IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI,
STATE OF NEBRASKA,
STATE OF ARKANSAS,
STATE OF KANSAS,
STATE OF IOWA,
STATE OF WYOMING,
STATE OF ALASKA,
STATE OF SOUTH DAKOTA,
STATE OF NORTH DAKOTA, and
STATE OF NEW HAMPSHIRE,

Plaintiffs,

v.

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

THE UNITED STATES OF AMERICA;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services;

CENTERS FOR MEDICARE AND MEDICAID SERVICES;

CHIQUITA BROOKS-LASURE in her official capacity as Administrator for the Centers for Medicare and Medicaid Services;

MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare;

DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services;

Defendants.

No. 4:21-cv-01329-MTS

FIRST AMENDED COMPLAINT

1. Plaintiff States, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire, bring this action to challenge the Centers for Medicare and Medicaid Services' ("CMS") Interim Final Rule with Comment Period ("IFR," "IFC," or "CMS Mandate") entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 (Nov. 5, 2021). That IFR imposes an unprecedented federal vaccine mandate on nearly every full-time employee, part-time employee, volunteer, and contractor working at a wide range of healthcare facilities receiving Medicare or Medicaid funding.

2. The CMS vaccine mandate threatens the jobs of millions of healthcare workers who risked their lives in the early days of the COVID-19 pandemic to care for strangers and friends in their communities.

3. The CMS vaccine mandate also threatens to exacerbate the alarming shortage of healthcare workers, particularly in rural communities, that has already reached a tipping point. Indeed, the circumstances in the Plaintiff States—circumstances that CMS, which skipped notice-and-comment rulemaking, did not fully consider—foreshadow an impending disaster in the healthcare industry. By ignoring the facts on the ground and unreasonably dismissing concerns about workforce shortages, the CMS vaccine mandate jeopardizes the healthcare interests of rural Americans.

4. This case illustrates why the police power over compulsory vaccination has always been the province of—and still properly belongs to—the States. Vaccination requirements are matters that depend on local factors and conditions. Whatever might make sense in New York City, St. Louis, or Omaha could be decidedly counterproductive and harmful in rural communities like

Memphis, Missouri or McCook, Nebraska. Federalism allows States to tailor such matters in the best interests of their communities. The heavy hand of CMS's nationwide mandate does not.

5. One of the mandate's most fundamental defects is its failure to account for the only well-established features of the COVID-19 pandemic: that change is inevitable, circumstances are constantly shifting, and variants are ever evolving. Despite acknowledging that new variants might arise and that the available COVID-19 vaccines might not be effective at preventing the transmission of those new variants, CMS created a rigid, Delta-inspired rule that has no place—and indeed is utterly irrational—in the Omicron-dominated world we now inhabit.

6. Plaintiffs intend this amended complaint to add to, rather than supplant, the allegations in their original complaint. Thus, Plaintiffs not only plead new allegations in this complaint, but also reassert the allegations in their original complaint.

7. For all the reasons explained in this amended complaint, this Court should set aside the CMS mandate as unlawful agency action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706.

PARTIES

8. Plaintiff State of Missouri is a sovereign State of the United States of America. Missouri sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

9. Eric S. Schmitt is the 43rd Attorney General of the State of Missouri. Attorney General Schmitt is authorized to bring actions on behalf of Missouri that are "necessary to protect the rights and interests of the state, and enforce any and all rights, interests, or claims any and all persons, firms or corporations in whatever court or jurisdiction such action may be necessary." Mo. Rev. Stat. § 27.060.

10. Plaintiff State of Nebraska is a sovereign State of the United States of America. Nebraska sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

11. Douglas J. Peterson is the Attorney General of Nebraska. Attorney General Peterson is authorized to bring legal actions on behalf of the State of Nebraska and its citizens.

12. Plaintiff State of Arkansas is a sovereign State of the United States of America. Arkansas sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

13. Leslie Rutledge is the Attorney General of Arkansas. Attorney General Rutledge is authorized to bring legal actions on behalf of the State of Arkansas and its citizens.

14. Plaintiff State of Kansas is a sovereign State of the United States of America. Kansas sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

15. Derek Schmidt is the Attorney General of Kansas. Attorney General Schmidt is authorized to bring legal actions on behalf of the State of Kansas and its citizens.

16. Plaintiff State of Iowa is a sovereign State of the United States of America. Iowa sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

17. The Attorney General of Iowa is authorized and required to prosecute legal actions on behalf of the State of Iowa and its citizens when requested to do so by the Governor.

18. Plaintiff State of Wyoming is a sovereign State of the United States of America. Wyoming sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

19. Bridget Hill is the Attorney General of Wyoming. Attorney General Hill is authorized to bring legal actions on behalf of the State of Wyoming and its citizens. Wyo. Stat. Ann. § 9-1-603(a).

20. Plaintiff State of Alaska is a sovereign State of the United States of America. Alaska sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

21. Treg Taylor is the Attorney General of Alaska. Attorney General Taylor is authorized to bring legal actions on behalf of the State of Alaska and its citizens. The Attorney General is acting pursuant to his authority to bring any action which he thinks necessary to protect the public interest and to represent the State of Alaska in any suit to which it is a party. Alaska Stat. § 44.23.020(1), (3), (9).

22. Plaintiff State of South Dakota is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought by the State in its sovereign capacity in order to protect the interests of the State of South Dakota and its citizens as *parens patriae*, by and through Mark Vargo, the Attorney General of the State of South Dakota. The Attorney General is acting pursuant to his authority to appear for the State and prosecute any civil matter in which the State is a party or interested when, in his judgment, the welfare of the State demands. S.D. Codified Laws §1-11-1(2).

23. Plaintiff State of North Dakota is a sovereign State of the United States of America. North Dakota sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

24. Drew H. Wrigley is the North Dakota Attorney General. Attorney General Wrigley is authorized to bring legal actions on behalf of the State of North Dakota and its citizens. N.D. Cent. Code 54-12-02.

25. Plaintiff State of New Hampshire is a sovereign State of the United States of America. New Hampshire sues to vindicate its sovereign, quasi-sovereign, proprietary, and *parens patriae* interests.

26. The Attorney General of New Hampshire is authorized to bring legal actions on behalf of the State of New Hampshire and its citizens.

27. Collectively, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire are referred to herein as the "Plaintiff States."

28. Defendants are United States governmental officials and agencies responsible for adopting and implementing the CMS vaccine mandate.

29. Defendant Joseph R. Biden, Jr., is the President of the United States of America. He is sued in his official capacity.

30. Defendant United States Department of Health and Human Services ("HHS") is an independent federal agency.

31. Defendant Xavier Becerra is the Secretary of HHS. He is sued in his official capacity.

32. Defendant CMS is part of HHS.

33. Defendant Chiquita Brooks-LaSure is the Administrator for the Centers for Medicare and Medicaid Services. She is sued in her official capacity.

34. Defendant Meena Seshamani is the Deputy Administrator and Director of the Center for Medicare. She is sued in her official capacity.

35. Defendant Daniel Tsai is the Deputy Administrator and Director of the Center for Medicaid and CHIP Services. He is sued in his official capacity.

JURISDICTION AND VENUE

36. This Court has jurisdiction pursuant to 5 U.S.C. §§ 702–703 and 28 U.S.C. §§ 1331, 1361, and 2201.

37. This Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. §§ 702 and 706, 28 U.S.C. §§ 1361 and 2201–2202, and its inherent equitable powers.

38. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)(2) and 1391(e). Defendants are United States agencies or officers sued in their official capacities. Plaintiff State

of Missouri is a resident of this judicial district, and a substantial part of the events or omissions giving rise to this case occurred within this district.

39. The Plaintiff States bring this action to redress harms to their sovereign interests, their quasi-sovereign interests, their proprietary interests, their interests as *parentes patriae*, and their interests under 5 U.S.C. § 702.

GENERAL ALLEGATIONS

The National Healthcare Worker Crisis and the Plaintiff States

40. For many years now, beginning before the COVID-19 pandemic, the healthcare industry in the United States has been experiencing severe workforce shortages.

41. At the time CMS issued the vaccine mandate, a study found that 97 of Missouri's 114 counties have a nursing shortage. Lori Schneidt, Anne Heyen & Tracy Greever-Rice, *Show Me the Nursing Shortage: Location Matters in Missouri Nursing Shortage*, 12 J. Nursing Reg. 52 (2021); *see also* Press Release, University of Missouri, *Nursing Shortage affects rural Missourians more, MU study finds* (June 24, 2021), https://showme.missouri.edu/2021/nursing-shortage-affects-rural-missourians-more-mu-study-finds/. In addition, rural areas in Missouri have fewer nurses than metropolitan areas. *Id.*; s*ee also* Mo. State. Bd. of Nursing, *2021 Missouri Nursing Workforce Report* 5 (2021), https://pr.mo.gov/boards/nursing/2021-workforce-report.pdf; Mo. State Bd. of Nursing, *2020 Missouri Nursing Workforce Report* 1 (2021), https://pr.mo.gov/boards/nursing/2020-workforce-report.pdf.

42. Similarly, at the start of 2021, Missouri had a staff nurse vacancy of 12% with 4,894 vacant staff nurse positions. Mo. Hosp. Ass'n, *2021 Workforce Report* (2021), https://www.mhanet.com/mhaimages/Workforce/2021/2021_WF_report.pdf. Additionally, staff

nurse turnover is the highest it has been in 20 years at 18.1%. *Id*. The combined turnover rate among all healthcare professions is 21.5%. *Id*.

43. The president of eight SSM Health St. Louis-area hospitals, Jeremy Fotheringham, has said that the nursing shortage in Missouri is "severe" with about 80 out of his 5,500 system nurses leaving each month. *Pandemic Making Nursing Shortage a Crisis in St. Louis*, Associated Press (Oct. 4, 2021), https://www.usnews.com/news/best-states/missouri/articles/2021-10-03/pandemic-making-nursing-shortage-a-crisis-in-st-louis. Likewise, Mercy is losing about 160 out of 8,500 system nurses each month. *Id*.

44. Nurses are leaving their positions because they are burnt-out from the COVID-19 pandemic or they are attracted to the increased demand and inflated hourly rates of travel nursing. Michelle Munz, *St. Louis-area hospitals face staffing crisis as burnout and high 'traveler' salaries cause nurses to leave* (Oct. 4, 2021), https://www.stltoday.com/news/local/metro/st-louis-area-hospitals-face-staffing-crisis-as-burnout-and-high-traveler-salaries-cause-nurses/article_26ad26f2-8c3a-50a6-8ddf-1253bf745d86.html. Fotheringham says, "A year ago, there were about 2,000 open traveler positions across the U.S. They have since ballooned to 30,000." *Id*. This boom in demand for travel nurses is especially difficult for smaller, rural hospitals who cannot afford to pay their nurses more to stay nor can they afford the exorbitant rates of travel nurses. *See* Leticia Miranda, *Rural hospitals losing hundreds of staff to high-paid traveling nurse jobs* (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.

45. There was no relief through 2021. "[B]oth turnover and vacancy rates among all [healthcare] professions surveyed reached an all-time high statewide." Mo. Hosp. Ass'n, *2022 Workforce Report* 1 (2022), https://www.mhanet.com/mhaimages/workforce/2022/2022_

WorkforceReport.pdf. There was "an 87% increase in vacancies since 2020." *Id.* For nurses, the rates were higher—the report found "staff nurse vacancy at 19.8%," as compared to 12% in 2021, "the highest it's been in the history of the survey." *Id.* at 2. And staff nurse turnover increased from 18.1% to 22.1%—a level that "is costly and disruptive for health care systems, and can impact morale, disrupt the nurse and patient experience, and exacerbate an already pressing shortage of qualified talent." *Id.* The resulting strains on the healthcare workforce "contribute[ ] to a perfect storm driving significant staffing shortages." *Id.* Indeed, the director of the Missouri Nurses Association said that the situation is so bad that "[w]e're getting to the point where we are not going to be able to meet the need here in the state. … The nurses that are currently still in the workforce are so overstretched and overworked. And, it's just going to get worse." Siobhan Harms, *Missouri Nurses Association Addresses Statewide Staffing Shortage*, KOMU8 (Aug. 26, 2022), https://www.komu.com/news/state/missouri-nurses-association-addresses-statewide-staffing-shortage/article_d3b234ca-24b2-11ed-b8f8-43393c4c9ad8.html.

46. Those issues prompted a statewide response. On August 27, 2021, Missouri Governor Michael L. Parson signed Executive Order 21-09 declaring a targeted State of Emergency for Missouri's healthcare system. Mo. Exec. Order 21-09 (Aug. 27, 2021), https://www.sos.mo.gov/library/reference/orders/2021/eo9. The Order declared that "a state of emergency exists relative to staff shortages in the State's healthcare system and the State's recovery efforts from the COVID-19 public health threat."

47. The Order suspended "certain statutory and regulatory provisions related to telemedicine" and vested state agencies, executive boards, and commissions with "authority [1] to waive or suspend statutory or regulatory requirements, [. . .] where strict compliance would hinder the State's recovery from COVID-19, and [2] to ease licensing requirements to eliminate barriers to

the provision of health care services and other professions." Specifically, the Director of the Missouri Department of Health and Senior Services could temporarily waive or suspend any requirements or rules that would "prevent, hinder, or delay necessary action by the department to respond to staff shortages[.]" The Order also "direct[ed] the members of the [Missouri] National Guard to provide assistance to the Department of Health and Senior Services to ensure on-time reporting of data in electronic records from medical providers relative to COVID-19 testing, and as otherwise needed to help aid the department to respond to staff shortages[.]"

48. Executive Order 21-09 expired on December 31, 2021, by its own terms.

49. In 2022, the Missouri General Assembly appropriated $3 million in grant funding for Missouri schools "to help enhance nursing education programs and develop solutions to help alleviate staffing shortages felt nationwide." Press Release, Mo. Gov. Michael L. Parson, Nearly $3 Million in Grants Approved for Eleven Missouri Colleges and Universities to Help Enhance Nursing Programs Across Missouri (Sept. 21, 2022), https://governor.mo.gov/press-releases/archive/nearly-3-million-grants-approved-eleven-missouri-colleges-and-universities.

50. According to the Missouri Department of Health and Senior Services, there were 48 Small Rural Hospitals operating in the State of Missouri as of September 24, 2020. *Missouri Rural Hospitals and Critical Access Hospitals*, Missouri Department of Health and Senior Services (Sept. 24, 2020), https://health.mo.gov/living/families/ruralhealth/pdf/rural-hospitals.pdf.

51. Dr. Randy Tobler, former CEO of Scotland County Hospital in Memphis, Missouri—a small rural hospital—said a COVID-19 vaccine mandate will encourage his staff to quit rather than receive the vaccine. Elle Reeve, *A Covid-19 vaccine mandate won't force staff at this rural Missouri hospital to get the shot, CEO says. It will make them quit.*, CNN (Oct. 12, 2021), https://www.cnn.com/2021/10/12/us/unvaccinated-missouri-hospital-covid-19/index.html.

According to Dr. Tobler: "There were people in the hospital that freely shared that if the vaccine mandate happened . . . , they would not work here. That's just something they weren't going to put in their body." *Id*.

