiffs cannot succeed on the merits of their sole claim that the vaccination requirements violate the Due Process Clause of the Fifth Amendment. For more than a century, courts have upheld the constitutionality of even more restrictive vaccination requirements—not simply (as here) conditions on employment. *Second*, plaintiffs are not at imminent risk of irreparable injury. If plaintiffs' exception requests are granted, they will not suffer *any* harm, and the most severe penalty plaintiffs could conceivably face for refusing vaccination would be removal from their jobs, which this Court and the Supreme Court have long recognized does not constitute irreparable harm. *Third*, the equities and the public interest weigh heavily against preliminary relief. In sharp contrast to plaintiffs' noncognizable claims of injury, plaintiffs' requested injunction would seriously injure the public interest. An injunction would disrupt efforts to slow the spread of COVID-19 within the federal workforce, impede the government's ability to promote the efficiency of the federal

service and to handle government employment disputes through the exclusive administrative procedures established by Congress, and undermine economy and efficiency in federal procurement.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 2201 and 2202. Supp. App. 141.¹ The district court denied plaintiffs' motion for a temporary restraining order and/or a preliminary injunction on November 8, 2021. App. 2-31. Plaintiffs filed a timely notice of appeal on November 10, 2021. App. 1. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

The issues presented in this appeal are:

1. Whether the district court lacks jurisdiction because (a) plaintiffs' claims are not ripe, (b) the federal-employee plaintiffs' claims are precluded by the Civil Service Reform Act, and (c) plaintiffs cannot obtain injunctive relief against the President in his official capacity.

2. Whether the district court abused its discretion in denying a preliminary injunction.

¹ Citations beginning with "App." are to the Appendix that plaintiffs filed with their opening brief. Citations beginning with "Supp. App." are to the Supplemental Appendix that the government is seeking leave to file concurrently with this brief.

STATEMENT OF THE CASE

A. The COVID-19 Pandemic

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency because of COVID-19, a respiratory disease caused by the novel coronavirus SARS-CoV-2. HHS, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), <https://go.usa.gov/xenGt>. And on March 13, 2020, the President declared a national emergency to contain and combat the virus. *See* 85 Fed. Reg. 15,337 (Mar. 18, 2020).

COVID-19 “spreads when an infected person breathes out droplets and very small particles that contain the virus.” CDC, *How COVID-19 Spreads*, <https://go.usa.gov/xenGS> (last updated July 14, 2021). In July 2021, the United States began to experience “a rapid and alarming rise in . . . COVID-19 case and hospitalization rates,” driven by an especially contagious strain of SARS-CoV-2 known as the Delta variant. *See* CDC, *Delta Variant*, <https://go.usa.gov/xen7c> (last updated Aug. 26, 2021). As of this filing, community transmission rates of SARS-CoV-2 remain high in 44 states and the District of Columbia, and substantial in the other six states. *See* CDC, *COVID Data Tracker*, <https://go.usa.gov/xen7j> (last updated Dec. 9, 2021).

B. The Development And Authorization Of COVID-19 Vaccines

1. Shortly after COVID-19 emerged, a number of pharmaceutical companies began developing COVID-19 vaccines. Moderna and Pfizer-BioNTech developed

COVID-19 vaccines that use messenger RNA (mRNA) technology; those vaccines are designed to instruct the vaccine recipient's cells to make a harmless piece of the "spike protein" found in the SARS-CoV-2 virus and to trigger the immune system to produce antibodies and activate other immune cells to protect against future infection with the actual virus. *See* CDC, *mRNA Vaccines*, <https://go.usa.gov/xenAb> (last updated Nov. 3, 2021) (*mRNA Vaccines*). These mRNA vaccines "do not affect or interact with [the recipient's] DNA in any way." *Id.* Janssen (whose parent company is Johnson & Johnson) developed a vaccine that uses "viral vector" technology, which introduces an essentially harmless adenovirus shell containing instructions for the SARS-CoV-2 spike protein into the vaccine recipient's body, also causing the recipient's cells to produce a piece of the spike protein, thus generating antibodies and activating immune cells to protect against the actual virus. *See* CDC, *Viral Vector Vaccines*, <https://go.usa.gov/xenAU> (last updated Oct. 18, 2021) (*Viral Vector Vaccines*).

2. The Food and Drug Administration (FDA) has authority to review and approve the interstate marketing of "biological product[s]," including vaccines. 42 U.S.C. § 262(a)(1), (i)(1). In an emergency, FDA may issue an "emergency use authorization" (EUA), which authorizes the marketing of vaccines (and other FDA-regulated products) "intended for use" in responding to the emergency. *See generally* 21 U.S.C. § 360bbb-3.

In March 2020, the Secretary of HHS declared that “circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic.” 85 Fed. Reg. 18,250, 18,250-51 (Apr. 1, 2020). Based on that determination and other criteria, FDA issued EUAs in December 2020 for the Pfizer-BioNTech and Moderna vaccines and a third EUA in February 2021 for the Janssen/Johnson & Johnson vaccine.² These EUAs are based on FDA’s review of extensive safety and efficacy data, including from a Pfizer clinical trial with approximately 46,000 participants, a Moderna clinical trial with approximately 30,000 participants, and a Janssen clinical trial with approximately 43,000 participants. *See* Pfizer EUA Letter 3; Moderna EUA Letter 2; Janssen EUA Letter 2.

On August 23, 2021, the Pfizer-BioNTech COVID-19 vaccine, marketed under the name Comirnaty, obtained FDA approval to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. *See* Aug. 23, 2021 Letter Approving Biologics License Application from FDA to BioNTech Mfg., <https://go.usa.gov/xen6E>. FDA’s approval of Comirnaty was based on data demonstrating that the vaccine was 91.1% effective in preventing COVID-19 and

² *See* Nov. 19, 2021 Letter of Authorization from FDA to Pfizer Inc., <https://go.usa.gov/xenMa> (Pfizer EUA Letter) (revising and reissuing the December 2020 EUA); Nov. 19, 2021 Letter of Authorization from FDA to ModernaTX, Inc., <https://go.usa.gov/xenMZ> (Moderna EUA Letter) (same); Nov. 19, 2021 Letter of Authorization from FDA to Janssen Biotech, Inc., <https://go.usa.gov/xenMK> (Janssen EUA Letter) (revising and reissuing the February 2021 EUA).

between 95% and 100% effective in preventing severe symptoms of COVID-19, based on an analysis of effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients. FDA, *Comirnaty Approved Prescribing Information* 7, 15-18, <https://go.usa.gov/xen6u> (last revised Aug. 2021). FDA concluded that the product is safe based on data from approximately 12,000 vaccine recipients who were followed for safety outcomes for at least six months after their second dose. *Id.* at 12.

C. Vaccination Requirements For Federal Employees And Contractors

On September 9, 2021, President Biden issued two executive orders announcing COVID-19 vaccination requirements for federal employees and federal contractors and subcontractors. *See* 86 Fed. Reg. 50,989 (civilian federal employees); 86 Fed. Reg. 50,985 (federal contractors).

Executive Order 14043 instructs federal agencies to “implement, to the extent consistent with applicable law, a program to require COVID-19 vaccination for all of [their] Federal employees, with exceptions only as required by law.” 86 Fed. Reg. at 50,990. That directive, which is based on “public health guidance” assessing 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,” directs the Safer Federal Workforce Task Force (Task Force) to issue guidance on implementation of the vaccination requirement. *Id.* at 50,989-90.

The Task Force guidance recognizes that federal employees may be eligible for exceptions from the vaccination requirement based on medical conditions or religious objections, *see* Task Force, *Vaccinations, Limited Exceptions to Vaccination Requirement*, <https://go.usa.gov/xe5aC> (last visited Dec. 9, 2021) (*Exception FAQs*), and indicates that each agency should “follow its ordinary process to review and consider what, if any, accommodation [the agency] must offer” under applicable federal law, *see* Task Force, *Vaccinations, Enforcement of Vaccination Requirement for Federal Employees*, <https://go.usa.gov/xe5aC> (last visited Dec. 9, 2021) (*Enforcement FAQs*). Federal employees who have not requested or received an exception should be fully vaccinated “no later than November 22, 2021,” Task Force, *COVID-19 Workplace Safety: Agency Model Safety Principles 2*, <https://go.usa.gov/xe5a4> (last updated Sept. 13, 2021), but employees who request an exception should not be subject to discipline while the request is under consideration, *Enforcement FAQs*. And the Task Force guidance states that, if an exception request is denied, the employee should be given two weeks from the denial to receive the first (or only) dose of a COVID-19 vaccine before an agency initiates any enforcement proceedings. *See Exception FAQs*.