52. During the first year and half of the pandemic, the hospital had already lost 10 of its 57 nurses (approximately 18 percent) and, at times, has had to turn away patients amid a surge in COVID-19 cases due to staff shortages. Lauren Weber Kaiser, *In Missouri, the lack of a vaccine mandate becomes competitive advantage in hospital staffing wars*, St. Louis Post-Dispatch (Aug. 31, 2021), https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/in-missouri-the-lack-of-a-vaccine-mandate-becomes-competitive-advantage-in-hospital-staffing-wars/article_64cc03c0-5924-578e-9adc-d26e0e43db11.html. To fill the gaps, the hospital hired travel nurses, which cost $200 an hour or more—a price that small rural hospitals cannot easily afford. *Id*.; *see also* Mo. Hosp. Ass'n, *2022 Workforce Report*, *supra*, at 2.

53. Upon information and belief, Scotland County Hospital's experience is not atypical.

54. Nebraska likewise has been experiencing a significant shortage in healthcare workers. This crisis started long before the COVID-19 pandemic began. For example, the latest statistics available from 2018 indicate that more than 4,300 job openings for registered nurses existed in Nebraska.

55. According to data from the Nebraska Department of Health and Human Services, nine assisted living facilities and 20 nursing homes in rural Nebraska have closed since 2019.

56. On August 26, 2021, Nebraska Governor Pete Ricketts, much like Missouri Governor Parson, issued Executive Order No. 21-12. That order declared that "Nebraska hospitals, clinics, and other health care facilities are facing a shortage of health care professionals" and that "a hospital capacity emergency exists." Neb. Exec. Order 21-12 (Aug. 26, 2021),

https://www.dropbox.com/s/sm3dpu7t094ymum/Executive%20Order%2021-12%20-%20Additional%20Healthcare%20Workforce%20Capacity.pdf?dl=0. Governor Ricketts issued the order, which temporarily waived certain statutes and regulations governing healthcare workers, to "protect[] the citizens of Nebraska from the public health threat of a hospital capacity and workforce emergency." *Id.* The order addressed the hospital capacity issue by "expand[ing] the pool of healthcare professionals who are eligible to care for Nebraskans." Gov. Ricketts Takes Action to Help Hospitals Increase Staffing (Aug. 27, 2021), https://governor.nebraska.gov/press/gov-ricketts-takes-action-help-hospitals-increase-staffing.

57. Also, on August 26, 2021, Governor Ricketts announced a Directed Health Measure, *see id.*, suspending certain elective surgeries that could wait four weeks or longer without substantially changing a patient's outcome. Directed Health Measure Order 2021-002, Nebraska Department of Health and Human Services, https://dhhs.ne.gov/Archived%20DHMs/DHM%202021-002.pdf.

58. In August 2021, just weeks before President Biden announced the CMS vaccine mandate, Nebraska state officials started specifically recruiting unvaccinated healthcare workers to address their workforce shortage. Alyssa Lukpat and Lauren McCarthy, *Nebraska is recruiting unvaccinated nurses to plug a staffing shortage*, N.Y. Times (Aug. 26, 2021), https://www.nytimes.com/2021/08/26/us/nebraska-delta-nurses-unvaccinated.html. The advertisements that state officials posted for positions in veterans' homes, psychiatric treatment facilities, and other locations explicitly said, "No mandated Covid-19 vaccinations." *Id.*

59. In late September 2021, Troy Bruntz—the President and Chief Executive Officer of Community Hospital in McCook, Nebraska, a small rural community—announced that some of his hospital's employees will quit rather than get vaccinated. Andrew Ozaki, *Federal vaccine mandate will cause exodus of staff, rural hospital leader warns*, KETV (Sept. 29, 2021),

https://www.ketv.com/article/federal-vaccine-mandate-will-cause-exodus-of-staff-rural-hospital-leader-warns/37780945. He said that his hospital "might end up losing a lot of services . . . that our communities definitively need[]." *Id.*

60. Mary Lanning Healthcare—a hospital in Hastings, Nebraska, which is a rural community with less than 25,000 residents—is also concerned about the CMS vaccine mandate's effect. The hospital already has 45 vacancies within its 270 registered nurse staff positions, and it projects that the mandate will only make matters worse. Moreover, some of its critical units, such as its emergency department and intensive care unit, have current vaccination rates at or below 50%, thus adding to its concerns.

61. Great Plains Health—a hospital in North Platte, Nebraska, which is a rural community with less than 25,000 residents—shares these concerns about the CMS vaccine mandate. Because of its ongoing workforce shortages, the hospital is currently able to staff only around 70 of its 116 beds. To make matters worse, the hospital has received notice from a majority of the personnel within its behavioral health unit that they will resign rather than submit to vaccination. Because its behavioral health unit is one of only two in western Nebraska, the impact of reducing those services will be felt throughout the western half of the State.

62. Other Medicare- and Medicaid-qualifying healthcare providers have expressed similar concerns about the negative impacts of the CMS vaccine mandate.

63. As of October 24, 2021, 101 of the 195 nursing homes in Nebraska (51.8%) had staff vaccination rates under 75%. Breaking down those numbers further, 24 of the 195 nursing homes (12.3%) had staff vaccination rates under 50%, and 77 of the 195 (39.4%) had staff vaccination rates between 50% and 75%.

64. In late September 2021, Governor Ricketts publicly said: "I don't think the Administration understands the devastating effect it will have on rural health care if they go forward with this vaccine mandate." Ozaki, *supra*.

65. Wyoming has also been experiencing a significant shortage in healthcare workers. Wyoming's hospitals have sought additional support to respond to the COVID-19 pandemic and the surge in hospitalized patients.

66. To help with the healthcare workforce crisis, on September 21, 2021, Wyoming Governor Mark Gordon activated the Wyoming National Guard to provide temporary assistance to hospitals throughout Wyoming. Governor Gordon called approximately 95 soldiers and airmen to State active duty orders assigning them to hospital locations at 24 different sites within 17 Wyoming counties to augment hospital and Wyoming Department of Health staff to ease workloads.

67. The Wyoming National Guard members' responsibilities include assisting in environmental cleanup in hospital facilities; food and nutrition service; COVID-19 screening; managing personal protective equipment supplies; and other support tasks.

68. Nearly every county in Wyoming is designated a HIPSA (health professional shortage area) by the Health Resources and Services Administration.

69. Certain Wyoming healthcare providers have been forced to operate in crisis standards of care in order to mitigate COVID-19 and the resultant staffing shortages, which are significant in Wyoming.

70. The State of Wyoming, through the Department of Health, operates several safety net healthcare facilities to serve the mentally ill, the disabled, and the elderly. These facilities operate in rural frontier areas and experience significant staffing shortages.

71. The State of Alaska also faces a significant shortage in healthcare workers. Alaska has been dealing with that issue before the COVID-19 pandemic began.

72. An October 2021 survey from the Kaiser Family Foundation confirmed that vaccine mandates pose substantial threats to existing workforce shortages. That survey found that *72 percent* of "unvaccinated workers say they will quit" rather than submit to a vaccine mandate. Chris Isidore and Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021), https://www.cnn.com/2021/10/28/business/covid-vaccine-workers-quit/index.html.

73. The CEO of the National Rural Health Association, Alan Morgan, has acknowledged the serious challenge that a vaccine mandate presents for rural healthcare providers: "Obviously, it's going to be a real challenge for these small, rural hospitals to mandate a vaccine when they're already facing such significant workforce shortages." Weber Kaiser, *supra*.

74. The Plaintiff States anticipate that the CMS vaccine mandate will have devastating adverse effects on healthcare services in their States, particularly in their rural communities.

The Plaintiff States' Role in Medicare and Medicaid

75. Medicaid is a cooperative state-federal program in which States may choose to participate.

76. Medicaid is a program that helps States finance the medical expenses of their citizens.

77. The Plaintiff States have all entered into agreements with the federal government to participate in Medicaid.

78. Medicaid providers receive funding for services through a provider contract with individual States. The Plaintiff States thus bear the burden of issuing sanctions or terminating provider contracts. CMS, *Quality, Safety & Oversight – General Information*, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo.

79. Medicare is a medical-funding program paid for and administered by the federal government.

80. The Plaintiff States employ state surveyors who regularly evaluate healthcare facilities' compliance with Medicare and Medicaid requirements. When the state surveyors conduct inspections, they assess compliance with both federal and state regulations at the same time. For example, Nebraska currently employs over 60 state surveyors who work under its Department of Health and Human Service's Division of Public Health. Iowa currently employs about 80 state surveyors within its Health Facilities Division of the Iowa Department of Inspections and Appeals.

81. Unless state surveyors confirm a healthcare facilities' compliance with Medicare and Medicaid requirements, those facilities are not entitled to obtain Medicare or Medicaid reimbursements.

82. When state surveyors find that a healthcare facility is not in compliance with federal Medicare or Medicaid regulations, they send the facility a violation report informing it of the deficiencies.

83. The Plaintiff States also have state-run healthcare facilities that receive Medicare and Medicaid funding.

84. Missouri has at least 13 state-run healthcare facilities that receive Medicare and Medicaid funding and fall within the scope of the CMS vaccine mandate. These include five adult inpatient facilities, one children's psychiatric hospital, six Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICFs-IDD"), and one hospital system. The Center for Behavioral Medicine, Fulton State Hospital, Northwest Missouri Psychiatric Rehabilitation Center, Southwest Missouri Mental Health Center, and the St. Louis Forensic Treatment Center provide inpatient and residential psychiatric services. These five facilities, which collectively have over 1,100 beds,

qualify as hospitals under the CMS vaccine mandate. The Hawthorn Children's Psychiatric Hospital is a 28-bed Psychiatric Residential Treatment Facility that provides acute and residential services to children and youth. The Bellefontaine Habilitation Center, Higginsville Habilitation Center, St. Charles Habilitation Center, SEMO Residential Services in Sikeston and Poplar Bluff, and the South County Habilitation Center each provide 24-hour accommodation, board, personal care, and basic health and nursing care services to individuals with intellectual disabilities. They qualify as ICFs-IID under the CMS vaccine mandate.

85. Nebraska has two state-run healthcare facilities that receive Medicare and Medicaid funding. The first is the Lincoln Regional Center, which is a 250-bed inpatient psychiatric hospital that falls within the scope of the CMS vaccine mandate. It serves people who need very specialized psychiatric services and people who, because of mental illness, require a highly structured treatment setting. As of November 2021, only 68% of the staff at the Lincoln Regional Center had received a COVID-19 vaccine. The second facility is the Beatrice State Developmental Center. It is a residential treatment facility dedicated to providing specialized psychological, medical, and developmental support to people with intellectual and developmental disabilities. It qualifies as an ICF-IID and is covered by the CMS vaccine mandate. As of November 2021, only 57.5% of the staff at the Beatrice State Developmental Center had received a COVID-19 vaccine.

86. Alaska has one state-run health care facility that receives Medicare and Medicaid funding, the Alaska Psychiatric Institute ("API"). API is an 80-bed psychiatric hospital that falls within the CMS mandate. The state of Alaska is required by state law to make mental health treatment available at a state-operated hospital to any individual ordered to be involuntarily committed for treatment under state law. Alaska Stat. § 47.30.760.

87. Iowa has five state-run healthcare facilities that receive Medicare and Medicaid funding and fall under the CMS vaccine mandate as written. The Cherokee and Independence Mental Health Institutes serve children, adolescents, and adults in need of specialized psychiatric services and people who, because of persistent mental illness, require a highly structured treatment setting or higher level of specialized care. These facilities serve as a provider of last resort and collectively treated more than 400 people within state fiscal year 2020. The Glenwood and Woodward Resource Centers are residential treatment facilities dedicated to providing specialized psychological, medical, and developmental supports to people with intellectual and developmental disabilities. Both are licensed as ICFs-IID. Today, Glenwood and Woodward are home to more than 200 Iowans. The Iowa Veterans serves as a long-term health care facility providing nursing and residential levels of care for honorably discharged veterans and their dependent spouses, surviving spouses, and gold star parents. It provides a continuum of care to more than 500 veterans and family members, including at its 113-bed licensed residential care facility.

88. The State of Wyoming, through the Department of Health, operates three state-run facilities that receive Medicare and Medicaid funding. The facilities are the Wyoming State Hospital, the Wyoming Life Resource Center, and the Wyoming Retirement Center. These facilities serve the mentally ill, the disabled, and the elderly. These facilities operate in rural frontier areas and experience significant staffing shortages.

The President's Announcement of Widespread Federal Vaccine Mandates

89. For the first six months of President Biden's Administration, none of his agencies sought to impose vaccine mandates on the American people. On July 23, 2021, the White House announced that mandating vaccines is "not the role of the federal government." Press Briefing by Press Secretary Jen Psaki (July 23, 2021), The White House, https://www.whitehouse.gov

/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

90. On September 9, 2021, amid flagging poll numbers due to the crisis in Afghanistan and on the southern border, the Administration's policy on federal vaccine mandates underwent a dramatic about-face.

91. On September 9, President Biden gave a speech announcing his six-point Plan to "turn the tide on COVID-19." Joseph Biden, Remarks at the White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ ("Biden Speech").

92. President Biden announced that the first plank of his plan is to "require more Americans to be vaccinated." *Id.* The purpose of this plan, he said, is to "reduce the number of unvaccinated Americans." *Id.*

93. President Biden laid primary responsibility for the ongoing pandemic with unvaccinated Americans, saying that he is "frustrated with the nearly 80 million Americans who are still not vaccinated." *Id.* He stated that "[t]his is a pandemic of the unvaccinated," and that the "nearly 80 million Americans [who are] not vaccinated . . . can cause a lot of damage—and they are." *Id.* He even blamed the unvaccinated for healthcare shortages: "The unvaccinated overcrowd our hospitals, are overrunning the emergency rooms and intensive care units, leaving no room for someone with a heart attack . . . or cancer." *Id.* Scolding the unvaccinated, he stated: "[O]ur patience is wearing thin. And your refusal has cost all of us." *Id.* And in an apparent effort to foment national discord, he said: "For the vast majority of you who have gotten vaccinated, I understand your anger at those who haven't gotten vaccinated." *Id.*

94. President Biden announced several federal vaccine mandates—(1) a mandate from the Occupational Safety and Health Administration ("OSHA") for companies with more than 100 employees, (2) a mandate for federal employees, (3) a mandate for employees of federal contractors and subcontractors, and (4) the CMS vaccine mandate challenged here. *Id.* Except for the CMS mandate, federal courts enjoined those mandates in whole or in part. *See*, *e.g.*, *NFIB v. OSHA*, 142 S. Ct. 661 (2022) (OSHA mandate); *Georgia v. President of the U.S.*, 46 F.4th 1283 (11th Cir. 2022) (contractor mandate); *Feds for Med. Freedom v. Biden*, 581 F. Supp. 3d 826 (S.D. Tex. Jan. 21, 2022) (federal employee mandate).[1] And the OSHA mandate has been withdrawn by the agency. *See* 87 Fed. Reg. 3,928, 3,928 (Jan. 26, 2022).

95. President Biden also expressed a dismissive view of States that have used their constitutionally guaranteed police powers to adopt contrary public-health policies. *Id.* He stated: "Let me be blunt. My plan also takes on elected officials and states that are undermining . . . these lifesaving actions." *Id.* Speaking scornfully of "governor[s]" who oppose the new federal mandates, he promised that "if these governors won't help us beat the pandemic, I'll use my power as President to get them out of the way." *Id.*

96. The President's rhetoric stands in stark contrast to other statements and policies implemented by this administration. For example, early in 2022, the CDC rescinded an order—known as the Title 42 order—barring certain aliens from entering the United States in order to prevent the spread of COVID-19. Public Health Determination and Order Regarding Suspending the Right to Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease, 87 Fed. Reg. 19,941, 19,941 (Apr. 6, 2022). Expressly disclaiming reliance on "full

[1] A panel of the Fifth Circuit vacated the preliminary injunction, 30 F.4th 503, 511 (5th Cir. 2022), but the en banc court vacated the decision and set the case for argument, 37 F.4th 1093, 1094 (5th Cir. 2022).

COVID-19 vaccination," the CDC said that "partial vaccination provides some level of protection against severe illness and hospitalization and helps maintain U.S. healthcare resources." *Id.* at 19,953. The CDC noted that as of April 6, 2022, "the United States ha[d] high rates of vaccine and infection-induced immunity in the population, as well as availability of effective therapeutics, testing, and well-fitting masks," thus rendering the Title 42 order "no longer commensurate with the extraordinary measures instituted by the CDC Orders." *Id.*

Overview of the CMS Vaccine Mandate

97. On November 5, 2021, nearly two months after President Biden announced his federal vaccine mandates, CMS finally published the IFR challenged here, which contains the CMS vaccine mandate. 86 Fed. Reg. 61,555.

98. The CMS vaccine mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers. By expanding its reach in this way, the mandate broadly sweeps in a diverse set of healthcare providers. These include, among others, rural health clinics, hospitals, long-term-care facilities, and home health agencies. 86 Fed. Reg. at 61,569–70. Demonstrating the far reach of the mandate, CMS reported that "Medicare-participating hospitals . . . include nearly all hospitals in the U.S." *Id.* at 61,577.

99. The Plaintiff States are home to many healthcare providers that fall within the fifteen categories of Medicare- and Medicaid-certified providers and suppliers covered by the CMS vaccine mandate.

100. CMS recognized that the "providers and suppliers regulated under this rule are diverse in nature, management structure, and size." 86 Fed. Reg. at 61,602. Despite this, CMS relied predominantly on facts and figures involving long-term-care facilities—providers who serve mostly elderly and often immunocompromised patients—to make its case for applying the vaccine

mandate to fourteen other categories of Medicare- and Medicaid-certified providers. *See, e.g.*, *id.* at 61,585 (discussing "case rates among [long-term-care] facility residents," and claiming, without citation, that those facilities' "experience may generally be extrapolated to other settings"). CMS did this while acknowledging that "[a]ge remains a strong risk factor for severe COVID–19 outcomes," *id.* at 61,566, and that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person," *id.* at 61,610 n.247.

101. CMS acknowledged that psychiatric residential treatment facilities serve individual under 21 years of age, *see id.* at 61576, and that "rural and other community-care oriented health centers serve the full age spectrum and a lower fraction of severely health-impaired," *id.* at 61,612. Even though the individuals served by these facilities are generally at a low risk from COVID-19, the IFC imposed the same stringent vaccine mandate on psychiatric residential treatment facilities and rural health centers as it did on long-term-care facilities.

102. CMS applied its vaccine mandate to practically every full-time employee, part-time worker, trainee, student, volunteer, or contractor working at the covered facilities. The mandate requires vaccination for all "facility staff"—a term that includes employees, trainees, students, volunteers, or contractors—"who provide any care, treatment, or *other services* for the facility," "*regardless of . . . patient contact*." *Id.* at 61,570 (emphasis added). This includes "administrative staff" and "housekeeping and food services," to name a few. *Id.* CMS also imposed its mandate on "any individual that . . . has the *potential* to have contact with anyone at the site of care." *Id.* at 61,571 (emphasis added). This includes "staff that primarily provide services remotely via tele-work" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61, 570. Illustrating its breadth, the mandate also covers a contracted "crew

working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks[.]" *Id.* at 61,571.

103. Maximizing the scope of the mandate, CMS allowed exemptions only to the extent necessary to "comply with applicable Federal anti-discrimination laws and civil rights protections" such as medical exemptions required by the Americans with Disabilities Act ("ADA") and religious exemptions required by Title VII of the Civil Rights Act of 1964. *Id.* at 61,568.

104. The IFR became immediately effective on November 5, 2021—the day it was published. *Id.* at 61,555.

105. The IFR originally directed providers to ensure that employees submit to at least one vaccine dose by December 6, 2021, and that employees be fully vaccinated by January 4, 2022. *Id.* at 61,571. This Court issued a preliminary injunction enjoining the mandate on November 29, 2021. After the Supreme Court granted a stay of this Court's injunction on January 13, 2022, and allowed the IFR to take effect, *see Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam), CMS ordered that covered workers in the Plaintiff States must receive the first vaccine dose by February 14, 2022, and achieve full vaccination by March 15, 2022. CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022), https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf. CMS told covered facilities in the Plaintiff States that they would not face enforcement action until the middle of April 2022 so long as they maintain a certain percentage of compliance beginning February 14, 2022, and they have a plan to achieve full compliance by the middle of April 2022. *Id.*

106. CMS recognized the breadth of its vaccine mandate, acknowledging its "near-universal applicability" to health-care staff, and observing that under the rule "virtually all health

care staff in the U.S. will be vaccinated for COVD–19 within a matter of months." 86 Fed. Reg. at 61,573. CMS estimated that approximately 10.3 million employees will fall under the mandate. *Id.* at 61,603.

107. CMS settled on the draconian course of mandating vaccines because it determined that the "most important inducement [for vaccination] will be the fear of job loss." *Id.* at 61,607.

108. CMS "expect[s]" its vaccine mandate "to remain relevant for some time beyond the end" of the formal public health emergency and anticipates retaining the mandate "as a permanent requirement for facilities." *Id.* at 61,574.

The CMS Vaccine Mandate and Healthcare Worker Shortages

109. CMS admitted that "currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier[s]." 86 Fed. Reg. at 61,607. "1 in 5 hospitals," CMS noted, "report that they are currently experiencing a critical staffing shortage." *Id.* at 61,559. In addition, "approximately 23 percent of [long-term-care] facilities report[] a shortage in nursing aides; 21 percent report[] a shortage of nurses; and 10 to 12 percent report[] shortages in other clinical and non-clinical staff categories." *Id.* It is thus not surprising, CMS relayed, that "[o]ver half (58 percent) of nursing homes participating in a recent survey . . . indicated that they are limiting new admissions due to staffing shortages." *Id.*

110. In creating the rule, CMS was "aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated" and knew that "there might be a certain number of health care workers who choose to do so." *Id.* at 61,569. In fact, CMS reported that "a large long term care association" recently issued a policy statement observing that "some in the sector fear that a vaccine mandate could lead to worker resignations." *Id.* at 61,565-66. But CMS dismissed these concerns because "there is insufficient evidence to quantify" them. *Id.* at 61,569.

Instead, CMS optimistically believed, based only on a few anecdotes and without reliable data, that "the COVID-19 vaccine requirements . . . will result in *nearly all* health care workers being vaccinated." *Id.* (emphasis added); *see also id.* at 61,609 (finding that only a "relatively small fraction" of turnover "will be due to vaccination").

111. CMS repeatedly admitted that the current "endemic staff shortages . . . may be made worse if any substantial number of unvaccinated employees leave health care employment altogether." *Id.* at 61,607; *see also id.* at 61,608 ("[T]here may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients"); *id.* at 61,609 ("[I]t is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places.").

112. CMS also recognized that these staffing concerns apply even if providers do not lose a substantial number of employees. In fact, "[e]ven a small fraction" of what CMS called "recalcitrant unvaccinated employees" who decline to take a vaccine "could disrupt facility operations." *Id.* at 61,612.

113. CMS additionally recognized facts indicating that potential disaster awaits rural communities, including minority health-care workers in those communities. CMS acknowledged that "vaccination rates are disproportionately low among nurses and health care aides" in rural locations and other "communities that experience social risk factors." *Id.* at 61,566. And it admitted that "early indications are that rural hospitals are having greater problems with employee vaccination . . . than urban hospitals." *Id.* at 61,613. In addition, CMS observed that "nurses and aides in these [rural and other underprivileged] settings are more likely to be members of racial

and ethnic minority communities." *Id.* at 61,566. This means minority workers in rural communities are among the most likely groups to lose their jobs under the mandate.

114. CMS nonetheless dismissed these workforce concerns because it thought that the unvaccinated employees would get jobs in other healthcare positions, such as "physician and dental offices," that are not covered by the CMS vaccine mandate. *Id.* at 61,607. Yet this speculation does nothing to abate the debilitating losses threated to the healthcare facilities falling under this mandate. It does not suggest that the healthcare worker shortage will disappear but only that shortages will be further concentrated among the healthcare facilities covered by the CMS mandate—including institutions in the Plaintiff States and run by the Plaintiff States.

115. CMS also said that staffing deficiencies at facilities covered by the mandate "might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated and hence provide some risk[] to those who have completed the primary vaccination series for COVID–19." *Id.* at 61,607. This was pure speculation. CMS cited no evidence that such vaccinated workers exist. In any event, a worker who harbored such fears would still have to regularly work with unvaccinated *patients*, and it is irrational to assume that they would be willing to work with unvaccinated patients but not unvaccinated co-workers.

116. CMS additionally dismissed workforce shortage concerns by assuming "a dynamic labor market" where "net employment opportunities . . . do not change." *Id.* at 61,608 (finding "no reason to believe" that "net employment opportunities" will "change"). But an industry with admittedly "endemic staff shortages," *id.* at 61,607, is not a dynamic labor market. Net employment opportunities in the existing healthcare industry can and do change. Indeed, if the CMS vaccine mandate drives out enough employees from particular facilities, those facilities

might be forced to close certain divisions, cancel certain services, or shutter altogether—any of which would decrease net employment opportunities.

117. If CMS is wrong in its optimism that "nearly all health care workers" will submit to the mandate, the results will be disastrous. *Id.* at 61,569. CMS itself concluded that approximately 2.4 million healthcare workers will get vaccinated under this IFR in the first year. *Id.* at 61,603. If even 10 percent of those workers decline vaccination, the healthcare industry will lose over 200,000 employees, dealing a devastating blow to an already struggling industry. *See id.* at 61,607.

118. Further confirming that this vaccine mandate threatens grave staffing concerns, CMS observed that many healthcare workers decline other vaccines. It did so by noting that "studies on annual seasonal influenza vaccine uptake consistently show that half of health care workers may resist seasonal influenza vaccination nationwide." *Id.* at 61,568.

119. Despite the very real concerns about the vaccine mandate pushing many healthcare workers out of their jobs, CMS remarkably concluded that existing staffing shortages are actually *a reason to impose the mandate*. In CMS's words, "the urgent need to address COVID-related staffing shortages that are disrupting patient access to care[] provides strong justification as to the need to issue this" mandate. *Id.* at 61,567. Because "unvaccinated staff" are "at greater risk for infection" and "absenteeism," CMS elaborated, allowing providers to continue hiring them might "create staffing shortages." *Id.* at 61,559. But this speculation ignores the obvious fact that maintaining a larger pool of potential workers, even if some might have a bout with COVID-19, is better than categorically excluding a class of individuals.

120. CMS's speculation also appears to have ignored any chance that COVID-19 related absenteeism would decrease naturally. For example, people with immunity appear to have some

form of protection against COVID that reduced the severity and time of their illness. Alternatively, SARS-CoV-2 could mutate and cause less severe illness, thus reducing or eliminating the need for long absenteeism due to infection or exposure. Indeed, that is what happened. On December 27, 2021, the CDC shortened "the recommended time for isolation" for people with COVID who were asymptomatic or unvaccinated people exposed to the disease. CDC, *CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population* (Dec. 27, 2021), https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html.

The CMS Vaccine Mandate's Contradictions, Concessions, and Omissions

121. CMS "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination. 86 Fed. Reg. at 61,614. But it chose the vaccine mandate for one reason: because it believes that "vaccination is a more effective infection control measure." *Id.* In so doing, CMS failed to discuss how other countervailing considerations—such as workforce shortages and personal liberty considerations—factored into the rejection of the periodic testing option. Nor did CMS acknowledge the disparity between its rejection of testing and OSHA's Emergency Temporary Standard ("ETS"), *see* COVID–19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021), which allowed regular testing as an adequate alternative.

122. CMS "considered whether it would be appropriate to limit COVID-19 vaccination requirements to staff who have not previously been infected by SARS-CoV-2." 86 Fed. Reg. at 61,614. Yet it decided against that option because it did not think that "infection-induced immunity, also called 'natural immunity,'" is "equivalent to receiving the COVID-19 vaccine." *Id.* at 61,559. But elsewhere, CMS recognized the value of natural immunity when it stated that each day 100,000 people are "recover[ing] from infection," that they "are *no longer sources of*

future infections," and that their natural immunity "reduce[s] the risk to both health care staff and patients substantially." *Id.* at 61,604 (emphasis added).

123. CMS ignored key evidence indicating that natural immunity effectively guards against the Delta variant. A large study of individuals in Israel compared vaccine-mediated immunity to natural immunity and concluded that "[n]aturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 2-dose vaccine-[induced] immunity." Sivan Gazit et al., *Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity Verses Vaccine-Induced Immunity, Reinfections Versus Breakthrough Infections: A Retrospective Cohort Study*, 75 Clinical Infectious Disease 545, 545 (2022).

124. CMS repeatedly said, much like President Biden had in his September 9 speech, that the currently authorized COVID-19 vaccines are "highly effective at protecting vaccinated people against symptomatic and severe COVID-19." 86 Fed. Reg. at 61,560.

125. CMS also recognized that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." *Id.* at 61,615.

126. CMS's various directives sent conflicting messages on "booster" or additional doses. On the one hand, CMS said that its mandate does not require "booster doses" or additional doses of the vaccine. 86 Fed. Reg. at 61,563. But on the other hand, CMS included a "booster" shot in its cost calculations, *id.* at 61,608, and acknowledged that "[s]ome in the scientific community believe that 'booster' vaccinations after 6 or 8 months would be desirable to maintain a high level of protection against the predominant Delta version of the virus," *id.* at 61,609.

127. CMS recognized that vaccines, like all other medical interventions, are not without risks. "Serious adverse reactions also have been reported following COVID–19 vaccines," even

though "they are rare." *Id.* at 61,565. The adverse reactions include "anaphylaxis," "thrombosis," and "myocarditis and/or pericarditis," to name a few. *Id.*

128. CMS never considered other important aspects of imposing its mandate. Among those are the interests of healthcare workers who—for any number of varying personal reasons—do not want to take one of the currently authorized vaccines.

129. Upon information and belief, some religious healthcare institutions received Medicare and Medicaid funding and will be subject to the CMS vaccine mandate. The mandate will thus require those religious institutions to terminate ministerial employees in violation of the First Amendment. *Our Lady of Guadalupe Sch. v. Morrissey-Berru*, 140 S. Ct. 2049, 2061 (2020). But CMS never considered this problem when imposing its mandate.

130. Upon information and belief, CMS did not consider the cost to healthcare institutions of determining whether an employee is entitled to an exemption.

131. Upon information and belief, CMS failed to consider the possibility that events would develop that would render a vaccine mandate unnecessary on the agency's own terms. For example, CMS appears to have failed to consider the possibility that the pandemic would progress in such a way as to render absenteeism less of a problem or that mutations would result in variants that render COVID-19 less dangerous and so decrease absenteeism.

132. Upon information and belief, CMS failed to consider the fact that vaccine immunity wanes or the extent to which it wanes.

133. Upon information and belief, CMS failed to consider evidence showing that the vaccines do not prevent transmission. That seems to be the import of CMS's statement that "the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the

risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known." 86 Fed. Reg. at 61,615.