Executive Order 14042 directs federal executive departments and agencies, “to the extent permitted by law,” to include in qualifying contracts a clause requiring compliance with workplace safety guidance issued by the Task Force, provided that the Director of the Office of Management and Budget (OMB) approves the guidance and determines that adherence to the guidance will promote economy and efficiency

in federal contracting. 86 Fed. Reg. at 50,985. The purpose of this directive is to “decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government.” *Id.*; *see also id.* at 50,986-87 (listing the categories of contracts to which the order applies).

The Task Force has also issued guidance regarding Executive Order 14042 (approved by the OMB Director), explaining that covered contractor employees should be fully vaccinated against COVID-19—except insofar as any such employee is legally entitled to an accommodation—by January 18, 2022. Task Force, *COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors* 5, <https://go.usa.gov/xe5NP> (last updated Nov. 10, 2021) (*Contractor Guidance*); *see also* Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis, 86 Fed. Reg. 63,418 (Nov. 16, 2021).³ After that date, all covered contractor employees must be fully vaccinated on the first day of a new contract or when there is a renewal, extension, or exercised option on an existing

³ The Task Force had initially issued guidance requiring that covered federal contractor employees be fully vaccinated by December 8, 2021. *See* Task Force, *COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors* 5, <https://go.usa.gov/xe5aB> (last updated Sept. 24, 2021); *see also* Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors and the Revised Economy & Efficiency Analysis, 86 Fed. Reg. 53,691 (Sept. 28, 2021).

contract. *Contractor Guidance* 5. The guidance further states that covered contractors “may be required to provide an accommodation to covered contractor employees . . . because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance,” and those contractors “should review and consider what, if any, accommodation [they] must offer.” *Id.* “The contractor is responsible for considering, and dispositioning, such requests for accommodation” Task Force, *Federal Contractors, Vaccination and Safety Protocols*, <https://go.usa.gov/xeVaz> (last visited Dec. 9, 2021) (*Contractor FAQs*).

D. Factual Background And Prior Proceedings

1. Plaintiffs are three federal employees subject to Executive Order 14043 (Erich Smith, Frank Garwood, and Daniel Donofrio) and one employee of a covered federal contractor that is allegedly subject to Executive Order 14042 (Maribel Lorenzo). App. 8. Plaintiffs aver that they do not wish to be vaccinated against COVID-19 for “a range of personal reasons.” *Id.*

Plaintiffs filed suit on October 29, 2021, seeking to enjoin the enforcement of Executive Orders 14042 and 14043, naming only President Biden as a defendant, and claiming that the Executive Orders violate plaintiffs’ Fifth Amendment “rights to liberty and privacy.” Supp. App. 162 (capitalization omitted). On November 3, plaintiffs filed a motion for a “temporary restraining order and/or preliminary injunction,” Supp. App. 107, and on November 6, plaintiffs filed a motion for leave to file a second amended complaint, attempting to name defendants other than the

President and to add a claim that the Executive Orders violate plaintiffs' Fifth Amendment right to equal protection, Supp. App. 54-90. The district court has not yet ruled on plaintiffs' motion to amend their complaint.

Plaintiffs initially failed to notify the district court that they had requested exceptions from the applicable vaccination requirements. However, after questioning plaintiffs' counsel on the matter during the hearing on plaintiffs' motion for injunctive relief, the district court ordered plaintiffs to provide information about any exceptions they had requested. *See* App. 34-35 (text order entered Nov. 8, 2021); *see also* Supp. App. 17 (district court expressing "serious misgivings" about plaintiffs' failure to disclose that they had sought exceptions). In response, plaintiffs submitted a declaration explaining that all of the federal-employee plaintiffs had submitted exception requests to their employing agencies and were awaiting decisions. Supp. App. 1-2. That declaration further explained that plaintiff Lorenzo, who is employed by a federal contractor, "had tried to request an exception to the Covid-19 Vaccine Mandates, but her company told her they are not accepting any requests for exceptions because they do not have any guidance on what to do with them." Supp. App. 1.

2. On November 8, the district court denied plaintiffs' motion for a temporary restraining order or preliminary injunction. App. 2-31. The district court explained that, even in the proposed second amended complaint, Lorenzo's "claims lie solely against the President," and a court cannot grant injunctive relief against the President.

App. 18. The court noted that plaintiffs' proposed second amended complaint named additional defendants for the federal-employee plaintiffs' claims, and the court stated that it would "consider" that proposed pleading "[f]or purposes" of ruling on injunctive relief, even though the court had not yet ruled on the motion for leave to amend. App. 6, 18. And although the district court concluded that plaintiffs' claims are ripe and not precluded by the CSRA, App. 16-17, 19, the court found that all four plaintiffs were unlikely to succeed on the merits, "easily conclud[ing]" that the Executive Orders survive constitutional scrutiny. App. 24-25.

Relying on *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the district court first explained that "there is no fundamental right to refuse a COVID-19 vaccination" and that the Executive Orders are therefore subject only to rational-basis review. App. 20-21. The court rejected plaintiffs' argument that *Jacobson* does not apply because plaintiffs believe the COVID-19 vaccines are not vaccines but are instead "gene therapy products," noting that plaintiffs provided "no medical authority or competent evidence to support [that] argument." App. 21. The court also rejected plaintiffs' attempt to distinguish *Jacobson* by arguing that the federal government "lacks police power" to mandate vaccination, explaining that the government issued the requirements at issue in its role as an employer. App. 21-24. In that capacity, the district court explained, the government is entitled to "at least as much, if not broader, power and deference . . . than the State of Massachusetts had in *Jacobson* in exercising its police power." App. 23-24. The district court thus concluded that the executive

orders easily survive rational-basis scrutiny, as “there can be no serious question that the government has a legitimate interest in preventing the spread of COVID-19” and “vaccines are a safe and effective way to” achieve that end. App. 24-25; *see also* App. 25 (citing numerous cases upholding employers’ COVID-19 vaccine requirements under rational-basis scrutiny).

The district court also found that “the irreparable harm factor heavily weighs against injunctive relief.” App. 26. The court noted that, according to Task Force guidance, agencies should not take any disciplinary action against an employee who has requested an exception from the vaccine requirement while that request is pending. App. 27; *see also Enforcement FAQs*. The court also explained that even if plaintiffs’ requests were ultimately denied and plaintiffs were subsequently disciplined for refusing the COVID-19 vaccine, “loss of employment itself is not sufficient to give rise to irreparable injury.” App. 28 (quotation marks omitted). The district court additionally noted that plaintiffs “waited nearly two (2) months to seek relief,” further “dispel[ling] any claim of irreparable harm.” *Id.*

On the other side of the balance, the district court explained that the federal government issued the Executive Orders “to prevent the spread of COVID-19 and keep people safe” and to promote “the efficiency of the civil service.” App. 30 (quoting 86 Fed. Reg. at 50,989). The court found that plaintiffs’ requested relief “would likely increase the risk of harm to the public.” *Id.* The court thus concluded that the balance of harms and the public interest decisively favor the government. *Id.*

On November 10, plaintiffs filed a notice of appeal. App. 1. On November 18, they filed an emergency motion seeking an expedited merits briefing schedule, as well as a motion for an injunction pending appeal. On November 19, this Court granted plaintiffs' request for expedited briefing and referred plaintiffs' motion for an injunction pending appeal to the merits panel assigned to the appeal.

SUMMARY OF ARGUMENT

The district court correctly denied plaintiffs' request to preliminarily enjoin Executive Orders 14042 and 14043, which require that federal employees and covered federal contractor employees be vaccinated against COVID-19 unless they obtain an exception for a disability (which would include medical conditions) or a sincerely held religious belief. Because the district court lacked jurisdiction to entertain this suit, this Court should both affirm the denial of preliminary relief and remand the case with instructions to dismiss for lack of jurisdiction.

I. The district court lacks jurisdiction over plaintiffs' claims.

A. Plaintiffs' claims are not ripe. A dispute is unripe if it is "dependent on contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam) (quotation marks omitted). Plaintiffs allege that the Executive Orders injure them because they may yet be "coerced" to receive a vaccine or could potentially suffer job-related discipline if they decline to do so. But they have not yet received decisions on their pending requests for exceptions, much less been subjected to any discipline. Plaintiffs' alleged

injuries are therefore “riddled with contingencies and speculation that impede judicial review.” *Id.* In similar circumstances, courts have denied requests for preliminary injunctions on ripeness grounds, *see, e.g., McCray v. Biden*, No. 21-2882, 2021 WL 5823801, at *8-9 (D.D.C. Dec. 7, 2021); *Church v. Biden*, No. 21-2815, 2021 WL 5179215, at *8-10 (D.D.C. Nov. 8, 2021), and this Court may affirm the district court’s denial of a preliminary injunction here solely on this basis.

B. The district court also lacks jurisdiction over the federal-employee plaintiffs’ claims on the independent ground that they are precluded by the Civil Service Reform Act, which provides the “exclusive” means for federal employees to challenge adverse employment actions. *Semper v. Gomez*, 747 F.3d 229, 241-42 (3d Cir. 2014). The CSRA requires that employees first seek administrative review of disciplinary actions from the Merit Systems Protection Board (MSPB), even with respect to constitutional claims; then, if necessary, they may seek judicial review in the Federal Circuit. *See Elgin v. Department of the Treasury*, 567 U.S. 1, 5-6 (2012). Plaintiffs’ suit—which amounts to a preemptive challenge to hypothetical, future personnel actions—is “barred by the comprehensive statutory scheme provided in the CSRA.” *Sarullo v. U.S. Postal Serv.*, 352 F.3d 789, 797 (3d Cir. 2003).

C. Plaintiffs’ operative complaint alleges claims only against President Biden, *see* Supp. App. 140, but it is well established that a court cannot issue injunctive or declaratory relief against the President in his official capacity. *See Franklin v. Massachusetts*, 505 U.S. 788, 802-03 (1992). The district court thus correctly denied

plaintiffs' requested injunctive relief to the extent they sought to enjoin the President. *See* App. 17-18.

II. Apart from the threshold jurisdictional problems with plaintiffs' claims, the district court did not abuse its discretion in denying the "extraordinary remedy" of a preliminary injunction. *Greater Phila. Chamber of Commerce v. City of Philadelphia*, 949 F.3d 116, 133 (3d Cir. 2020). The court properly found that plaintiffs satisfied none of the requirements for injunctive relief.

A. As the district court recognized, plaintiffs are unlikely to succeed on the merits of their claim that the Executive Orders violate substantive due process. Much of plaintiffs' argument proceeds as if the Executive Orders force employees to be vaccinated, rather than establish a condition of employment. But courts have repeatedly held that even mandatory vaccine requirements (as opposed to the mere conditions of employment here) do not violate the Constitution. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 25-30 (1905); *Klaassen v. Trustees of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021). The court also properly recognized that the vaccination requirements are directly connected to the government's compelling interest in combating the spread of COVID-19 among the federal workforce and contracting base and fall well within the government's broad authority to establish terms and conditions of employment and to direct federal procurement policy.

B. The district court also correctly found that plaintiffs cannot establish the irreparable injury necessary to obtain preliminary relief. Plaintiffs have not yet

received decisions on their exception requests. Even if those requests were ultimately denied, the most severe harm plaintiffs could potentially face would be a loss of employment, which courts have long recognized is ordinarily insufficient to warrant injunctive relief. *See, e.g., Sampson v. Murray*, 415 U.S. 61, 92 & n.68 (1974).

C. The public interest and balance of harms also decidedly disfavor injunctive relief. Plaintiffs' requested injunction would undermine the strong public interest in slowing the spread of COVID-19 among federal employees and contractors and the millions of Americans they serve. An injunction would also circumvent Congress's long-established processes for resolving federal employees' employment disputes exclusively through the comprehensive administrative and judicial procedures set forth in the CSRA. *See, e.g., United States v. Fausto*, 484 U.S. 439, 444 (1988) ("A leading purpose of the CSRA was to replace the [prior] haphazard arrangements for administrative and judicial review of personnel action").

STANDARD OF REVIEW

The Court reviews the denial of a preliminary injunction for "an abuse of discretion, an error of law, or a clear mistake in the consideration of proof," reviewing the district court's legal conclusions de novo but reviewing its factual findings for clear error. *Doe ex rel. Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 526 (3d Cir. 2018) (citations and quotation marks omitted).

ARGUMENT

I. The District Court Lacks Jurisdiction Over Plaintiffs' Claims.

As the district court correctly concluded, plaintiffs do not satisfy any of the requirements for a preliminary injunction. *See infra* Part II. Because the district court also lacks jurisdiction over plaintiffs' claims, however, this Court should affirm the court's denial of a preliminary injunction and remand with instructions to dismiss. *See Munaf v. Geren*, 553 U.S. 674, 691 (2008) (“[A] reviewing court has the power on appeal from an interlocutory order to examine the merits of the case . . . and upon deciding them in favor of the defendant to dismiss the bill.” (ellipsis in original) (quotation marks omitted)); *Blake v. Papadakos*, 953 F.2d 68, 69 (3d Cir. 1992) (vacating a preliminary injunction and remanding “with an instruction to dismiss . . . for lack of subject matter jurisdiction”).

A. Plaintiffs' Claims Are Not Ripe.

“[R]ipeness works to determine whether a party has brought an action prematurely . . . and counsels abstention until such a time as a dispute is sufficiently concrete to satisfy the constitutional and prudential requirements of the doctrine.” *Plains All Am. Pipeline L.P. v. Cook*, 866 F.3d 534, 539 (3d Cir. 2017) (alteration in original) (quotation marks omitted). Plaintiffs have suffered no adverse employment action due to their refusal to be vaccinated against COVID-19; indeed, they have not even received decisions on their requests for exceptions from the challenged

vaccination requirements. Plaintiffs' claims are therefore unripe and must be dismissed.

1. “The purpose of the ripeness doctrine is to ‘prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.’” *Wyatt, Virgin Islands, Inc. v. Virgin Islands ex rel. Virgin Islands Dep’t of Labor*, 385 F.3d 801, 806 (3d Cir. 2004) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). This Court and the Supreme Court have made clear that a dispute is constitutionally unripe “if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Id.* (quotation marks omitted); *see also, e.g., Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam) (same). The ripeness doctrine is therefore “[i]ntertwined with Article III’s requirement that a party suffer injury or be in danger of imminent injury.” *Planned Parenthood of Cent. N.J. v. Farmer*, 220 F.3d 127, 147 (3d Cir. 2000). And the case-or-controversy inquiry is “especially rigorous when reaching the merits of the dispute would force [a court] to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional.” *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997); *see also Flast v. Cohen*, 392 U.S. 83, 96 (1968) (“When the federal judicial power is invoked to pass upon the validity of actions by the Legislative and Executive Branches of the Government, the rule against advisory opinions

implements the separation of powers prescribed by the Constitution and confines federal courts to the role assigned them by Article III.”).

Prudential ripeness, which overlaps in some ways with the doctrine’s constitutional form, assesses “the fitness of the issues for judicial decision” and “the hardship to the parties from withholding judicial consideration.” *Comite’ De Apoyo A Los Trabajadores Agricolas v. Perez*, 774 F.3d 173, 183 (3d Cir. 2014). In evaluating fitness for review, the Court considers “whether the issues presented are purely legal” and “the degree to which the challenged action is final,” as well as factors such as “whether the claim involves uncertain and contingent events that may not occur as anticipated or at all.” *Philadelphia Fed’n of Teachers v. Ridge*, 150 F.3d 319, 323 (3d Cir. 1998). And in assessing the hardship of withholding consideration, the Court considers “whether the challenged action creates a ‘direct and immediate’ dilemma for the parties, such that the lack of pre-enforcement review will put the plaintiffs to costly choices.” *Id.* (quoting *Abbott Labs.*, 387 U.S. at 152).

Plaintiffs’ claims are both constitutionally and prudentially unripe because their alleged injuries—either “coercion” to receive a vaccine that they would prefer not to receive or potential adverse employment action—are speculative and may never occur. All three federal-employee plaintiffs have requested that their employing agencies exempt them from the vaccination requirement. Supp. App. 1-2. Each plaintiff’s employing agency will consider that request and grant any exception required by law, and discipline will not be imposed in the meantime. *See supra* p. 9.

And even if plaintiffs' exception requests are not granted, it is as yet undetermined what discipline would ultimately be imposed if plaintiffs refused vaccination. The Task Force guidance recommends a procedure for progressive discipline that begins with a five-day period of education and counseling, followed by a suspension of up to 14 days and then, if noncompliance continues, additional discipline up to and including potential removal from federal service. *See Enforcement FAQs*. Federal employees may also enjoy additional procedural protections prior to termination, such as 30 days' advance written notice of the proposed action, an opportunity to respond (orally and in writing), and a written decision setting forth the basis for removal. *See generally* 5 C.F.R. § 752.404; *see also* Supp. App. 20 (acknowledgment by plaintiffs' counsel that no plaintiff had received notice of any impending disciplinary action at the time of the district court hearing).