134. Upon information and belief, that statement is misleading because it conceals the fact that the evidence the vaccines prevent transmission was incredibly tenuous. For example, "[a] senior Pfizer executive has admitted that the drug company did not know whether its Covid vaccine prevented transmission of the virus when it began rolling out the shots globally." Frank Chung, *Pfizer Did Not Know Whether COVID Vaccine Stopped Transmission Before Rollout, Executive Admits*, News.Com.Au (Oct. 13, 2022), https://www.news.com.au/technology/science/human-body/pfizer-did-not-know-whether-covid-vaccine-stopped-transmission-before-rollout-executive-admits/news-story/f307f28f794e173ac017a62784fec414.

135. Statements by federal officials around the time CMS published the IFR also admit that the COVID vaccines do not prevent transmission. In a CNN interview, for example, Dr. Fauci said that vaccinated individuals could catch COVID-19 "because no vaccine is 100% effective." Jacqueline Howard & Dakin, *Fully Vaccinated Family Members Can Celebrate the Holidays Without Masks, Fauci Says*, CNN (Nov. 21, 2021), https://www.cnn.com/2021/11/21/health/fauci-covid-thanksgiving-vaccines-boosters/index.html. Another report says that Dr. Fauci made a similar claim on November 19, 2022, to argue that individuals should receive booster shots. *See* Vivian Lam, *No, Fauci did not admit that COVID-19 vaccines aren't working*, PolitiFact (Nov. 23, 2021), https://www.politifact.com/factchecks/2021/nov/23/alex-jones/no-fauci-did-not-admit-covid-19-vaccines-arent-wor/. The hedging, as well as the use of the fact that protection against infection is limited to promote boosters, suggests that the administration altered its position on vaccine efficacy based on the policy it was advancing.

136. Those statements also suggest that IFR is ill-suited to accomplish a "reduction in the transmission of SARS-CoV-2 . . . ." 86 Fed. Reg. at 61,560.

137. It thus appears that CMS's claim that it is "not currently known" how effective the vaccines would be at preventing transmission, 86 Fed. Reg. at 61,615, is meant to conceal the fact that the evidence before the agency suggested that vaccines do not prevent transmission and infection.

138. Those failures to consider pertinent information, and CMS's refusal to acknowledge facts that undermine any justification for the mandate, show that the agency was bound and determined to impose the mandate as directed by President Biden and failed to engage in reasonable decisionmaking.

The CMS Vaccine Mandate's Unprecedented Intrusion on States' Police Powers

139. CMS repeatedly recognized that the vaccine mandate is unprecedented because CMS has never before mandated any vaccination. *See, e.g.*, 86 Fed. Reg. at 61,567 ("We have not previously required any vaccinations"); *id.* at 61,568 ("[W]e have not, until now, required any health care staff vaccinations"); *id.* ("We acknowledge that we have not previously imposed such requirements").

140. CMS made clear that the vaccine mandate is an attempt to nationalize the COVID-19 vaccination response. For example, it explained that "the inconsistent web of State, local, and employer COVID–19 vaccination requirements have established a pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds." *Id.* at 61,584.

141. CMS made clear that it intends for the vaccine mandate to preempt any arguably inconsistent state and local laws. *See, e.g.*, *id.* at 61,568 ("We intend . . . that this nationwide

regulation preempts inconsistent State and local laws"); *id.* at 61,572 ("[T]his IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC"); *id.* at 61,613 ("This rule would pre-empt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID–19.").

142. The CMS vaccine mandate requires certain state-run healthcare facilities that receive Medicare or Medicaid funding to force their state employees to get vaccinated. *Id.* at 61,613 ("[T]o the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them).").

143. The CMS vaccine mandate forces certain state-run healthcare facilities that receive Medicare or Medicaid funding to comply with overbearing, invasive, and unnecessary record-keeping obligations. Even for the rare healthcare staff who fall outside the IFR, the facility still must "identify and monitor these individuals" by "documenting and tracking [their] vaccination status." *Id.* at 61,571. To what end or purpose, CMS does not say. And though the mandate purports to require only initial vaccination and not booster shots, covered facilities must track and document the "vaccination status of any staff who have obtained any booster doses." *Id.* Again, CMS does not disclose the purpose of this seemingly arbitrary demand. In addition, "[v]accine exemption requests and outcomes must also be documented" and preserved. *Id.* at 61,572. This is so even though CMS has no interest in knowing whether healthcare facilities comply with the ADA or Title VII.

144. CMS announced that it will coopt state employees to enforce the vaccine mandate. As it explained, CMS "will advise and train State surveyors on how to assess compliance with the new requirements." *Id.* at 61,574. Those state employees will need to "review[] the entity's records of staff vaccinations" and "interview[] staff to verify their vaccination status." *Id.* The surveyors will also "cite providers and suppliers when noncompliance is identified." *Id.*

145. Non-compliant healthcare providers are "subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement)." *Id.* at 61,574.

146. It appears that a covered healthcare provider that flatly refuses to comply—or otherwise cooperate—with the vaccine mandate will face termination of its Medicare/Medicaid provider agreement. *Id.* at 61,574 (noting that the available "remedies" include "termination of the Medicare/Medicaid provider agreement"); Background Press Call on OSHA and CMS Rules for Vaccination in the Workplace (Nov. 4, 2021), The White House, https://www.whitehouse.gov/briefing-room/press-briefings/2021/11/04/background-press-call-on-osha-and-cms-rules-for-vaccination-in-the-workplace/ ("If a facility were not making steps to come into compliance, we have a range of remedies. . . . We could . . . certainly, as a last resort, terminate them from the Medicare and Medicaid programs.").

147. CMS recognized that governing statutes require HHS Secretary Becerra to "consult with appropriate State agencies" when determining the "conditions of participation by providers of services," 42 U.S.C. § 1395z, and that no such consultation occurred before the IFR issued, 86 Fed. Reg. at 61,567. Yet CMS claimed that it did not violate that statute because it "intend[s] to engage in consultations with appropriate State agencies . . . following the issuance of this rule,"

and it does not "understand the statute to impose a temporal requirement to do so in advance of the issuance of this rule." 86 Fed. Reg. at 61,567. To date, CMS has not consulted with the Plaintiff States regarding the vaccine mandate, nor has it consulted with the Plaintiff States about any of the subsequent binding guidance documents it has issued concerning that mandate.

148. On January 4, 2022, many of the Plaintiff States sent a comment letter to CMS explaining that the agency's reliance on the Delta variant to justify its actions is "already stale" in light of the Omicron variant. Even after receiving such notice, CMS still failed to consult with the Plaintiff States concerning the vaccine mandate.

149. On November 17, 2022, many of the Plaintiff States joined a petition asking CMS to repeal the vaccine mandate. Section 553(e) Petition for Rulemaking, Att'y Gen. Mont., to Secretary Becerra and Administrator Brooks-LaSure (Nov. 17, 2022), https://content.govdelivery.com/attachments/MTAG/2022/11/17/file_attachments/2332228/11.17.22%20CMS%20petition%20for%20rulemaking.pdf.

The CMS Vaccine Mandate's Failure to Comply with Notice and Comment Requirements

150. CMS recognized that the Administrative Procedure Act, 5 U.S.C. § 553, and the Social Security Act, 42 U.S.C. 1395hh(b)(1), ordinarily require notice and a comment period before a rule like this one takes effect. *See* 86 Fed. Reg. at 61,583. But CMS "believe[d] it would be impracticable and contrary to the public interest . . . to undertake normal notice and comment procedures." *Id.* at 61,586. It thus found "good cause to waive" those procedures. *Id.*

151. Trying to justify its good cause finding, CMS stated that "[t]he data showing the vital importance of vaccination" indicates that it "cannot delay taking this action." *Id.* at 61,583. But CMS did not reconcile that finding with its acknowledgement that "the effectiveness of the

vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known." *Id*. at 61,615. Nor did it address evidence showing that the vaccines do not, in fact, prevent transmission.

152. Central to CMS's "good cause" finding—and its justification for the broader mandate itself—was the public health threat posed by the Delta variant and the vaccines' alleged effectiveness against that variant. *See Biden*, 142 S. Ct. at 651 ("That good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season."). Consider the depth of CMS's reliance on the Delta variant (with emphases added):

> Emerging evidence also suggests that vaccinated people who become infected with the SARS-CoV-2 *Delta variant* have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk. 86 Fed. Reg. at 61,558.
>
> COVID-19 case rates among [healthcare] staff have also grown in tandem with broader national incidence trends since the emergence of the *Delta variant*. *Id.* at 61,559.
>
> Vaccination is thus a powerful tool for protecting health and safety of patients, and, with the emergence and spread of the highly transmissible *Delta variant*, it has been an increasingly critical one to address the extraordinary strain the COVID-19 pandemic continues to place on the U.S. health system. *Id.*
>
> While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, *the emergence of the Delta variant* reversed these trends. *Id.*
>
> In a recent study of reported COVID-19 cases, hospitalizations, and deaths in 13 U.S. jurisdictions that routinely link case surveillance and immunization registry data, CDC found that unvaccinated individuals accounted for over 85 percent of all hospitalizations in the period between June and July 2021, when *Delta* became the predominant circulating variant. *Id.*
>
> Moreover, available evidence suggests that *these vaccines offer protection against known variants, including the Delta variant* . . . , particularly against hospitalization and death. *Id.* at 61,565.
>
> [T]he COVID-19 pandemic presents a serious and continuing threat to the health and to the lives of staff of health care facilities and of consumers of these providers' and suppliers' services. This threat has grown to be particularly severe since the emergence of the *Delta variant*. *Id.* at 61,567.

> The 2021 outbreaks associated with the SARS-Cov-2 *Delta variant* have shown that current levels of COVID-19 vaccination coverage up until now have been inadequate to protect health care consumers and staff. *Id.* at 61,583.
>
> Over the first 6 months of 2021, COVID-19 cases, hospitalizations and deaths declined. *The emergence of the Delta variant* reversed these trends. *Id.*
>
> [A] combination of factors now have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response . . . . These include, but are not limited to, the following: Failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements; ongoing risk of new COVID-19 variants; potential harmful impact of unvaccinated healthcare workers on patents; continuing strain on the healthcare system, *particularly from Delta-variant-driven surging case counts* beginning in summer 2021; *demonstrated efficacy, safety and real-world effectiveness of available vaccines*; FDA's full licensure of the Pfizer-BioNTech's Comirnaty vaccine; our observations of the efficacy of COVID-19 vaccine mandates in other settings; and the calls from numerous stakeholders for Federal intervention. *Id.* at 61,584.
>
> COVID-19 case rates among [healthcare] staff have also grown in tandem with broader national incidence trends since the *Delta variant's* emergence. *Id.* at 61,585.
>
> *Vaccines continue to be effective in preventing COVID-19 associated with the now-dominant Delta variant*. *Id.*
>
> Emerging evidence also suggest that *vaccinated people who become infected with Delta* have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk. *Id.*
>
> *Given the emergency situation with respect to the Delta variant* detailed more fully above, the time did not permit usual consultation procedures with the States, and such consultation would therefore be impracticable. *Id.* at 61,613.

153. When CMS issued its vaccine mandate on November 5, 2021, the Delta variant was the prominent strain of the virus, accounting for approximately 98% to 99% of all reported cases in the United States. *See* CDC COVID Data Tracker, *Variant Proportions*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (updated Feb. 22, 2022, looking at data for the week ending November 20, 2021).

154. CMS also asserted that it must immediately implement the vaccine mandate because "the 2021–2022 influenza season" will soon begin. 86 Fed. Reg. at 61,584. CMS offered

this justification while simultaneously admitting that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted" and that "influenza activity during the 2020–2021 season was low throughout the U.S." *Id.*

155. In claiming that it must immediately implement the vaccine mandate, CMS ignored that it waited almost two months after President Biden's directive before it promulgated the IFR to the public.

156. In claiming that it must immediately implement the vaccine mandate, CMS ignored that it had waited nearly seven months after the date (May 1, 2021) that the Department of Health and Human Services directed COVID-19 vaccine providers to make the vaccine generally available. *See* Dep't Health & Human Servs., *Secretarial Directive on Eligibility to Receive COVID-19 Vaccines* (Mar. 17, 2021), https://www.hhs.gov/sites/default/files/secretarial-directive-eligibility-for-covid-19-vaccines.pdf.

157. In claiming that it must immediately implement the vaccine mandate, CMS ignored that it waited nearly a year after the Pfizer and Moderna vaccines received their EUA and deliveries of the vaccine began. *See* Dep't of Health & Human Servs., *COVID-19 Vaccines* (last updated Oct. 24, 2022), https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html.

CMS's Cited Statutory Authority for the Vaccine Mandate

158. CMS's alleged statutory authority for its vaccine mandate rests on two sets of laws. *Id.* at 61,567. First, it relies on two statutes that grant general rulemaking power to HHS. *Id.* Second, it relies on more specific statutes that purportedly give it authority to apply the vaccine mandate to the specific covered classes of healthcare facilities. *Id.*

159. The two statutes that grant general rulemaking power to HHS are in the Social Security Act. The first—42 U.S.C. § 1302(a)—provides that "the Secretary of Health and Human

Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act." The second—42 U.S.C. § 1395hh(a)(1)—states that the "Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" Title 18 of the Social Security Act (Medicaid). These statutes do not establish that the Secretary may mandate vaccines.

160. CMS cites one specific statute to support its inclusion of Psychiatric Residential Treatment Facilities ("PRTFs") in the vaccine mandate. That statute—42 U.S.C. § 1396d(h)(1)(B)(i)—defines the term "inpatient psychiatric hospital services for individuals under age 21" to "include[] only . . . inpatient services which . . . involve active treatment which meets such standards as may be prescribed in regulations by the Secretary." This statute implies that the Secretary may create regulations setting "standards" for the "active treatment" of individuals under age 21 needing inpatient psychiatric services. But this statute does not establish that the Secretary may impose mandatory vaccines on the staff at PRTFs.

161. CMS cites one specific statute to support its inclusion of Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICFs-IID") in the vaccine mandate. That statute—42 U.S.C. § 1396d(d)(1)—defines those facilities to mean an institution whose "primary purpose . . . is to provide health or rehabilitative services for [intellectually disabled] individuals" if "the institution meets such standards as may be prescribed by the Secretary." This statute implies that the Secretary may create standards concerning the kinds of "health or rehabilitative services" the facility provides. But this statute does not establish that the Secretary may impose mandatory vaccines on the staff at ICFs-IID.

162. CMS cites one specific statute to support its inclusion of Critical Access Hospitals ("CAHs") in the vaccine mandate. That statute—42 U.S.C. § 1395i–4(e)—says that "[t]he Secretary shall certify a facility as a critical access hospital if the facility—(1) is located in a State that has established a medicare rural hospital flexibility program . . . ; (2) is designated as a critical access hospital by the State in which it is located; and (3) meets such other criteria as the Secretary may require." This statute implies that the Secretary may create "other criteria" similar to the two expressly listed requirements. But this statute does not establish that the Secretary may impose mandatory vaccines on the staff at CAHs.

163. CMS cites one specific statute to support its inclusion of End-Stage Renal Disease ("ESRD") facilities in the vaccine mandate. That statute—42 U.S.C. § 1395rr(b)(1)(A)—authorizes payments for end-stage renal disease services to "providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies . . . , transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode . . . ." This statute acknowledges that the Secretary may create "requirements" for "institutional dialysis services," "transplantation services," and the like. But this statute does not establish that the Secretary may impose mandatory vaccines on the staff at ESRD facilities.