Plaintiff Lorenzo, who is employed by a federal contractor, likewise submitted an exception request to her employer. *See* Supp. App. 1. She avers that her employer said it would not accept the request because it “d[id] not have any guidance on what to do with” such requests. *Id.* But the Task Force has provided extensive guidance for federal contractors, which makes clear that Lorenzo's employer is obligated to “review and consider” her request to determine whether she is legally entitled to an accommodation under federal law. *See, e.g., Contractor Guidance; Contractor FAQs*. If Lorenzo has a grievance then, it is with her employer, not the federal government. And even putting that aside, Lorenzo's conclusory allegations do not establish an

injury traceable to Executive Order 14042—plaintiffs have provided no details about Lorenzo’s role as a federal contractor or what federal contracts, if any, Lorenzo performs. That is a crucial omission because Executive Order 14042 requires the inclusion of a new clause mandating compliance with the Task Force safety protocols only in “new contract[s]” and “extensions or renewals of existing contracts,” 86 Fed. Reg. at 50,986-87; for existing contracts, agencies are “strongly encouraged, to the extent permitted by law,” to include the clause but are not required to do so, *see id.* at 50,987. Thus, to the extent that Lorenzo is working on an existing contract, any injury is not traceable to Executive Order 14042 but rather to a specific agency’s decision, in its own discretion, to include the clause. And even if Lorenzo were working on a new contract or an extension or renewal of an existing contract, federal contractors control how to provide appropriate accommodations to their employees and are responsible for “determin[ing] the appropriate means of enforcement with respect to [their] employee[s].” Task Force, *Federal Contractors, Compliance*, <https://go.usa.gov/xeVaz> (last visited Dec. 9, 2021); *see also* Supp. App. 14 (acknowledgment by plaintiffs’ counsel that Lorenzo’s employer had not told her what would happen if she did not get vaccinated).

All four plaintiffs’ claims are, therefore, “riddled with contingencies and speculation that impede judicial review.” *Trump*, 141 S. Ct. at 535; *see also Clapper v. Amnesty Int’l, USA*, 568 U.S. 398, 416 (2013) (explaining that “fears of hypothetical future harm that is not certainly impending” do not satisfy Article III). While the

federal-employee plaintiffs' exception requests are pending, they are not required to be vaccinated and are not subject to discipline. Lorenzo has likewise requested an exception, and the record does not reflect that her employer is threatening discipline in the interim. *See* Supp. App. 14, 20. If plaintiffs' requests are ultimately granted, they will not have to be vaccinated and will face no possibility of discipline for that decision. They accordingly face no "direct and immediate' dilemma," *Philadelphia Fed'n*, 150 F.3d at 323, and their claims of potential future injury are woefully speculative. As another court recently concluded in rejecting a similar challenge to Executive Order 14043, plaintiffs have "failed to demonstrate that any injury is imminent or certainly impending, and therefore have not carried their burden of demonstrating a likelihood that their claims create a ripe, justiciable controversy." *Church v. Biden*, No. 21-2815, 2021 WL 5179215, at *9 (D.D.C. Nov. 8, 2021) (quotation marks omitted); *see also McCray v. Biden*, No. 21-2882, 2021 WL 5823801, at *8-9 (D.D.C. Dec. 7, 2021) (holding similar claims to be constitutionally unripe where the plaintiff's "purported injury is contingent upon his employers denying his application for a medical exemption"); *Rodden v. Fauci*, No. 21-cv-317, 2021 WL 5545234, at *2-3 (S.D. Tex. Nov. 27, 2021) (concluding that employees who had requested exceptions could not establish irreparable harm and that only the plaintiff who did not request an exception had "potentially ripe claims").

2. The district court concluded that plaintiffs' claims were ripe, reasoning that they "seek to enjoin the entire process set forth in Executive Orders 14042 and

14043.” App. 16. But plaintiffs are not injured by the mere existence of “the entire process”: even a challenge to a regulation is not ripe until “its factual components” have been “fleshed out[] by some concrete action applying the regulation to the claimant’s situation in a fashion that harms or threatens to harm him.” *National Park Hosp. Ass’n v. Department of Interior*, 538 U.S. 803, 808 (2003). In *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158 (1967), for example, the Supreme Court rejected a pre-enforcement challenge to an FDA facility-inspection regulation, explaining that “[a]t this juncture we have no idea whether or when such an inspection will be ordered,” that “judicial appraisal” of the regulation’s validity would be “likely to stand on a much surer footing in the context of a specific application of th[e] regulation,” and that judicial review of individual inspection disputes, after manufacturers exhausted their administrative remedies, would “provide an adequate forum for testing the regulation in a concrete situation.” *Id.* at 163-65; *see also Philadelphia Fed’n of Teachers*, 150 F.3d at 324-26. The same is true here.

The district court further stated that “the case presents a pure legal question and the record is adequate.” App. 16. But even where a case *might* ultimately turn on purely legal questions, there is no justiciable controversy unless and until the plaintiff actually suffers a concrete injury from the application of challenged agency action to his or her conduct. *See, e.g., National Park Hosp. Ass’n*, 538 U.S. at 812 (acknowledging that “the question presented” was “purely legal” but concluding that it was nonetheless not fit for adjudication); *Texas v. United States*, 523 U.S. 296, 302 (1998)

(dismissing a request for a declaratory judgment interpreting the Voting Rights Act where it was “too speculative whether the problem Texas present[ed] w[ould] ever need solving”); *Philadelphia Fed’n of Teachers*, 150 F.3d at 325 (holding that a “predominately legal” claim was unripe absent “a real and immediate threat of injury from the denial of pre-enforcement review”). “Where, as here, the ‘possibility that further [administrative] consideration will actually occur before implementation is not theoretical, but real,’” plaintiffs cannot “demonstrate[] that they will suffer immediate and significant hardship in the absence of immediate judicial intervention.” *Church*, 2021 WL 5179215, at *10 (alteration in original) (quoting *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999)).

B. The Federal-Employee Plaintiffs’ Claims Are Precluded By The Civil Service Reform Act.

The district court also lacks jurisdiction over the federal-employee plaintiffs’ claims because they are precluded by the CSRA. In the CSRA, Congress “established a comprehensive”—and exclusive—“system for reviewing personnel action taken against federal employees” who are covered by the statutory scheme. *United States v. Fausto*, 484 U.S. 439, 455 (1988). More serious “adverse actions”—including removal and suspension for more than 14 days, 5 U.S.C. § 7512—may generally be appealed directly to the Merit Systems Protection Board, with judicial review of the Board’s decision in the Federal Circuit. *See id.* §§ 7513(d), 7703(b)(1). A challenge to a less severe “personnel action” may generally be sought through any agency administrative

or negotiated grievance procedures, through an Equal Employment Opportunity Commission complaint if a prohibited basis is alleged, or from the Office of Special Counsel (OSC) if the applicant or employee alleges a prohibited reason for the action. *Id.* §§ 1214(a)(3), 2302.⁴

The Supreme Court has held that the CSRA provides the exclusive means by which federal employees may challenge adverse employment actions (aside from limited exceptions for certain types of discrimination claims not at issue here), depriving district courts of jurisdiction to hear challenges to covered employment actions: “[g]iven the painstaking detail with which the CSRA sets out the method for covered employees to obtain review of adverse employment actions, it is fairly discernible that Congress intended to deny such employees an additional avenue of review in district court.” *Elgin v. Department of the Treasury*, 567 U.S. 1, 11-12 (2012). The Supreme Court has described this as an “implied preclusion of district court jurisdiction.” *Id.* at 12; *see also Fausto*, 484 U.S. at 455; *Semper v. Gomez*, 747 F.3d 229, 241-42 (3d Cir. 2014). This is equally true where an employee challenges an adverse

⁴ The CSRA defines “personnel actions” broadly to extend beyond disciplinary or predisciplinary corrective actions. *See* 5 U.S.C. § 2302(a). Congress authorized OSC to investigate whether a challenged “personnel action” constitutes a “prohibited personnel practice,” including the violation of a law that directly concerns “fair and equitable treatment” of federal employees “with proper regard for their . . . constitutional rights.” *Id.* §§ 1212(a)(2), 1214(a)(1)(A), 2301(b)(2), 2302(b)(1)-(13). OSC thus has jurisdiction to investigate an employee’s claim that a personnel action violated the Constitution. *See, e.g. Fleming v. Spencer*, 718 F. App’x 185, 188 (4th Cir. 2018).

employment action on constitutional grounds. *Elgin*, 567 U.S. at 5. In *Sarullo v. U.S. Postal Service*, 352 F.3d 789 (3d Cir. 2003), for example, this Court held that a district court lacked jurisdiction to consider a former federal employee’s *Bivens* claim alleging that he had unconstitutionally been discharged from his position, holding that “the comprehensive statutory scheme provided in the CSRA” provides the “sole remedy” for claims “aris[ing] in the employment context.” *Id.* at 797.

There is no dispute that the federal-employee plaintiffs here are subject to the CSRA. And their claims are, at bottom, a preemptive challenge to potential future personnel actions, which covered employees may challenge only through the CSRA’s exclusive scheme. *See* 5 U.S.C. § 7512. At least one district court has thus held that the CSRA likely precludes a challenge to the federal employee vaccine requirement. *See Rydie v. Biden*, No. 21-2696, 2021 WL 5416545, at *2 (D. Md. Nov. 19, 2021) (“To the extent Plaintiffs challenge their future terminations, they likely have to proceed through the CSRA process, even though they assert constitutional challenges.”); *see also McCray*, 2021 WL 5823801, at *9 n.3 (noting that the CSRA might preclude the plaintiff’s claims). Plaintiffs do not claim that they have sought to initiate the CSRA process—much less exhausted it—and they cannot circumvent the CSRA’s exclusive-review framework by invoking the district court’s general federal-question jurisdiction. *See, e.g., Semper*, 747 F.3d at 242 (“[T]he CSRA precludes a federal employee from litigating constitutional claims for equitable and declaratory relief in a § 1331 action

where the employee could pursue meaningful relief under a remedial plan that provides for meaningful review of his or her claims by judicial officers”).

The district court concluded that the CSRA did not bar the federal-employee plaintiffs from litigating this suit because they “do not, as of yet, have cognizable claims to be brought under the CSRA”; “adverse action is being threatened but has not yet been taken.” App. 19. But the court’s recognition that plaintiffs have no ripe claim under the CSRA provides no basis to allow them to circumvent the CSRA’s exclusive remedial scheme by pursuing a similarly unripe claim in district court. As this Court has recognized, the CSRA “provides the full scheme of remedies available” for “a case arising out of the employment context,” *Sarullo*, 352 F.3d at 795, and a plaintiff who has not yet suffered any adverse employment action cognizable under the CSRA may not simply resort to an action in district court, *see American Fed’n of Gov’t Emps. v. Secretary of Air Force*, 716 F.3d 633, 639 (D.C. Cir. 2013) (“[A] plaintiff’s inability to use the APA to circumvent the CSRA’s requirements applies to a systemwide challenge to an agency policy interpreting a statute just as it does to the implementation of such a policy in a particular case.” (quotation marks omitted)).

Indeed, permitting plaintiffs to file preemptive attacks on potential adverse employment actions that might someday result from application of Executive Order 14043 “would reintroduce the very potential for inconsistent decisionmaking and duplicative judicial review that the CSRA was designed to avoid.” *Elgin*, 567 U.S. at 14. District courts around the country would be left to deal with preemptive

challenges, while challenges to actual employment actions would continue to arise under the CSRA's scheme. Such bifurcated review would squarely contravene "[t]he CSRA's objective of creating an integrated scheme of review." *Id.* And that disruption would not be limited to preemptive challenges related to Executive Order 14043 or vaccine requirements; the district court's reasoning would suggest that a federal employee who anticipated potential future discipline on *any* basis could circumvent the CSRA's reticulated scheme by preemptively bringing suit in federal court, so long as she went to court before actually facing discipline.

The district court further suggested that it would be "illogical" for "subordinate agencies of the Executive Branch [to] have exclusive jurisdiction to determine whether an Executive Order issued by the President, that they have been directed to implement, is constitutional." App. 19. That suggestion, however, is inconsistent with the Supreme Court's holding in *Elgin* that "Congress intended covered employees appealing covered agency actions to proceed exclusively through the statutory review scheme, even in cases in which the employees raise constitutional challenges to federal statutes." *Elgin*, 567 U.S. at 10. Even assuming the MSPB would not pass on the constitutionality of the Executive Orders, "the CSRA provides review in the Federal Circuit, an Article III court fully competent to adjudicate [plaintiffs'] claims." *Id.* at 17; *see also Semper*, 747 F.3d at 242. The district court thus erred in exercising jurisdiction over the federal-employee plaintiffs' claims.

C. Plaintiffs Cannot Obtain Injunctive Relief Against The President, The Sole Defendant Named In The Operative Complaint.

Plaintiffs' claims are jurisdictionally barred on the additional ground that the operative complaint asserts claims only against the President. *See* Supp. App. 140. Neither declaratory nor injunctive relief is proper against the President in his official capacity: "in general '[a] court has no jurisdiction of a bill to enjoin the President in the performance of his official duties.'" *Franklin v. Massachusetts*, 505 U.S. 788, 802-03 (1992) (quoting *Mississippi v. Johnson*, 71 U.S. (4 Wall.) 475, 501 (1866)); *see also Newdow v. Roberts*, 603 F.3d 1002, 1013 (D.C. Cir. 2010) ("With regard to the President, courts do not have jurisdiction to enjoin him and have never submitted the President to declaratory relief." (citations omitted)).

As Justice Scalia explained in *Franklin*, an "apparently unbroken historical tradition supports the view, . . . implicit in the separation of powers established by the Constitution, that the principals in whom the executive and legislative powers are ultimately vested . . . may not be ordered to perform particular executive or legislative acts at the behest of the Judiciary." 505 U.S. at 827 (Scalia, J., concurring). "For similar reasons," courts "cannot issue a declaratory judgment against the President." *Id.* The reasons for this rule are "painfully obvious": because the President and the judiciary are "coequal branch[es] of government," the latter ordering the former to perform specific executive acts "at best creates an unseemly appearance of constitutional tension and at worst risks a violation of the constitutional separation of

powers.” *Swan v. Clinton*, 100 F.3d 973, 978 (D.C. Cir. 1996) (citing *Franklin*, 505 U.S. at 827 (Scalia, J., concurring)). Other district courts considering similar challenges to the Executive Orders at issue here have rejected claims on this basis. *See McCray*, 2021 WL 5823801, at *5-8; *Rydie*, 2021 WL 5416545, at *3; *Rodden*, 2021 WL 5545234, at *2 & n.2; *Navy Seal 1 v. Biden*, No. 21-cv-2429, 2021 WL 5448970, at *2 (M.D. Fla. Nov. 22, 2021); *Foley v. Biden*, No. 21-cv-1098, slip op. at 3 (N.D. Tex. Oct. 6, 2021), ECF No. 18.

The Supreme Court has “left open the question whether the President might be subject to a judicial injunction requiring the performance of a purely ‘ministerial’ duty.” *Franklin*, 505 U.S. at 802. But contrary to plaintiffs’ suggestion (Br. 42), no “ministerial duty” is at issue here—plaintiffs challenge President Biden’s authority to require that federal civilian employees and certain federal contractors be vaccinated against COVID-19, an act that goes to the core of the President’s prerogatives to oversee management of the Executive Branch. *Cf. Swan*, 100 F.3d at 977 (“A ministerial duty is one that admits of no discretion, so that the official in question has no authority to determine whether to perform the duty.”). And in any event, courts have declined to compel the President to perform even ministerial duties due to the separation-of-powers problems raised by such relief. *See, e.g., National Wildlife Fed’n v. United States*, 626 F.2d 917, 926 (D.C. Cir. 1980); *National Treasury Emps. Union v. Nixon*, 492 F.2d 587, 616 (D.C. Cir. 1974).

The district court thus appropriately rejected the claims in plaintiffs’ operative complaint, which asked the court to enjoin the President. App. 17-18. The court noted that plaintiffs had sought leave to file a second amended complaint naming additional defendants for the federal-employee plaintiffs’ claims and stated that it would “consider” that proposed complaint “[f]or purposes of” adjudicating plaintiffs’ motion for injunctive relief. App. 6, 18. But plaintiffs would be entitled to a preliminary injunction only if (among other things) they were likely to succeed on the claims they have actually asserted in this suit, and because the district court has not granted their motion to file the second amended complaint, the only operative claims here are against President Biden. *See Beberman v. U.S. Dep’t of State*, 675 F. App’x 131, 134-35 (3d Cir. 2017) (limiting review to the complaint that was before the district court when it denied a preliminary injunction, even though the plaintiff had requested leave to file an amended complaint asserting a new claim). And in any event, the district court recognized that even in the proposed second amended complaint, Lorenzo (the federal contractor plaintiff) continues to assert claims only against President Biden. App. 18.

Plaintiffs argue that, even if the President cannot be enjoined for purposes of Lorenzo’s claims, an injunction against him would bind “whatever” unnamed “federal agencies have contracts with Ms. Lorenzo’s employers” on the theory that they “are in active concert or participation with the President.” Br. 40 (citing Fed. R. Civ. P. 65(d)(2)(C)). Plaintiffs did not raise this argument below, so it is waived here. *See, e.g.,*

Deborah Heart & Lung Ctr. v. Virtua Health, Inc., 833 F.3d 399, 403 n.12 (3d Cir. 2016).