164. CMS cites a few specific statutes to support its inclusion of Ambulatory Surgical Centers ("ASCs") in the vaccine mandate. The main statute that CMS cites—42 U.S.C. § 1395k(a)(2)(F)(i)—provides that Medicaid benefits shall include payments for "services furnished in connection with surgical procedures specified by the Secretary . . . performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the

Secretary in regulations)." Though this statute implies that the Secretary may create regulations setting "health, safety, and other standards," it does not establish that the Secretary's regulatory power is so broad that he may mandate vaccines.

165. CMS cites two specific statutes to support its inclusion of Programs of All-Inclusive Care for the Elderly ("PACE") facilities in the vaccine mandate. The first—42 U.S.C. § 1395eee(f)—provides that "[t]he Secretary shall issue interim final or final regulations to carry out this section," and that "[n]othing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program." The second—42 U.S.C. § 1396u–4(f)—is materially indistinguishable in its relevant language. Though these statutes authorize the Secretary to adopt some health- and safety-related regulations, they do not establish that the Secretary's regulatory power is so broad that he may mandate vaccines.

166. CMS cites a few specific statutes to support its inclusion of Rural Health Clinics ("RHCs") in the vaccine mandate. The primary statute that CMS cites—42 U.S.C. § 1395x(aa)(2)(K)—defines the term "rural health clinic" to "mean[] a facility which," among certain qualifying factors, "meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic." The expressly listed qualifying factors include the types of services provided, staff qualifications, medication requirements, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

167. CMS cites one specific statute to support its inclusion of Home Infusion Therapy ("HIT") Suppliers in the vaccine mandate. That statute—42 U.S.C. § 1395x(iii)(3)(D)(i)(IV)—defines the term "qualified home infusion therapy supplier" to "mean[] a pharmacy, physician, or

other provider of services or supplier" that, among certain qualifying factors, "meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector." The expressly listed qualifying factors include the types of services provided and staff qualifications. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

168. CMS cites one specific statute to support its inclusion of facilities that provide outpatient physical therapy and speech-language pathology services in the vaccine mandate. That statute—42 U.S.C. § 1395x(p)(4)(A)(v)—defines "outpatient physical therapy services" to exclude services "furnished by a clinic or rehabilitation agency" that does not, among certain qualifying factors, "meet[] such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

169. CMS cites a few specific statutes to support its inclusion of Community Mental Health Centers ("CMHCs") in the vaccine mandate. The primary statute that CMS cites—42 U.S.C. § 1395x(ff)(3)(B)—defines a "community mental health center" to "mean[] an entity that," among certain qualifying factors, "meets such additional conditions as the Secretary shall specify to ensure . . . the health and safety of individuals being furnished such services." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

170. CMS cites one specific statute to support its inclusion of hospitals in the vaccine mandate. That statute—42 U.S.C. § 1395x(e)(9)—defines the term "hospital" to "mean[] an institution which," among certain qualifying factors, "meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

171. CMS cites one specific statute to support its inclusion of hospices in the vaccine mandate. That statute—42 U.S.C. § 1395x(dd)(2)(G)—says that "[t]he term 'hospice program' means a public agency or private organization (or a subdivision thereof) which," among certain qualifying factors, "meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

172. CMS cites one specific statute to support its inclusion of Comprehensive Outpatient Rehabilitation Facilities (CORFs) in the vaccine mandate. That statute—42 U.S.C. § 1395x(cc)(2)(J)—provides that "[t]he term 'comprehensive outpatient rehabilitation facility' means a facility which," among certain qualifying factors, "meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities." The expressly listed qualifying factors include the

types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

173. CMS cites two specific statutes to support its inclusion of long-term-care ("LTC") facilities in the vaccine mandate. The first—42 U.S.C. § 1395i–3(d)(4)(B)—states that "[a] skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." The second—42 U.S.C. § 1396r(d)(4)(B)—likewise provides that "[a] nursing facility must meet such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." The expressly listed qualifying factors include the types of services provided, staff qualifications, licensing requirements, sanitation issues, and administrative matters. They do not include vaccination. These statutes thus do not give the Secretary the power to mandate vaccines.

174. CMS cites a few specific statutes to support its inclusion of Home Health Agencies ("HHAs") in the vaccine mandate. The first—42 U.S.C. § 1395x(o)(6)—defines a "home health agency" to "mean[] a public agency or private organization, or a subdivision of such an agency or organization, which," among certain qualifying factors that do not include vaccination requirements, "meets the conditions of participation specified in [42 U.S.C. § 1395bbb(a)] and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization." The second—42 U.S.C. § 1395bbb—outlines various "conditions of participation that a home health agency is required to meet," none of which include vaccination requirements. *See* 42 U.S.C. § 1395bbb(a). That statute also says that "[i]t is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to [42 U.S.C.

§ 1395x(o)] and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency." 42 U.S.C. § 1395bbb(b). While these statutes give the Secretary authority to protect the health and safety of people served by HHAs, they do not give the Secretary the power to mandate vaccines.

The CMS Vaccine Mandate Entirely Failed to Account for Important Known Contingencies that Have Rendered the Mandate Irrational

175. When CMS issued the mandate, the agency knew that new SARS-CoV-2 variants would continue to arise. *See*, *e.g.*, 86 Fed. Reg. at 61,583 (discussing "the advent of the Delta variant and the potential for new variants"); *id* at 61,584 (recognizing the "ongoing risk of new COVID-19 variants"). Specifically, CMS knew that "Delta may be overtaken by other virus mutations." *Id.* at 61,609.

176. When CMS issued the mandate, the agency knew that new SARS-CoV-2 variants could change the trajectory of the pandemic or the risk of the virus and thereby undermine the mandate's rationale. *See, e.g.*, *id.* at 61,559 ("While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the Delta variant reversed these trends."); *id.* at 61,583 ("Over the first 6 months of 2021, COVID-19 cases, hospitalizations and deaths declined. The emergence of the Delta variant reversed these trends."); *id.* at 61,610 n.248 (noting that "another variant of the [virus] might arise and create new risks or shifts in risks within the U.S.").

177. When CMS issued the mandate, the agency knew that the COVID-19 vaccines are less effective against certain variants. For example, CMS recognized that the available vaccines had shown to be less effectiveness against the Delta variant than against the original variants. *See, e.g.*, *id.* at 61,565 (acknowledging that one of CMS's relied-upon studies shows that "vaccine

effectiveness point estimates did decline over the course of the study as the Delta variant became predominant").

178. When CMS issued the mandate, the agency knew about "the possibility of new virus variants that reduce the effectiveness of currently authorized and approved vaccines." *Id.* at 61,602.

179. Despite knowing all this, CMS adopted a rigid one-size-fits-all rule that did not account for the advent of a new dominant variant against which the vaccines are ineffective at stopping transmission.

180. The Delta variant has effectively disappeared in the United States, and it has been replaced by the milder Omicron variant, which now accounts for 100% of COVID-19 cases in the country. CDC COVID Data Tracker, *Variant Proportions*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (updated Feb. 22, 2022).

181. The Omicron variant was first detected in the United States on December 1, 2021, after adoption of the CMS vaccine mandate. CDC, *Omicron Variant: What You Need to Know*, https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html (updated Feb. 2, 2022).

182. Omicron presents a greatly reduced risk of severe health outcomes compared to Delta. *Id.* ("Omicron infection generally causes less severe disease than infection with prior variants."); A. Danielle Iuliano, *Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous Sars-CoV-2 High Transmission Periods — United States, December 2020 – January 2022*, CDC Morbidity and Mortality Weekly Report (Jan. 28, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e4.htm?s_cid=mm7104e4_w ("[D]isease severity indicators, including length of stay, ICU admission, and death,

were lower [with Omicron] than during previous pandemic peaks"); Aziz Sheikh et al., *Severity of Omicron variant of concern and vaccine effectiveness against symptomatic disease: national cohort with nested test negative design study in Scotland*, The University of Edinburgh (Dec. 22, 2021), https://www.research.ed.ac.uk/en/publications/severity-of-omicron-variant-of-concern-and-vaccine-effectiveness- (Scotland's data revealed that "Omicron is associated with a two-thirds reduction in the risk of COVID-19 hospitalisation when compared to Delta.").

183. CDC Director Rochelle Walensky has acknowledged that the Omicron variant is far less severe than Delta. *CDC's Walensky cites study showing Omicron has 91% lower risk of death than Delta*, Yahoo News (Jan. 12, 2022), https://news.yahoo.com/cdc-walensky-cites-study-showing-173151295.html?guccounter=1 ("[W]e are seeing early evidence that [O]micron is less severe than [D]elta and that those infected are less likely to require hospitalization").

184. National Institute of Allergy and Infectious Diseases ("NIAID") Director Dr. Anthony Fauci has recognized the greatly reduced risk of severe health outcomes with Omicron: "In the United States, we are getting accumulation of data. The spike in cases is out of proportion to the increase in hospitalization. So, if one looks at 14-day averages, the data, as of last night, indicate a plus 126 percent increase in cases [but only] an 11 percent increase in hospitalizations. Now, we must remember that hospitalizations and deaths are lagging indicators. However, the pattern and disparity between cases and hospitalization strongly suggest that there will be a lower hospitalization-to-case ratio when the situation becomes more clear." Press Briefing by White House COVID-19 Response Team and Public Health Officials, The White House (Dec. 29, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/12/29/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-76/.

185. The available COVID-19 vaccines are ineffective in preventing transmission of the Omicron variant. Indeed, research shows that the standard COVID-19 vaccines without boosters provide practically no protection against transmission of the Omicron variant. *No Omicron immunity without booster, study finds*, The Harvard Gazette (Jan. 7, 2022), https://news.harvard.edu/gazette/story/2022/01/no-omicron-immunity-without-booster-study-finds/ ("[T]raditional dosing regimens of COVID-19 vaccines available in the United States do not produce antibodies capable of recognizing and neutralizing the Omicron variant.").

186. The CDC acknowledges that "anyone with Omicron infection can spread the virus to others, even if they are vaccinated." CDC, *Omicron Variant: What You Need to Know*, *supra*. The CDC also recognizes that "breakthrough infections in people who are vaccinated are likely to occur" with Omicron. *Id.*

187. The CDC's initial data on the Omicron variant demonstrated that the existing vaccines are not effective at preventing transmission. Mrinalika Roy, *Most reported U.S. Omicron cases have hit the fully vaccinated – CDC*, Reuters (Dec. 10, 2021), https://www.reuters.com/world/us/most-reported-us-omicron-cases-have-hit-fully-vaccinated-cdc-2021-12-10/ ("[CDC] said that of the 43 [initial] cases attributed to Omicron variant, 34 people had been fully vaccinated.").

188. Pfizer and BioNTech, the manufacturers of the leading COVID-19 vaccine in the United States, have admitted that their two-dose vaccine "may not be sufficient to protect against infection with the Omicron variant." *Pfizer and BioNTeach Provide Update on Omicron Variant*, Pfizer Press Release (Dec. 8, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant.

189. Moderna, the manufacturer of the second leading COVID-19 vaccine in the United States, has similarly admitted that people who have received its two-dose vaccine "had low neutralizing antibody levels in the Omicron [pseudovirus neutralization titer] assay prior to boosting." *Moderna Announces Preliminary Booster Data and Updates Strategy to Address Omicron Variant*, Moderna (Dec. 20, 2021), https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Preliminary-Booster-Data-and-Updates-Strategy-to-Address-Omicron-Variant/default.aspx.

190. NIH-funded researchers at Duke University confirmed that "neutralizing titers to Omicron are 49-84 times lower than neutralization titers to [prior SARS-CoV2 variants] after 2 doses of [the Moderna vaccine], which could lead to an increased risk of symptomatic breakthrough infections." Nicole A. Doria-Rose et al., *Booster of mRNA-1273 Vaccine Reduces SARS-CoV-2 Omicron Escape from Neutralizing Antibodies*, medRxiv (Dec. 20, 2021), https://www.medrxiv.org/content/10.1101/2021.12.15.21267805v2.

191. While Omicron caused a spike in COVID-19 cases in the United States throughout December and January, case counts have fallen precipitously. CDC, *Trends in Number of Covid-19 Cases and Deaths in the US Reported to CDC, by State/Territory*, https://covid.cdc.gov/covid-data-tracker/#trends_dailycases. The CDC reports that daily COVID-19 cases in the United States reached their peak at 1,335,999 cases on January 10, 2022. *Id.* (reviewing data available on February 23, 2022). But that number plummeted to 90,265 by February 6, 2022, and 26,104 by February 20, 2022. *Id.* (reviewing the data available on February 23, 2022).

192. Given CMS's failure to consider evidence that vaccines do not prevent transmission, which includes failing to consider how changes to the SARS-CoV-2 virus may affect vaccine efficacy, the agency's failure to consider the possibility that a variant like Omicron would

arise is more evidence of the arbitrariness of the agency's actions and the pretextual nature of its provided explanation.

Additional Facts Demonstrating that the Mandate Imposes Great Burdens

193. Recent events have proven that healthcare worker crisis is getting worse and that the CMS vaccine mandate is imposing onerous and unnecessary burdens on the Plaintiff States and healthcare providers.

194. While the CMS mandate was preliminarily enjoined, several of the nation's largest healthcare providers that had previously implemented a vaccine mandate suspended the requirement because it exacerbated existing labor shortages. Robbie Whelan & Melanie Evans, *Some Hospitals Drop Covid-19 Vaccine Mandates to Ease Labor Shortages*, Wall St. J. (Dec. 13, 2021), https://on.wsj.com/3ojiwW8.

195. Multiple governors have requested that CMS grant them broader exemptions from the CMS vaccine mandate because of the acute labor shortages in rural areas. John Raby & Sarah Rankin, *Youngkin, Justice Seek Relief From Health Worker Vax Rule*, U.S. News and World Report (Jan. 21, 2022), https://www.usnews.com/news/best-states/west-virginia/articles/2022-01-31/w-va-seeks-covid-shot-waiver-for-rural-hospital-workers.

196. The CDC has recognized severe staffing shortages by issuing new guidance that permits COVID-19-*positive* employees to return to work even if they are still testing positive, while the CMS vaccine mandate prohibits COVID-19-*negative* unvaccinated employees from working in covered facilities at all unless they obtain a medical or religious exemption. CDC, *Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2* (Jan. 21, 2022), https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.

197. States that have previously implemented a vaccine mandate for healthcare workers have experienced adverse consequences. For instance, since New York's mandate on healthcare workers took effect in October 2021, "*31,858 health care workers* at nursing homes, hospitals and other health providers have been terminated, furloughed or forced to resign because they would not comply with the mandate." Emma Colton, *Termination of unvaccinated health care workers backfires as Biden pledges help amid COVID surge*, Fox News (Dec. 28, 2021), https://www.foxnews.com/us/terminated-health-care-workers-joe-biden-vaccine-mandates-national-guard (emphasis added). Not surprisingly, New York's vaccine mandate for healthcare workers resulted in a reduction in healthcare services in the State. *See, e.g.*, *Long Island hospital temporarily closing ER*, ABC 7 New York (Nov. 22, 2021), https://www.msn.com/en-us/health/medical/long-island-hospital-temporarily-closing-er-due-to-nursing-staff-shortages-amid-vaccine-mandate/ar-AAR0C5t ("The emergency department at a Nassau County hospital has temporarily closed due to nursing staff shortages as a result of New York's vaccine mandate.").

198. After CMS issued its vaccine mandate, the Missouri Department of Health and Senior Services ("DHSS") issued an emergency amendment to Mo. Code Regs. Ann. tit. 19, § 30-82.010 (filed November 10, 2021, and published in the Missouri Register on December 15, 2021). *See* 46 Mo. Reg. 2,323, 2,323–24 (Dec. 15, 2021). According to DHSS, approximately 44% of staff working at Missouri's long-term-care facilities are not fully vaccinated. *Id.* at 2,323. DHSS anticipates that "many of the [44%] of unvaccinated staff working at these long term facilities will not choose to get vaccinated, even with this vaccine mandate from CMS." *Id.* DHSS thus predicts that because of the CMS vaccine mandate, some long-term-care facilities—namely, skilled nursing facilities and intermediate care facilities—"will not have enough staff to care for the residents in their facilities and be in compliance with federal and state law." *Id.* The emergency amendment

thus creates a temporary closure procedure for facilities should they need to "make plans to begin discharging residents and pursing temporary closures before" CMS's deadlines. *Id.* The temporary closure option enables the facilities to keep their license so that there will not be unnecessary licensure delays if they are able to reopen in the future.

199. Since CMS announced on January 14, 2022, that the deadline for the first vaccine doses in the Plaintiff States would be February 14, 2022, DHSS has received closure plans from three facilities in Missouri. One of those facilities has already closed, and its residents have been displaced.

200. In addition, the State of Nebraska received notice on January 13, 2022—the day of the Supreme Court's ruling—that a skilled nursing facility in rural Hooper, Nebraska will be closing in March 2022 because of staffing issues. And Nebraska received notice on February 22, 2022, that another nursing facility in Mullen, Nebraska will be closing in April 2022 because of the increasing challenges of operating a nursing facility in a small rural area.

201. When discussing the CMS mandate, Jalene Carpenter, president and CEO of the Nebraska Health Care Association, recently said: "We are at a tipping point in the [healthcare staffing] crisis [so] that every team member, literally every single one, is crucial. . . . And any loss of any team member can be devastating." Julie Anderson, *Nebraska hospitals, nursing homes prepare to meet vaccine mandate*, Omaha World-Herald (Feb. 5, 2022), https://omaha.com/lifestyles/health-med-fit/nebraska-hospitals-nursing-homes-prepare-to-meet-vaccine-mandate/article_b593321e-8449-11ec-a389-771fd79afeee.html.

202. The CMS vaccine mandate is making it particularly difficult for healthcare providers in the Plaintiff States to keep adequate staff in nonmedical positions such as housekeeping, cleaning, information technology, accounting, and kitchen staff. Those nonmedical employees

can move into countless other industries if they want to avoid the CMS vaccine mandate. Thus, healthcare facilities are struggling to keep adequate nonmedical staff to support their ongoing operations. The federal government's withdrawal of the OSHA ETS exacerbated this problem because businesses in many industries outside the healthcare field do not mandate COVID-19 vaccines.

203. The administrative burden that the CMS vaccine mandate imposes on healthcare providers is difficult to overstate. Troy Bruntz—the President and Chief Executive Officer of Community Hospital in rural McCook, Nebraska—"said he has roughly 30 people working on various aspects of complying with the mandate. 'I hate to say we don't have time for this right now,' he said, 'but we don't have time for this right now.'" *Id.*

204. Among those burdens is the need for covered healthcare providers to track not only their own staff's vaccination status but also the vaccination status of their contractors and vendors. Bruntz expressed concerns that the mandate "could make it difficult to hire contractors who can supply vaccinated workers to complete jobs." *Id.* This complicates not only large-scale construction jobs and smaller renovations but also the most routine tasks, such as scheduling regular visits from the healthcare facility's copier repair vendor or water delivery service. This burden on the healthcare providers is exacerbated by the federal government's withdrawal of the OSHA ETS because many of the vendors for these healthcare facilities are not under a vaccine mandate. Worse yet, if healthcare facilities cannot hire a vendor, they need to bring those services in-house, which only compounds the nonmedical personnel hiring challenges discussed above.

205. Many of the 10,132 comments submitted in response to the IFR, which were due by January 4, 2022, highlight how difficult compliance is. Even comments supportive of the rule point out that compliance is extremely burdensome—if not impossible. *See, e.g.*, Letter of

Spectrum Health, https://www.regulations.gov/comment/CMS-2021-0168-1491 (requesting changes to the mandate on behalf of a large healthcare system that employs 31,000 people).

Other Core Circumstances Have Changed Since CMS Issued the Mandate

206. Recently released CDC data shows that "[b]y early October [2021], persons who survived a previous [COVID-19] infection" (and thus have natural immunity) "had lower case rates than persons who were vaccinated alone." Tomás M. León et al., *COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May – November 2021*, CDC Morbidity and Mortality Weekly Report (Jan. 28, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm. This directly undermines CDC's claim in the IFR that natural immunity is inferior to vaccine immunity.

207. Data published earlier this year also calls into question the effectiveness of the vaccines in preventing transmission of the Delta variant, particularly over time. *See*, *e.g.*, David W. Eyre, et al., *Effect of Covid-19 Vaccination on Transmission of Alpha and Delta Variants*, New Eng. J. Med. (Jan. 5, 2022) ("Vaccination was associated with a smaller reduction in transmission of the delta variant than of the alpha variant, and the effects of vaccination decreased over time."); *id.* ("[S]imilar viral loads in vaccinated and unvaccinated persons who are infected with the delta variant call into question the degree to which vaccination prevents transmission.").

208. The Omicron variant, as noted above, is less virulent and more transmissible, and escapes whatever protection the COVID vaccines provide against infection and transmission.

209. Finally, CMS's vaccine mandate was issued in conjunction with the OSHA and federal contractor mandate vaccines. Neither mandate is fully in force. As noted above, the OSHA mandate has been rescinded in full, and the contractor mandate has been enjoined in a number of

States, including in many of the Plaintiff States, *see Missouri v. Biden*, 576 F. Supp. 3d 622, 635 (E.D. Mo. 2021), *appeal docketed*.

The Federal Government's Policy of Ignoring Evidence that Contradicts Its Preferred COVID Policy and Censoring Contrary Views

210. Over the last few months, the public has received information about a coordinated campaign in the federal government to censor what the government believes is "inaccurate information." Ken Klippenstein & Lee Fang, *Truth Cops*, The Intercept (Oct. 31, 2022), https://theintercept.com/2022/10/31/social-media-disinformation-dhs/ (quoting a draft copy of the Department of Homeland Security's Quadrennial Homeland Security Review).

211. That includes efforts to censor information that challenged the federal government's COVID response, including its vaccine policy. For example, a draft copy of the Department of Homeland Security's (DHS) Quadrennial Homeland Security Review said that DHS intended to target allegedly inaccurate information pertaining to "the efficacy of COVID-19 vaccines." *Id.*

212. HHS officials were involved in that effort.

213. For example, Dr. Francis Collins, Dr. Anthony Fauci, and Cliff Lane were involved in an attempt to censor the Great Barrington Declaration and the views of the Declaration's authors, a group of epidemiologists and public health scientists. *See* Exhibit A ¶¶13–14 (Declaration of Dr. Jayanta Bhattacharya, *Missouri ex rel. Schmitt v. Biden*, No. 3:22-cv-01213 (W.D. La. June 14, 2022), ECF 10-3); Exhibit B ¶¶12, 15, 30 (Declaration of Dr. Martin Kulldorff, *Missouri ex rel. Schmitt v. Biden*, No. 3:22-cv-01213 (W.D. La. June 14, 2022), ECF 10-4).

214. The Great Barrington Declaration was critical of the then-prevailing COVID-19 policies. *See The Great Barrington Declaration*, https://gbdeclaration.org/ (Oct. 4, 2020).

215. The district court for the Western District of Louisiana has permitted discovery into communications between certain HHS employees and Meta in *Missouri ex rel. Schmitt v. Biden* to determine if those employees were engaged in censoring information, including information pertaining to the federal government's COVID-19 response. Mem. Ruling & Order on Disc. Disputes, at 8–9 (W.D. La. Sept. 6, 2022), ECF No. 72.

216. CMS is a component of HHS. Given that, plus the wide-ranging—indeed government-wide—policy of promoting the federal government's views of COVID-19 *and* suppressing contrary views, it is logical to believe that CMS was involved in that effort, and that the CMS mandate and the agency's proffered reasoning was the product of that mentality.

217. That is, the evidence that federal government officials, including HHS officials, actively worked to suppress information that challenged the federal government's preferred COVID-19 policies suggests that CMS, a component of HHS, ignored evidence that would undermine the rationale for the CMS Mandate and that the rationale the agency did provide is pretextual. That explains why, as discussed above, CMS ignored or appears to have dismissed contrary evidence out of hand and gave undue, perhaps dispositive, consideration to the administration's desire to push a particular policy or narrative in issuing the IFR.

218. Finally, upon information and belief, CMS ignored the federal government's own pandemic response plans, which do not contemplate a federal vaccine mandate.

Legal Proceedings Concerning the CMS Vaccine Mandate

219. On November 29, 2021, this Court preliminarily enjoined the CMS vaccine mandate in the Plaintiff States.

220. On December 13, 2021, the Eighth Circuit denied Defendants' motion to stay the preliminary injunction pending appeal.

221. On January 13, 2022, the Supreme Court stayed the preliminary injunction pending disposition of Defendants' appeal. *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

222. One day after the Supreme Court entered its stay, CMS resumed enforcement of its vaccine mandate in the Plaintiff States, requiring healthcare workers to receive the first dose of a COVID-19 vaccine by February 14, 2022, and to be fully vaccinated by March 15, 2022. *See* CMS, *Guidance for the Interim Final Rule*, *supra*.

223. But despite the dire emergency that CMS asserted in claiming good cause to bypass notice and comment and in seeking an immediate stay from the Supreme Court, CMS delayed full enforcement of its vaccine mandate in the Plaintiff States until the middle of April 2022. *Id.* In particular, the agency told covered facilities in the Plaintiff States that they would not face enforcement action until the middle of April 2022 so long as they maintain a certain percentage of compliance beginning February 14, 2022, and they have a plan to achieve full compliance by the middle of April 2022. *Id.*

224. CMS has continued to issue guidance relating to enforcement. *See* CMS, Dep't of Health & Human Servs., QSO-23-02-ALL, *Revised Guidance for Staff Vaccination Requirements* 2 (2022), https://www.cms.gov/files/document/qs0-23-02-all.pdf.

The CMS Vaccine Mandate Harms the Plaintiff States and their Citizens

225. The CMS vaccine mandate directly injures the Plaintiff States.

226. The Plaintiff States are parties to Medicaid agreements with HHS. But the CMS vaccine mandate seeks to transform that agreement in drastic ways far beyond any terms that the States have accepted.

227. The Plaintiff States operate state-run healthcare facilities that receive Medicare and Medicaid funding. They are thus required to impose the mandate on their own state employees.

228. The Plaintiff States' surveyors are state employees who enforce Medicare and Medicaid compliance. The CMS vaccine mandate seeks to commandeer those state employees to become enforcers of CMS's unlawful attempt to federalize national vaccine policy and override the States' police power on matters of health and safety.

229. The CMS vaccine mandate imposes nonrecoverable compliance costs on the Plaintiff States and healthcare providers in those States.

230. By requiring state-run healthcare facilities and state surveyors to enforce the CMS vaccine mandate, the Plaintiff States will face increased enforcement costs because CMS guidance requires multiple additional surveys of facilities subject to the mandate and the States have an obligation to respond to complaints filed against facilities that appear to be noncompliant.

231. Surveying is already a costly and complicated endeavor, and it is made even more so by the CMS vaccine mandate and accompanying guidance.

232. By February 14, 2022, state surveyors had to ensure that facilities have vaccine policies in place, that 100% of employees have received at least the first dose of the vaccine or have been granted an exemption, and that facilities falling short of 100% compliance with that "first dose" requirement have plans to achieve that benchmark. CMS, *Guidance for the Interim Final Rule*, *supra*.

233. By March 15, 2022, states surveyors had to ensure that facilities have vaccine policies in place, that 100% of employees have received all doses of the vaccine or have been granted an exemption, and that facilities falling short of 100% compliance with that "all dose" requirement have plans to achieve that benchmark. *Id.*

234. By the middle of April 2022, states surveyors had to again survey the facilities to ensure that 100% of employees have received all doses of the vaccine or have been granted an exemption.

235. Not only does the vaccine mandate and its accompanying guidance force the Plaintiff States to increase the number of surveys they must conduct, it also complicates their existing surveying schedules and requires them to conduct statewide training to facilitate this new task.

236. On February 9, 2022, CMS issued a memorandum addressing States' "obligations to survey . . . the entirety of Medicare and Medicaid health and safety requirements." CMS, *State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement* (Feb. 9, 2022). That memorandum threatens to withhold money from States that do not survey compliance with all Medicare and Medicaid requirements: "[A] state that unilaterally acts to reduce or suspend survey and certification activities in a manner inconsistent with the Act, regulations[,] and Secretary's direction does not support their full budgetary Survey and Certification allocation." The "reduced" funding will apply "for the current fiscal year and each successive year until the state resumes full oversight of the entirety of Medicare and Medicaid regulations." That memorandum also threatens the Medicare and Medicaid certification of health-care providers in States with deficient surveying: "The Medicare and Medicaid certification of providers and suppliers in a State whose oversight process is substantially deficient may be jeopardized if CMS cannot ensure that the regulatory minimum health and safety standards have been met." The Plaintiff States and healthcare facilities in those States thus stand to lose funding if the States decline to survey for compliance with the vaccine mandate.

237. By requiring state-run healthcare facilities and state surveyors to enforce the CMS vaccine mandate, the mandate directly infringes the Plaintiff States' sovereign authority.

238. By requiring state-run healthcare facilities and state surveyors to enforce the CMS vaccine mandate, the mandate imposes non-recoverable compliance costs on Plaintiff States.

239. The Plaintiff States are injured because the CMS vaccine mandate purports to preempt their state and local laws on matters of vaccines and the rights of their citizens. This violates the Plaintiff States' sovereign right to enact and enforce their laws. It also violates the Plaintiff States' sovereign right to exercise their police power on matters such as compulsory vaccination.

240. For example, the CMS vaccine mandate purports to preempt Missouri's Exec. Order No. 21-10 § 3 (Oct. 28, 2021) (Gov. Parson), which prohibits state agencies from penalizing individuals or businesses for non-compliance with any federal COVID-19 vaccine mandate if the "non-compliance is the result of an individual's sincerely held religious belief or for medical reasons."

241. Similarly, the CMS vaccine mandate purports to preempt Arkansas statutes, including Ark. Code § 20-7-143, which prohibits public entities from requiring vaccines, and Ark. Code § 11-5-118, which requires private employers to give employees a testing option in lieu of vaccination.

242. The mandate similarly conflicts with the laws of the State of Alaska. Under the Alaska Constitution, the State cannot mandate vaccination without running afoul of Alaskans' fundamental privacy right to make decisions about medical treatment. An individual's freedom to make medical decisions for themselves and their children is a fundamental liberty and privacy right under Article I, Section 22 of the Alaska Constitution. *Huffman v. State*, 204 P.3d 339, 346

(Alaska 2009). In *Huffman*, the Alaska Supreme Court held that although the State had a compelling interest in preventing the spread of contagious diseases, it must use the least restrictive means to achieve that interest. *Id*. at 347. In 2021, the State of Alaska enacted a statute that grants its citizens the right to object to COVID-19 vaccines "based on religious, medical, *or other* grounds," and that forbids any person from "requir[ing] an individual to provide justification or documentation to support the individual's decision to decline a COVID-19 vaccine." 2021 Alaska Sess. Laws ch. 2, § 17 (emphasis added).