And plaintiffs make no effort to provide information that might even begin to identify the nonparty “federal agencies” that they believe their requested injunction should bind—for example, they provide no information about which (if any) federal contracts Lorenzo works on or which agencies those contracts are with. *See* Supp. App. 13-14 (noting that plaintiffs failed to plead “any facts as to the status of [Lorenzo’s] employer’s contract with the federal government, what the terms of the contract are,” or “what her employer has said with respect to compliance . . . with the mandate or what the employer’s policy is”). In any event, Rule 65(d)(2)(C) “applies only when a plaintiff validly invokes federal jurisdiction by satisfying the traceability and redressability requirements of standing against a defendant.” *Jacobson v. Florida Sec’y of State*, 974 F.3d 1236, 1255 (11th Cir. 2020). “If a plaintiff sues the wrong defendant,” even “an order enjoining the correct official who has not been joined as a defendant cannot suddenly make the plaintiff’s injury redressable.” *Id.* Because the operative complaint at the time the district court ruled on plaintiffs’ motion for a preliminary injunction named only the President and not any other official(s) that could properly be enjoined, the court lacked jurisdiction to award any relief.

II. The District Court Did Not Abuse Its Discretion In Denying Injunctive Relief.

Although this Court need not reach the merits in light of this suit’s many jurisdictional deficiencies, the district court correctly concluded that plaintiffs satisfy

none of the preliminary injunction factors. *See* App. 20-26 (merits), App. 26-29 (irreparable injury); App. 29-30 (balance of equities and public interest). This Court has emphasized that a preliminary injunction is an “extraordinary remedy” that should be granted “only in limited circumstances.” *Greater Phila. Chamber of Commerce v. City of Philadelphia*, 949 F.3d 116, 133 (3d Cir. 2020) (quotation marks omitted). The plaintiff must establish “that it can win on the merits” and “that it is more likely than not to suffer irreparable harm in the absence of preliminary relief.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). “If these gateway factors are met, a court then considers the remaining two factors”—the possibility of harm to other interested persons and the public interest—“and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief.” *Id.*

A. Plaintiffs Are Unlikely To Succeed On The Merits.

Plaintiffs contend that the vaccination requirements imposed by Executive Orders 14042 and 14043 violate substantive due process. As the district court concluded, plaintiffs are unlikely to prevail on the merits: the vaccination requirements are subject to rational-basis review, which they easily survive.

1. This case concerns not whether an individual possesses a right to refuse vaccination, but whether an individual has a right to hold federal employment—or be employed by a federal contractor—while refusing to be vaccinated against COVID-19. *Cf. We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 294 (2d Cir. 2021) (per curiam)

(explaining that a challenged vaccination requirement was “a condition of employment in the healthcare field; the State is not forcibly vaccinating healthcare workers”). Plaintiffs have cited no case that holds that any such right exists.

Even assuming the challenged Executive Orders could be subject to the same analysis as vaccination requirements that apply to everyone within a jurisdiction, it is well established that vaccination requirements do not impermissibly burden any “fundamental right ingrained in the American legal tradition.” *Klaassen v. Trustees of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (noting that “vaccination requirements, like other public-health measures, have been common in this nation”); *see also Maniscalco v. New York City Dep’t of Educ.*, No. 21-CV-5055, 2021 WL 4344267, at *3 (E.D.N.Y. Sept. 23, 2021) (rejecting substantive due process challenge to vaccine requirement), *aff’d*, No. 21-2343, 2021 WL 4814767 (2d Cir. Oct. 15, 2021).⁵ That is consistent with the Supreme Court’s longstanding recognition that a government may require vaccination even under penalty of criminal sanctions. *See Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905); *see also Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944)

⁵ Justices Sotomayor and Barrett, respectively, denied applications for emergency injunctive relief in *Maniscalco* and *Klaassen*. *See Maniscalco v. New York City Dep’t of Educ.*, No. 21A50 (U.S. Oct. 1, 2021) (Sotomayor, J., in chambers); *Klaassen v. Trustees of Ind. Univ.*, No. 21A15 (U.S. Aug. 12, 2021) (Barrett, J., in chambers).

(reiterating that the Constitution does not provide “freedom from compulsory vaccination”); *Zucht v. King*, 260 U.S. 174, 176-77 (1922) (similar).⁶

Plaintiffs mistakenly attempt to characterize (Br. 21-23) the right at issue as “the fundamental right to decline medical procedures,” which they contend implicates the right to bodily integrity and the right to privacy. But even if plaintiffs could distinguish precedents like *Jacobson* by redefining the relevant right in those terms, the Executive Orders challenged here do not implicate such rights because they do not force anyone to receive medical care. As explained, federal employees and employees of covered federal contractors may seek an exception based on a disability (which would include medical conditions) or a sincerely held religious belief, and even if their exception requests are denied they are not forced to be vaccinated; they are simply subject to discipline up to and including removal. *See, e.g., We the Patriots USA*, 17 F.4th at 294 (rejecting a contention that requiring vaccines as a condition of employment amounted to “forcibly vaccinating healthcare workers”); *see also Klaassen*, 7 F.4th at 593-94; *Rydie*, 2021 WL 5416545, at *4. For that reason, this case does not

⁶ Within the past several months, several district courts have similarly concluded that there is no constitutional right to refuse a vaccine. *See, e.g., Rydie*, 2021 WL 5416545, at *4; *Rodriguez-Vélez v. Pierluisi-Urrutia*, No. 21-1366, 2021 WL 5072017, at *15 (D.P.R. Nov. 1, 2021); *Bauer v. Summey*, No. 21-CV-2952, 2021 WL 4900922, at *10 (D.S.C. Oct. 21, 2021); *Johnson v. Brown*, No. 21-CV-1494, 2021 WL 4846060, at *13 (D. Or. Oct. 18, 2021); *Dixon v. De Blasio*, No. 21-CV-5090, 2021 WL 4750187, at *8 (E.D.N.Y. Oct. 12, 2021); *Norris v. Stanley*, No. 21-CV-756, 2021 WL 4738827, at *1-2 (W.D. Mich. Oct. 8, 2021); *Valdez v. Grisham*, No. 21-CV-783, 2021 WL 4145746, at *5 (D.N.M. Sept. 13, 2021); *Doe v. Zucker*, 520 F. Supp. 3d 217, 251 (N.D.N.Y. 2021).

involve the forcible “taking things out of a person’s body against their will” or “putting things into a person’s body against their will.” Br. 21.

As a result, plaintiffs’ reliance (Br. 11-12, 22) on *Washington v. Glucksberg*, 521 U.S. 702 (1997), and *Cruzan ex rel. Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), is misplaced. *Glucksberg* upheld a state-law ban on assisted suicide, rejecting the plaintiff’s reliance on cases involving bodily integrity and privacy and holding that the asserted right at issue—properly construed as the “‘right’ to assistance in committing suicide”—“is not a fundamental liberty interest protected by the Due Process Clause.” 521 U.S. at 728. *Cruzan*, which assumed that a “competent person” had “a constitutionally protected right to refuse lifesaving hydration and nutrition,” 497 U.S. at 279, involved the forcible administration of medical treatment, unlike this case, and—as the Supreme Court later emphasized in *Glucksberg*—was “entirely consistent with this Nation’s history and constitutional traditions,” 521 U.S. at 725. Here, history and constitutional tradition point exactly the opposite way, demonstrating that individuals have no constitutional right to refuse vaccination (much less to do so only on pain of employment-related discipline).

In any event, the asserted liberty interests at issue in *Glucksberg* and *Cruzan* did not threaten the health of other persons; the Executive Orders at issue here, by contrast, require federal employees and employees of federal contractors to be vaccinated against COVID-19 infection to protect themselves and others in their workplaces from the spread of a highly contagious virus. *See, e.g.*, 86 Fed. Reg. at

50,989-90 (explaining, based on “public health guidance,” that “the best way to slow the spread of COVID-19 . . . is to be vaccinated”). Consistent with *Jacobson*, workers in a wide range of industries have long been subject to vaccination requirements, which “have been common in this nation.” *Klaassen*, 7 F.4th at 593; *see also* Teri Dobbins Baxter, *Employer-Mandated Vaccination Policies: Different Employers, New Vaccines, and Hidden Risks*, 2017 Utah L. Rev. 885. As the Supreme Court explained more than one hundred years ago, “[r]eal liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.” *Jacobson*, 197 U.S. at 26.

2. Under governing precedent, the Court must uphold a vaccination requirement so long as it rationally serves a “legitimate state interest.” *Holland v. Rosen*, 895 F.3d 272, 293 (3d Cir. 2018) (quotation marks omitted). Under this standard, the requirements are “presumed constitutional” and plaintiffs must negate “every conceivable basis which might support” them. *Combs v. Homer-Center Sch. Dist.*, 540 F.3d 231, 243 (3d Cir. 2008) (quotation marks omitted); *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2420 (2018) (noting that courts “hardly ever strike[] down a policy as illegitimate under rational basis scrutiny”).

Plaintiffs concede (Br. 24-25) that the government’s interest in combating the spread of COVID-19 is not merely legitimate, but “compelling.” *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) (per curiam) (“Stemming the

spread of COVID-19 is unquestionably a compelling interest”); *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief) (similar). And plaintiffs cannot seriously dispute that the Executive Orders are rationally related to that interest, as well as the government’s strong interest in promoting “[t]he health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact” during the COVID-19 pandemic. 86 Fed. Reg. at 50,989; *see also* 86 Fed. Reg. at 50,985 (explaining that Executive Order 14042 was issued to “promote[] economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID-19 safeguards”). Plaintiffs identify no case holding that a vaccination requirement lacked a rational basis, and there are many cases to the contrary. *See, e.g., We the Patriots USA*, 17 F.4th at 293-94 (rejecting plaintiffs’ claim that a mandatory vaccination requirement violates substantive due process); *Klaassen*, 7 F.4th at 593-94 (similar); *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App’x 348, 355-56 (4th Cir. 2011) (similar).

3. Plaintiffs make no effort to establish that the Executive Orders fail rational-basis scrutiny. And they concede that the Supreme Court applied rational-basis review in holding that cities and towns could constitutionally impose mandatory vaccination requirements on all of their adult inhabitants on pain of criminal sanctions. *See Jacobson*, 197 U.S. at 26-29. Plaintiffs nevertheless contend that *Jacobson* is distinguishable on a variety of grounds, none of which are persuasive.

Plaintiffs contend (Br. 16) that *Jacobson* concerned a state's exercise of its "police power" to mandate universal vaccination, which "cannot be plucked out of that context and grafted onto the federal government to imbue it with the same police powers the states hold." As the district court recognized, however, *see* App. 21-24, the Supreme Court has "long held . . . that there is a crucial difference, with respect to constitutional analysis, between the government exercising 'the power to regulate or license, as lawmaker,' and the government acting 'as proprietor, to manage [its] internal operation.'" *Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (alteration in original) (quoting *Cafeteria & Rest. Workers Union v. McElroy*, 367 U.S. 886, 896 (1961)); *see also National Aeronautics & Space Admin. v. Nelson*, 562 U.S. 134, 148 (2011) (reiterating that the government "has a much freer hand" when acting as "manager of its internal operation" than "when it brings its sovereign power to bear on citizens at large" (quotation marks omitted)). Plaintiffs offer no basis for the Court to conclude that the federal government lacks authority to require vaccination as a condition of employment or contract.

Plaintiffs separately argue (Br. 19-20) that *Jacobson* should be ignored because President Biden lacked the statutory authority under 5 U.S.C. §§ 3301, 3302, and 7301 to issue the vaccination requirements, arguing that those statutes do not provide the President "the authority to condition federal employment on undergoing a medical procedure." Plaintiffs never raised this argument before the district court, so it is waived. *Deborah Heart*, 833 F.3d at 403 n.12. In any event, it is well established that

“Congress delegated broad power to the President to establish qualifications and conditions of employment.” *DiLuigi v. Kafkalas*, 584 F.2d 22, 24 n.3 (3d Cir. 1978) (citing 5 U.S.C. § 3301); *see also National Treasury Emps. Union v. Horner*, 854 F.2d 490, 495 (D.C. Cir. 1988) (recognizing that Congress delegated “very broad discretion in the administration of the civil service” (quotation marks omitted)); *Rydie*, 2021 WL 5416545, at *3 (rejecting similar arguments). The President plainly has authority to condition federal employment—subject to exceptions “consistent with applicable law”—on compliance with a mechanism designed to “prevent infection” with a deadly virus during a global pandemic. 86 Fed. Reg. at 50,989-90.

Plaintiffs also seek to distinguish *Jacobson* (Br. 17-18) on the ground that the COVID-19 vaccines are not actually vaccines but are instead “mandated pharmaceuticals.” The district court rightly dismissed this contention, which plaintiffs “provide no medical authority or competent evidence to support.” App. 21. Each vaccine has undergone extensive testing and has been authorized for emergency use by FDA, and the Pfizer-BioNTech vaccine has received broader FDA approval. Numerous courts have recognized that *Jacobson*’s reasoning applies equally to COVID-19 vaccination requirements. *See, e.g., We the Patriots USA*, 17 F.4th at 293; *Klaassen*, 7 F.4th at 593; *see also, e.g., Harris v. University of Mass., Lowell*, No. 21-cv-11244, 2021 WL 3848012, at *6 (D. Mass. Aug. 27, 2021). Nor do plaintiffs’ blithe assurances (Br. 17) that COVID-19 is less dangerous than smallpox diminish *Jacobson*’s relevance. The point is that “the liberty secured by the Constitution of the United States to every

person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.” *Jacobson*, 197 U.S. at 26.

4. Plaintiffs spend the bulk of their opening brief (Br. 20-39) arguing that Executive Orders 14042 and 14043 should be subject to strict scrutiny and that the orders could not survive review under that standard because they “substantially burden” plaintiffs’ “liberty and privacy rights” and are not narrowly tailored. As explained above—and consistent with courts’ review of similar COVID-19 vaccination requirements—the Executive Orders are reviewed for rational basis, which they easily satisfy.

But certain of plaintiffs’ arguments warrant a brief response. Plaintiffs question (Br. 26-27) the COVID-19 vaccines’ effectiveness, and suggest (Br. 28-31) that the vaccines “carry risk,” including potentially making “individuals ill in the short term.” FDA has determined, however—based on analysis of wide-ranging data—that the COVID-19 vaccines are safe and effective. *See supra* pp. 7-8 (describing FDA’s evaluation of studies involving tens of thousands of participants); *see also* FDA, *Comirnaty Summary Basis for Regulatory Action* 27-28 (Nov. 8, 2021), <https://go.usa.gov/xeGms>; Pfizer EUA Letter at 4; Moderna EUA Letter at 2; Janssen EUA Letter at 2. As set forth in “public health guidance,” “the best way to slow the spread of COVID-19 and to prevent infection . . . is to be vaccinated,” 86 Fed. Reg. at 50,989, and plaintiffs offer nothing to seriously rebut this expert

consensus. The short-term “illness” that plaintiffs invoke—e.g., side effects such as headaches and fatigue—is merely the normal sign that the body is building protection to combat future infection from SARS-CoV-2. *See mRNA Vaccines, supra; Viral Vector Vaccines, supra*. Some people have no side effects, and allergic reactions are rare. Plaintiffs’ effort to cast aspersions on certain COVID-19 vaccine manufacturers (Br. 31-33) and on FDA itself (Br. 33-35) self-evidently has no bearing on the vaccines’ safety and effectiveness or the legality of the Executive Orders.

In arguing (Br. 12-13, 36) that the Executive Orders fail strict scrutiny because they are not “narrowly tailored,” plaintiffs repeatedly invoke *BST Holdings, LLC v. OSHA*, 17 F.4th 604 (5th Cir. 2021), in which a Fifth Circuit panel stayed an Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard that would require “employees of covered employers to undergo COVID-19 vaccination or take weekly COVID-19 tests and wear a mask,” holding that it exceeded OSHA’s statutory authority. *Id.* at 609. The government strongly disagrees with the Fifth Circuit’s ruling and is vigorously defending the OSHA Emergency Temporary Standard. But the Fifth Circuit’s ruling with respect to OSHA’s vaccination standard for certain *private* employers has no relevance to this case, which involves vaccine requirements that are imposed as a condition of employment for federal employees and covered contractor employees.

Finally, plaintiffs’ attempt (Br. 26, 37-38) to trivialize what they describe as the “objectively low” mortality rate from COVID-19 is particularly troubling. As of this

writing, more than 781,000 Americans have died from the virus, which has profoundly altered the fabric of American society. *See COVID Weekly Review, supra*. The federal government “unquestionably” has a “compelling interest” in curbing the spread of the virus and seeking to prevent further loss of life, *Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 67—including by issuing conditions on federal employment and federal contractors.

B. Plaintiffs Have Not Established Irreparable Injury.

Because plaintiffs cannot establish a likelihood of success on the merits, they are not entitled to a preliminary injunction. But the district court also properly concluded that plaintiffs have demonstrated no irreparable injury, the other “gateway factor[]” necessary to obtain relief. *Reilly*, 858 F.3d at 179. “[T]o demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial.” *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989). “The preliminary injunction must be the only way of protecting the plaintiff from harm,” *id.*, and the harm must be “*immediate*,” not predicted “in the indefinite future,” *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91 (3d Cir. 1992) (quotation marks omitted).

As the district court recognized, joining numerous other courts that have denied preliminary injunctions against vaccination requirements, plaintiffs here face no “imminent harm, let alone irreparable harm.” App. 27; *see, e.g., Rydie*, 2021 WL 5416545, at *5; *Church*, 2021 WL 5179215, at *13-15; *Altschuld v. Raimondo*, No. 21-cv-

2779, slip op. at 8 (D.D.C. Nov. 8, 2021), ECF No. 23; *Rodden*, 2021 WL 5545234, at *2.

As explained above, the federal-employee plaintiffs have requested exceptions from their employing agencies, those requests remain pending, and applicable guidance recommends that agencies “refrain from initiating enforcement action if the employee has received an exception and/or the agency is considering an exception request from the employee.” App. 27 (citing U.S. Office of Personnel Mgmt., Guidance on Enforcement of Coronavirus Disease 2019 Vaccination Requirements for Federal Employees—Executive Order 14043 (2021)); *see supra* Part I.A. Any potential disciplinary action is therefore speculative and limited to “the indefinite future.” *Campbell*, 977 F.2d at 91.

Plaintiff Lorenzo, who asserts that she is an employee of a federal contractor, likewise provides no details that would allow the Court to find that disciplinary proceedings are imminent. *See supra* Part I.A. Nor has she sued her employer, who would be responsible for any such discipline. Furthermore, Lorenzo states that she has attempted to request an exception, and federal guidance makes clear that her employer should follow relevant federal law when considering whether to provide an accommodation. *See Contractor Guidance*. At this early stage, and based on plaintiffs’ sparse allegations, it is impossible to know whether or when Executive Order 14042 might have any impact on Lorenzo’s employment.

But even if some plaintiff faced an imminent threat of workplace discipline, that would still not constitute irreparable harm. The most severe penalty that any

plaintiff could face for refusing to become vaccinated is loss of employment, which the Supreme Court has explained does not constitute irreparable harm absent a “genuinely extraordinary situation.” *Sampson*, 415 U.S. at 92 & n.68; *see also, e.g., Adams v. Freedom Forge Corp.*, 204 F.3d 475, 485 (3d Cir. 2000) (explaining that economic harm is rarely sufficient to demonstrate irreparable injury and that “there must be something uniquely threatening about the particular loss of money” for that loss to constitute irreparable injury).

As this Court has explained, harms from the wrongful deprivation of employment generally “may be remedied by appropriate judicial decrees if the plaintiffs should prove successful,” such as “provisions for employment, back-pay, fringe benefits and the like.” *Oburn v. Shapp*, 521 F.2d 142, 151 (3d Cir. 1975); *see also Beberman*, 675 F. App’x at 134 (rejecting a State Department employee’s request for a preliminary injunction against removal from her post). Depending on the claims asserted by a discharged-employee plaintiff and the nature of her employment, she may be able to pursue reinstatement or back pay in an appropriate forum pursuant to some combination of the CSRA, Title VII of the Civil Rights Act, the Rehabilitation Act, and the Back Pay Act. Plaintiffs provide no reason to think that those remedies would be inadequate for the prospective, speculative injuries alleged here. The mere possibility of economic loss does not suffice to establish irreparable injury. *See Sampson*, 415 U.S. at 92 n.68 (noting that “an insufficiency of savings or difficulties in immediately obtaining other employment” are inadequate); *Morton v. Beyer*, 822 F.2d

364, 372 (3d Cir. 1987) (“Although we are not insensitive to the financial distress suffered by employees whose wages have been terminated, we do not believe that loss of income alone constitutes irreparable harm.”).

Plaintiffs alternatively invoke (Br. 43) “the doctrine of unconstitutional conditions,” stating that “having been forced to comply with an unconstitutional intrusion on their bodies and privacy” is irreparable harm. But plaintiffs will not be forced to receive the vaccine: they can seek (and have sought) exceptions, and if the exceptions are denied, they may choose to pursue other employment. The worst harm that plaintiffs face is not the loss of a constitutional right but the possibility of workplace discipline if they decide not to comply with a condition of employment. Even if plaintiffs were correct on the merits, which they are not, *see supra* Part II.A, they could decline vaccination and obtain recompense for any adverse employment consequences at the conclusion of litigation.

C. The Public Interest And The Balance Of Harms Favor The Government.

Plaintiffs’ inability to succeed on the merits and their lack of irreparable injury provide a sufficient basis for affirming the district court’s denial of a preliminary injunction. *Reilly*, 858 F.3d at 179. But the district court also correctly found that the public interest and the balance of equities weighed heavily against plaintiffs’ request for injunctive relief. *See App.* 30 (finding that “the granting of injunctive relief would likely increase the risk of harm to the public”).

First, enjoining implementation of the Executive Orders would undermine the public interest in slowing the spread of COVID-19 among millions of federal employees and contractor employees and the members of the public with whom they interact. As the Supreme Court has recognized and plaintiffs have conceded (Br. 24-25), “[s]temming the spread of COVID-19 is unquestionably a compelling interest.” *Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 67. Accordingly, numerous courts reviewing “executive action designed to slow the spread of COVID-19” have concluded that “[t]he public interest in protecting human life—particularly in the face of a global and unpredictable pandemic—would not be served by” an injunction. *Tigges v. Northam*, 473 F. Supp. 3d 559, 573-74 (E.D. Va. 2020).⁷

Second, “[t]he effective administration of the federal government, in which Defendants and the public have a deep and abiding interest, would likely be hampered by an injunction.” *Rydie*, 2021 WL 5416545, at *5. The COVID-19 pandemic has interfered with numerous aspects of the government’s work, forcing office closures, hampering employees’ access to paper-based records, limiting official travel, and causing staffing shortages. *See generally* Pandemic Response Accountability Comm., *Top Challenges Facing Federal Agencies: COVID-19 Emergency Relief and Response Efforts* (June 2020), <https://go.usa.gov/xefTb>. These disruptions have affected the work of federal

⁷ *See also, e.g.*, *Rydie*, 2021 WL 5416545, at *5-6; *Altschuld*, No. 21-cv-779, slip op. at 11, ECF No. 23; *Church*, 2021 WL 5179215, at *18-19; *America’s Frontline Doctors v. Wilcox*, No. 21-1243, 2021 WL 4546923, at *8 (C.D. Cal. July 30, 2021).

employees and federal contractors alike. Requiring federal employees and covered federal contractor employees to become fully vaccinated against COVID-19, with exceptions only as required by law, reduces disruptions caused by worker absences associated with illness or exposure to the virus, generating meaningful gains in efficiency. Enjoining the Executive Orders would inhibit these gains and interfere with the government's ability to resume normal, pre-pandemic operations.

Third, as to the federal-employee plaintiffs, a preliminary injunction would undermine the elaborate and exclusive scheme Congress established for handling employment disputes. As discussed above, the CSRA creates comprehensive procedures for work-related controversies involving most federal civil servants. *See supra* Part I.B; *see also, e.g., Garcia v. United States*, 680 F.2d 29, 32 (5th Cir. 1982) (finding it “quite clear” that a preliminary injunction allowing a federal employee to circumvent administrative remedies “would have a far more disruptive effect on the administrative processes established by the government to handle cases such as these than would, on balance, be the burden on the employee resulting from a refusal to grant the injunction”).

Plaintiffs contend that the government would not be harmed by an injunction against “the enforcement of an unconstitutional law.” Br. 42 (quotation marks omitted). As explained in Part II.A, however, the Executive Orders are constitutional. And notwithstanding plaintiffs' untroubled assertion (Br. 43) that “there are alternative and constitutional methods that the government has at its disposal to

achieve its interest of stopping the spread of Covid,” the United States has endured the pandemic for nearly two years, at great human and economic cost, and there has long been broad agreement among public health experts and government officials that the pandemic will not end until safe and effective vaccines are widely administered.

CONCLUSION

For the foregoing reasons, the district court’s denial of a preliminary injunction should be affirmed, and this Court should remand with instructions to dismiss the case for lack of jurisdiction.

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

RACHAEL A. HONIG
Acting United States Attorney

MARLEIGH D. DOVER
CHARLES W. SCARBOROUGH
ABBY C. WRIGHT

s/ Sarah Carroll

SARAH CARROLL

CASEN B. ROSS

*Attorneys, Appellate Staff
Civil Division, Room 7511
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
202.514.1923
sarah.w.carroll@usdoj.gov*

DECEMBER 2021

COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.
2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,690 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.
3. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.
4. This document was scanned for viruses using Symantec Endpoint Protection version 14, and no virus was detected.

s/ Sarah Carroll

Sarah Carroll