243. The Plaintiff States will suffer further pocketbook injuries. The CMS vaccine mandate requires covered healthcare facilities to maintain documentation of their staff's vaccination status. 86 Fed. Reg. at 61,572. That documentation can consist of records from the "State immunization information system." *Id.* A predictable consequence of the CMS vaccine mandate is thus to increase the number of people seeking documentation from the Plaintiff States regarding vaccination status. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019).

244. The Plaintiff States also will incur overtime costs and increased costs related to termination and reassignment of employees due to the CMS vaccine mandate. The States will likewise incur costs through their need to recruit new employees in an already tight labor market. These new personnel, either full-time or contact workers, will be more expensive to hire.

245. The Plaintiff States have quasi-sovereign and *parens patriae* interests in protecting the rights of their citizens and vindicating them in court. The Plaintiff States thus may sue to challenge unlawful actions that "affect the [States'] public at large." *In re Debs*, 158 U.S. 561, 584 (1895). This includes States taking steps to protect "the health and well-being—both physical and economic—of its residents in general." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982).

246. On information and belief, a natural and predictable consequence of the CMS vaccine mandate is that numerous state and private healthcare workers may be fired, retire, or quit their jobs. This injures the Plaintiff States' quasi-sovereign and *parens patriae* interest in the health and economic well-being of their citizens. This injury is especially acute because of the already critical healthcare workforce shortage that the Plaintiff States are experiencing.

247. The CMS vaccine mandate will harm the Plaintiff States and their citizens by impeding access to healthcare for the underprivileged and the elderly—a complete reversal of the core objectives of Medicare and Medicaid—and another injury to the Plaintiff States' quasi-sovereign and *parens patriae* interest in the health and economic well-being of their citizens.

248. An exodus of healthcare workers further injures the Plaintiff States in that it will likely increase the burden on the Plaintiff States' unemployment insurance funds.

249. The Plaintiff States are injured because the CMS vaccine mandate discriminates between citizens of the Plaintiff States who are vaccinated and those who are not by denying the latter employment opportunities available to the former. The States have quasi-sovereign and *parens patriae* interests in protecting their citizens from discriminatory policies. *See Alfred L. Snapp & Son*, 458 U.S. at 609 ("This Court has had too much experience with the political, social, and moral damage of discrimination not to recognize that a State has a substantial interest in assuring its residents that it will act to protect them from these evils.").

250. The CMS vaccine mandate violates the Constitution in multiple ways as explained below, and the violation of constitutional rights, "for even minimal periods of time, unquestionably constitutes irreparable injury." *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

251. Because, as explained below, the CMS vaccine mandate violates the requirements the Tenth Amendment and Spending Clause impose on federal spending legislation, it injures the States' constitutionally protected sovereign interests in ensuring that spending legislation meets certain criteria. *See Nat'l Fed'n Indep. Bus. v. Sebelius*, 567 U.S. 519, 577 (2012) (opinion of Roberts, C.J.) (noting that those criteria ensure "that Spending Clause legislation does not undermine the status of the States as independent sovereigns in our federal system").

252. Declaratory relief announcing that the CMS vaccine mandate is unlawful, an injunction enjoining its enforcement, and an order vacating the IFR redress those harms.

CLAIMS FOR RELIEF

COUNT ONE – SUBSTANTIVE VIOLATION OF THE APA ARBITRARY AND CAPRICIOUS ACTION NOT IN ACCORDANCE WITH LAW

253. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

254. CMS and HHS are subject to the requirements of the APA.

255. CMS's adoption and promulgation of the vaccine mandate through an IFR was a major agency action that could not lawfully be conducted without compliance with the APA.

256. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

257. The APA forbids federal administrative agencies from relying on *post hoc* rationalizations. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907, 1909 (2020) (holding that it is a "foundational principle of administrative law" to reject an agency's "impermissible *post hoc* rationalizations").

258. CMS's justification for the vaccine mandate was necessarily a *post hoc* rationalization because nearly two months before the IFR issued, President Biden instructed CMS to adopt a rule mandating vaccination for healthcare workers.

259. The APA requires federal administrative agencies to engage in "reasoned decision-making." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 379 (1998) (cleaned up). Agency action is "lawful only if it rests on a consideration of the relevant factors" and "important aspects of the problem." *Michigan v. EPA*, 576 U.S. 743, 750-52 (2015) (cleaned up). Failing to consider—or arbitrarily rejecting—important factors affecting the efficacy of a policy renders agency action arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem"). At core, an agency must have "reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

260. As the foregoing discussions about CMS's numerous failures in analysis and reasoning show, the CMS vaccine mandate was not the product of reasoned decisionmaking.

261. To note some of the more egregious examples, CMS did not engage in reasoned decisionmaking in concluding that the mandate was necessary to protect patient health and safety and that the mandate will not exacerbate the staff shortages that already exist for almost all categories of employees at almost all kinds of health care providers.

262. CMS ignored or arbitrarily rejected the importance of numerous issues and relevant factors, including but not limited to the economic impacts on the healthcare industry, labor-force disruptions in the healthcare industry, loss of jobs in the healthcare industry, costs to States and their agencies, the current health risks of COVID-19, the limitations of COVID-19 vaccines, the

acknowledged benefits of natural immunity to COVID-19, and basic distinctions among workers like those who have natural immunity and those who have limited in-person contacts with patients or coworkers.

263. CMS ignored or arbitrarily rejected the adverse effects of resignations among unvaccinated healthcare workers, which is a particularly important problem for an economy already experiencing a critical labor shortage in healthcare, high levels of inflation, and a supply-chain crisis.

264. CMS ignored or arbitrarily rejected the adverse effects of resignations among unvaccinated healthcare workers, which is a particularly important problem facing rural communities.

265. CMS ignored or arbitrarily rejected the adverse effects on States, which operate state-run hospitals that participate in Medicare and Medicaid, and which incur costs associated with enforcing the vaccine mandate, including enforcement through state surveyors.

266. CMS ignored or arbitrarily rejected the fact that the vaccine mandate will have a disparate impact on minority and economically disadvantaged communities that have relatively low rates of vaccination by inflicting disproportionately greater unemployment, job losses, loss of healthcare services, and economic injury on those communities.

267. CMS ignored or arbitrarily rejected the interests of healthcare workers who—for any number of varying personal reasons—do not want to take one of the currently authorized COVID-19 vaccines.

268. CMS ignored that the vaccine mandate will cover religious healthcare institutions and thus require them to terminate ministerial employees in violation of the First Amendment. *Our Lady of Guadalupe Sch. v. Morrissey-Berru*, 140 S. Ct. 2049, 2061 (2020).

269. CMS ignored that its actions were contrary to law, as they were not authorized by the Social Security Act, and were also unconstitutional, as the vaccine mandate violates the Tenth Amendment by invading the States' police power over compulsory vaccinations.

270. CMS acted arbitrarily and capriciously by refusing to provide a testing option for employees who decline to take one of the available COVID-19 vaccines. This decision arbitrarily and capriciously conflicts with OSHA's now-withdrawn ETS, which allowed periodic testing as an alternative to compulsory vaccines.

271. CMS acted arbitrarily and capriciously by refusing to provide an exemption to persons with natural immunity to COVID-19 because natural immunity is at least as effective as vaccination in preventing re-infection, transmission, and severe health outcomes.

272. CMS's finding that the vaccine mandate is necessary was undermined by its delay in adopting it. Vaccines have been authorized for over a year, yet CMS did not impose this mandate until two months after it was instructed to do so by the President as part of his "six-point plan" to federalize public-health policy.

273. CMS acted arbitrarily and capriciously by ignoring or unreasonably rejecting the important reliance interests of many institutions and individuals in the Plaintiff States. These reliance interests are longstanding and deep-seated since the federal government has never before tried to impose a vaccine requirement on healthcare workers. These specific reliance interests include (1) the State's reliance interests in their healthcare providers continuing to operate under the existing rules without facing this new mandate that threatens to cause significant harm to the States' citizens, particularly those in rural communities; (2) healthcare providers' similar reliance interests in staffing their facilities under the existing rules without facing this new mandate that threatens their workforce, the services they provide, and their very existence; and (3) healthcare

workers' reliance interests, especially the interests of minority workers in rural communities, in selecting a job and building a career under the existing rules.

274. Upon information and belief, CMS arbitrarily and capriciously ignored that the mandate is a reversal of federal pandemic response policy that did not contemplate this type of mandate and that left decisions about compulsory vaccines to the States.

275. The broad scope of healthcare providers covered by the CMS vaccine mandate is arbitrary and capricious. The mandate reaches many categories of healthcare facilities, such as psychiatric residential treatment facilities for individual under 21 years of age, *see* 86 Fed. Reg. at 61576, that are not related to CMS's asserted interest in protecting elderly and infirm patients from the transmission of COVID-19. Indeed, CMS recognizes that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person." *Id.* at 61,610 n.247.

276. The broad scope of workers, volunteers, and contractors covered by the CMS vaccine mandate is arbitrary and capricious. The mandate applies to "any individual that . . . has the *potential* to have contact with anyone at the site of care." *Id.* at 61,571 (emphasis added). This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61,570. And the mandate also covers a contracted "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." *Id.* at 61,571. The vast reach of this mandate is far removed from the purported purpose of protecting patient safety.

277. CMS acted arbitrarily and capriciously by adopting a rigid one-size-fits-all mandate that did not account for the advent of a new dominant variant against which the vaccines are ineffective at stopping transmission—the very situation that now exists. When CMS issued the

mandate, it knew that (1) new SARS-CoV-2 variants would continue to arise, *see, e.g.*, 86 Fed. Reg. at 61,583 (discussing "the advent of the Delta variant and the potential for new variants"); *id* at 61,584 (recognizing the "ongoing risk of new COVID-19 variants"); (2) "Delta may be overtaken by other virus mutations," *id.* at 61,609; (3) new COVID-19 variants could change the trajectory of the pandemic, the risk of the virus, and the rationale for the mandate, *see, e.g.*, *id.* at 61,559 ("While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the Delta variant reversed these trends."); *id.* at 61,610 n.248 (noting that "another variant of the vaccine might arise and create new risks or shifts in risks within the U.S."); (4) the COVID-19 vaccines are less effective against certain variants, *see, e.g.*, *id.* at 61,565 (acknowledging that one of CMS's relied-upon studies shows that "vaccine effectiveness point estimates did decline over the course of the study as the Delta variant became predominant"); and (5) there was a "possibility of new virus variants that reduce the effectiveness of currently authorized and approved vaccines," *id.* at 61,602. Despite knowing all that, CMS arbitrarily and capriciously created a rule that does not even attempt to adjust to the pandemic-related changes that it contemplated.

278. The pandemic changes that CMS contemplated came to pass with the advent of the Omicron variant. Omicron presents a greatly reduced risk of severe health outcomes compared to Delta, and the available COVID-19 vaccines are ineffective in preventing transmission of Omicron. Omicron was identified the month CMS imposed the mandate. So it is now clear that the vaccine mandate irrationally demands mass vaccinations that provide no real-world benefit but will drive more healthcare workers out of their jobs and reduce the healthcare services available in the Plaintiff States.

279. CMS acted arbitrarily and capriciously by failing to consider the option of automatically terminating the mandate—or adjusting the mandate in some other way—once Delta was overtaken by another variant against which the available COVID-19 vaccines are ineffective at stopping transmission. Instead, CMS irrationally announced that it expects to retain the mandate "as a permanent requirement for facilities" even though that rule was designed for a set of circumstances that no longer exist. 86 Fed. Reg. at 61,574.

280. CMS acted arbitrarily and capriciously by enacting a rule that entirely fails to account for changes in pandemic-related circumstances, even though CMS knew that changes would occur, and changes have been a mainstay of the pandemic. The inherent design and structure of the mandate cannot account for the changed circumstances. Indeed, nothing in the mandate accommodates changing circumstances. That oversight is inexcusable given the constantly changing nature of the pandemic over the past two years. In this situation, such an inflexible rule is arbitrary and capricious.

281. CMS acted arbitrarily and capriciously by entirely failing to consider whether its vaccine mandate ought to incorporate some flexibility allowing States, healthcare facilities, and individuals to adapt to rapidly evolving information concerning different SARS-CoV-2 variants, vaccine effectiveness, and compliance problems.

282. CMS is acting arbitrarily and capriciously by continuing to enforce the vaccine mandate now that Omicron is the prevailing SARS-CoV-2 variant. It is irrational to enforce the mandate because Omicron poses a substantially reduced risk of severe health outcomes compared to Delta and the available COVID-19 vaccines are ineffective in preventing transmission of Omicron.

283. CMS is acting arbitrarily and capriciously by continuing to enforce the vaccine mandate despite the changes in the legal and regulatory landscape of mandated vaccines. The CMS mandate was initially designed to work in tandem with vaccine mandates on other employers. The collection of these mandates would have limited the alternative choices of employment for healthcare workers subject to the CMS vaccine mandate, further pressuring them to choose vaccination over job loss. Now that these other mandates are enjoined, withdrawn, or otherwise unenforceable, healthcare workers have choices. They are more likely and more freely able to leave employers covered by the CMS mandate and seek employment elsewhere. That, of course, will further worsen the staffing shortages in the healthcare sector. CMS did not consider the non-enforcement, or enjoinment of enforcement, of the other vaccine mandates. Rather, the agency was deeply reliant on this collective patchwork of mandates. This change in circumstances further demonstrates the irrationality of the vaccine mandate.

284. CMS and its parent agency HHS are acting arbitrarily and capriciously because when the CMS vaccine mandate is applied together with the CDC's updated guidance on isolation for COVID-19-positive healthcare workers, the result is utterly irrational. *See* CDC, *Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2*, *supra*. Healthcare facilities must *fire* a healthy COVID-19-*negative* unvaccinated employee but may *return to work* a COVID-19-*positive* employee. Such illogical and inconsistent agency action is the epitome of arbitrary and capricious behavior. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) ("An unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice") (cleaned up).

285. CMS acted arbitrarily and capriciously by insisting that the need for its vaccine mandate during the winter season required it to skip notice-and-comment rulemaking and warranted an immediate stay from the Supreme Court, but once the Supreme Court issued the requested stay, the agency delayed full enforcement of its mandate in the Plaintiff States until the middle of April 2022—after the winter season is over.

286. CMS's finding that the vaccine mandate is necessary was pretextual because the mandate is a blatant attempt to federalize public health issues involving vaccination that belong within the States' police power.

287. CMS's finding that the vaccine mandate is necessary was pretextual because the agency ignored all the evidence showing that the COVID vaccines do not provide effective protection against infection and transmission.

288. CMS's finding that the vaccine mandate is necessary was pretextual because that finding is part of the federal government's broader policy of ignoring and suppressing points of view that are opposed to its COVID policies.

289. Furthermore, CMS's decision to issue the mandate is arbitrary and capricious because it is, upon information and belief, part of the federal government's policy of ignoring and suppressing points of view that are contrary to its COVID policies.

290. For all these reasons, and more to be identified after the agency files the administrative record and any supplementation is permitted or discovery is conducted, CMS's promulgation and enforcement of the vaccine mandate is arbitrary, capricious, and unlawful under the APA, and the IFR should be set aside.

COUNT TWO – SUBSTANTIVE VIOLATION OF THE APA
ACTION IN EXCESS OF AUTHORITY AND NOT IN ACCORDANCE WITH LAW

291. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

292. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

293. CMS's adoption and promulgation of the vaccine mandate through an IFR is a major agency action that could not lawfully be conducted without compliance with the APA.

294. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law" or "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

295. The CMS vaccine mandate is contrary to law and in excess of statutory authority because CMS's statutory rulemaking power does not include the authority to impose a broad vaccine mandate that Congress has not authorized.

296. None of the statutes that CMS cited in its IFR authorize the vaccine mandate. This includes the two statutes that grant general rulemaking power to HHS—42 U.S.C. § 1302(a) and 42 U.S.C. § 1395hh(a)(1)—and the more than a dozen specific statutes discussed above that CMS invoked in support of its mandate.

297. The CMS vaccine mandate is unprecedented—never before has the agency tried to use its rulemaking authority to mandate vaccines. This confirms that CMS acted contrary to law and in excess of statutory authority.

298. Reading CMS's statutory authority to include the power to mandate vaccines throughout an industry violates the Supreme Court's major-questions doctrine. *See Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam) ("We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.") (cleaned up); *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

299. Reading CMS's statutory authority to include the power to mandate vaccines throughout an industry violates the nondelegation doctrine. *See Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality op.) (Congress must provide an "intelligible principle to guide the delegee's use of discretion" in the exercise of delegated power).

300. Reading CMS's statutory authority to include the power to mandate vaccines throughout an industry violates the Spending Clause for the reasons explained below.

301. Reading CMS's statutory authority to include the power to mandate vaccines throughout an industry violates the Tenth Amendment by trampling on the traditional authority of the States to regulate public health within their borders, including the topic of compulsory vaccination. *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2489 ("[Supreme Court] precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property.").

302. The CMS vaccine mandate is also contrary to law and in excess of statutory authority because it conflicts with 42 U.S.C. § 1395.

303. Section 1395 provides that nothing in Title 18 of the Social Security Act "shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

304. The CMS vaccine mandate violates 42 U.S.C. § 1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "selection" and "tenure" of employees (including state employees) and other persons "providing health services." It does so

by prohibiting covered healthcare facilities from hiring unvaccinated employees and forcing those facilities to terminate—and thus end the tenure of—unvaccinated employees.

305. The CMS vaccine mandate also violates that statute because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "administration" and "operation" of institutions, agencies, and persons that provide health services (including state facilities and employees). It does so by dictating the hiring and firing policies of these institutions concerning unvaccinated workers.

306. For all these reasons, CMS's promulgation of the vaccine mandate is contrary to law and in excess of statutory authority, and the IFR should be set aside.

COUNT THREE – PROCEDURAL VIOLATION OF THE APA ACTION WITHOUT NOTICE AND COMMENT

307. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

308. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

309. CMS's adoption and promulgation of the vaccine mandate through an IFR was a major agency action that could not lawfully be conducted without compliance with the APA.

310. Under the APA, a court must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

311. The APA requires a federal agency to publish "notice of proposed rule making … in the Federal Register" and then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b)–(c).

312. These requirements "are not mere formalities" but rather "are basic to our system of administrative law." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018).

313. Prior to publishing the vaccine mandate, CMS did not publish notice of proposed rulemaking in the Federal Register or give all interested members of the public an opportunity to comment.

314. CMS's decision to skip the notice-and-comment process was unlawful. The agency's rushed enactment of its vaccine mandate aimed to deliver on the President's mass vaccine demands rather than to respond to the pandemic by enacting measures based on—or capable of adjusting to—emerging data and best practices.

315. The APA's notice and comment requirements do not apply if "good cause" establishes that they "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 5 U.S.C. § 553(b)(B).

316. CMS failed to demonstrate that "good cause" excuses its failure to conduct notice-and-comment rulemaking.

317. Central to CMS's supposed "good cause" finding was the public health threat posed by the Delta variant and the vaccines' alleged effectiveness against that variant. *See Biden*, 142 S. Ct. at 651 ("That good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season.").

318. The premise of CMS's good cause finding is incorrect because the vaccines do not prevent infection and transmission of COVID-19.

319. The Omicron variant has displaced the Delta variant. Omicron presents a greatly reduced risk of severe health outcomes compared to Delta, and the available COVID-19 vaccines are ineffective in preventing transmission of Omicron.

320. The arrival of Omicron highlighted what has been plain throughout this pandemic—things change. There is thus no good cause to justify imposing the CMS vaccine mandate on an interim basis without notice and comment because, as Omicron shows, what might be a valid response one month becomes improper the next month.

321. In addition, CMS insisted that the need for its vaccine mandate during the winter season required it to skip notice-and-comment rulemaking and warranted an immediate stay from the Supreme Court. Yet once the Supreme Court issued the requested stay, the agency delayed full enforcement of its mandate in the Plaintiff States until the middle of April 2022—after the winter season is over.

322. For all these reasons, CMS's promulgation of the vaccine mandate violated APA procedural requirements, and the IFR should be set aside.

COUNT FOUR – PROCEDURAL VIOLATION OF THE SOCIAL SECURITY ACT ACTION WITHOUT NOTICE AND COMMENT

323. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

324. HHS, which includes CMS, is a subject to the procedural rulemaking requirements in the Social Security Act.

325. Congress has specifically emphasized the importance of notice and comment when considering changes to Medicare. The Supreme Court has explained that "Medicare touches the lives of nearly all Americans." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to Medicare "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816. "Recognizing this reality," *id.* at

1808, Congress doubled the standard 30-day comment period under the APA for any "substantive legal standard" affecting the payment for services under Medicare. 42 U.S.C. §1395hh(a)(2), (b)(1). Thus, under the Social Security Act, CMS "shall provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

326. Prior to publishing the vaccine mandate, CMS did not publish notice of proposed rulemaking in the Federal Register or give all interested members of the public an opportunity to comment.

327. CMS's decision to skip the notice-and-comment process was unlawful. The agency's rushed enactment of its vaccine mandate aimed to deliver on the President's mass vaccine demands rather than to respond to the pandemic by enacting measures based on—or capable of adjusting to—emerging data and best practices.

328. The Social Security Act's notice and comment requirements, like the APA's similar requirements, do not apply if "good cause" establishes that they "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 42 U.S.C. § 1395hh(b)(2)(C) (invoking 5 U.S.C. § 553(b)(B)).

329. Despite attempts to do so, CMS failed to demonstrate that "good cause" excuses its failure to conduct notice-and-comment rulemaking.

330. Central to CMS's supposed "good cause" finding was the public health threat posed by the Delta variant and the vaccines' alleged effectiveness against that variant. *See Biden*, 142 S. Ct. at 651 ("That good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season.").

331. For the reasons noted above, CMS did not establish good cause.

332. For all these reasons, CMS's promulgation of the vaccine mandate violated the Social Security Act's procedural requirements, and the IFR should be set aside.

COUNT FIVE – VIOLATION OF 42 U.S.C. § 1395z
FAILURE TO CONSULT WITH APPROPRIATE STATE AGENCIES

333. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

334. 42 U.S.C. § 1395z provides that "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies" when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and[] (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title."

335. 42 U.S.C. § 1395z applies to the CMS vaccine mandate because that mandate purports to establish conditions of participation for hospitals under 42 U.S.C. § 1395x(e)(9), long-term-care facilities (also known as skilled nursing facilities) under 42 U.S.C. § 1395x(j) and 42 U.S.C. § 1395i–3, Home Health Agencies ("HHAs") under 42 U.S.C. § 1395x(o)(6), Comprehensive Outpatient Rehabilitation Facilities ("CORFs") under 42 U.S.C. § 1395x(cc)(2), hospices under 42 U.S.C. § 1395x(dd)(2), Critical Access Hospitals ("CAHs") under 42 U.S.C. § 1395x(mm)(1) and 42 U.S.C. § 1395i–4(e), and Ambulatory Surgical Centers ("ASCs") under 42 U.S.C. § 1395k(a)(2)(F)(i).

336. CMS admitted that it did not comply with 42 U.S.C. § 1395z's requirement that it "consult with appropriate State agencies." 86 Fed. Reg. at 61,567.

337. By failing to consult with appropriate States agencies before issuing the vaccine mandate, CMS violated 42 U.S.C. § 1395z.

338. CMS's "inten[t] to engage in consultations with appropriate State agencies . . . following the issuance of th[e] rule," 86 Fed. Reg. at 61,567, does not satisfy 42 U.S.C. § 1395z. The statute plainly requires that the consultation with States occur before a rule is issued. The statutory text demands the consultation when the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services." 42 U.S.C. § 1395z. The Secretary, via CMS, already made his determination that the vaccine mandate should be a condition of participation by providers. It was at that time he was required to consult with the States. Since he did not, the Secretary, acting through CMS, violated 42 U.S.C. § 1395z.

339. Even if CMS's mandatory state consultation does not need to occur before the issuance of the rule, it must happen during the post-issuance comment period. But that comment period expired on January 4, 2022, and still the Secretary has not consulted with the Plaintiff States as 42 U.S.C. § 1395z requires.

340. For all these reasons, CMS's promulgation of the vaccine mandate violated 42 U.S.C. § 1395z, and the IFR should be set aside.

COUNT SIX – VIOLATION OF 42 U.S.C. § 1302
FAILURE TO PREPARE REGULATORY IMPACT ANALYSIS

341. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

342. 42 U.S.C. § 1302(b)(1) provides that "[w]henever the Secretary [of HHS] publishes a general notice of proposed rulemaking for any rule or regulation proposed under subchapter XVIII, subchapter XIX, or part B of [title IX of the Social Security Act] that may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis."

343. 42 U.S.C. § 1302(b)(1) applies to the CMS vaccine mandate because CMS's cited statutory authority for its vaccine mandate falls under Titles 18 and 19 of the Social Security Act

and because the mandate will have a significant impact on the operations of a substantial number of small rural hospitals.

344. The CMS vaccine mandate threatens to exacerbate already devastating shortages in healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. That, in turn, will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. These dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis.

345. For all these reasons, CMS's promulgation of the vaccine mandate violated 42 U.S.C. § 1302(b)(1), and the IFR should be set aside.

COUNT SEVEN – UNCONSTITUTIONAL EXERCISE OF THE SPENDING POWER

346. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

347. The CMS vaccine mandate is an unconstitutional condition on the Plaintiff States' receipt of federal funds.

348. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

349. Nothing in federal law gave States clear notice that forcing their employees at state-run hospitals to get a COVID-19 vaccination or forcing their state surveyors to enforce the CMS vaccine mandate would be a condition of accepting federal funds. More generally, nothing in federal law gave States clear notice that a vaccine mandate would be a condition of accepting federal Medicaid or Medicare funds. Indeed, the States had no reason to expect that the statutes cited by CMS to justify the IFR would authorize a federal vaccine mandate because the Supreme Court has held for over a century that compulsory-vaccination policies lie within the *States'* police

power and "do not ordinarily concern the national government." *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905).

350. "[C]onditions on federal funds must be related to the federal interest in particular national projects or programs." *Van Wyhe v. Reisch*, 581 F.3d 639, 650 (8th Cir. 2009).

351. The scope of the CMS vaccine mandate reaches far beyond a federal interest in patient safety. Because the mandate applies to "any individual that . . . has the *potential* to have contact with anyone at the site of care," it covers a contracted "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." 86 Fed. Reg. at 61,571 (emphasis added). Moreover, the mandate covers healthcare providers, such as psychiatric residential treatment facilities for individual under 21 years of age, that exclusively serve patients at very low risk from COVID-19. *Id.* at 61576. This vast reach of the mandate is far removed from the supposed purpose of protecting patients whose healthcare providers receive federal funding.

352. The CMS vaccine mandate goes far beyond the federal interest in patient health for another reason. The mandate is one element of President Biden's otherwise unsuccessful attempt to force COVID-19 vaccination on Americans in every sector of the economy. By treating Medicaid and Medicare as an "element of a comprehensive national plan" to "pressur[e] the States to accept policy changes" related to COVID-19 vaccines, Defendants have attempted to "accomplish[] a shift in kind, not merely degree," in the purpose of those federal programs. *NFIB v. Sebelius*, 567 U.S. 519, 580, 583 (2012) (op. of Roberts, C.J.). That violates the Spending Clause.

353. The federal government cannot use the spending power to "commandeer[] a State's … administrative apparatus for federal purposes," *id.* at 577, or "conscript state [agencies] into the national bureaucratic army," *id.* at 585.

354. The CMS vaccine mandate conscripts state agencies by forcing state-run hospitals that fall under the mandate to either fire their unvaccinated employees or give up all their Medicare and Medicaid funding. Because Plaintiff States must ensure sufficient funding to care for ailing patients in need, this does not present States will a realistic choice.

355. The CMS vaccine mandate conscripts state agencies by forcing state surveyors to enforce the mandate through verifying healthcare providers' compliance with it. If States instruct their surveyors not to enforce the CMS vaccine mandate, that will risk disqualifying Medicare- and Medicaid-certified providers and suppliers in their States. Forcing States to administer the CMS vaccine mandate on pain of losing Medicare and Medicaid funds flowing into the States compels States to participate in the mandate against their will.

356. Additionally, because noncompliance with the CMS vaccine mandate threatens a substantial portion of Plaintiff States' budgets, it violates the Spending Clause by leaving those States with no choice but to acquiesce. *See id.* at 581–82.

357. For all these reasons, the CMS vaccine mandate was adopted pursuant to an unconstitutional exercise of authority and must be invalidated.

COUNT EIGHT – VIOLATION OF ANTI-COMMANDEERING DOCTRINE

358. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

359. The federal government lacks "the power to issue direct orders to the governments of the States." *Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018). And the Constitution does not tolerate the federal government dragooning state employees "into administering federal law." *Printz v. United States*, 521 U.S. 898, 928 (1997).

360. The IFR compels States to administer the mandate by forcing state-run healthcare facilities to either fire their unvaccinated employees or give up all their Medicare and Medicaid

funding. Because Plaintiff States must ensure sufficient funding to care for ailing patients in need, this does not present States will a realistic choice.

361. The CMS vaccine mandate compels States, through their state surveyors, to enforce the mandate by verifying healthcare providers' compliance with it. If States instruct their surveyors not to enforce the CMS vaccine mandate, they risk the disqualification of Medicare- and Medicaid-certified providers and suppliers in their States. Forcing States to administer the CMS vaccine mandate or else jeopardize Medicare and Medicaid funds flowing into the States is a gun to the head that compels States to participate against their will.

362. The CMS vaccine mandate commandeers the Plaintiff States into enforcing federal policy by threatening their Medicare and Medicaid funds. States are left with no real choice but to allow their employees to be commandeered and used to enforce federal policy.

363. For all these reasons, the CMS vaccine mandate was adopted pursuant to an unconstitutional exercise of authority and must be invalidated.

COUNT NINE – VIOLATION OF TENTH AMENDMENT AND FEDERALISM

364. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

365. The structure of the U.S. Constitution and the text of the Tenth Amendment protect federalism.

366. The powers not delegated by the Constitution to the federal government are reserved to the States.

367. The CMS vaccine mandate seeks to exercise power far beyond what was delegated to the federal government by constitutional mandate or congressional action.

368. Neither Article II of the U.S. Constitution nor any act of Congress authorizes CMS to implement the vaccine mandate.

369. The power to impose vaccine mandates, to the extent that any such power exists, is a power reserved to the States.

370. "[T]he police power of a state" includes, above all, the authority to adopt regulations seeking to "protect the public health," including the topic of mandatory vaccination. *Jacobson*, 197 U.S. at 24–25. These matters "do not ordinarily concern the national government." *Id.* at 38; *see also Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 719 (1985) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.").

371. Reading CMS's authority as including the power to mandate vaccines throughout an entire industry violates the Tenth Amendment by trampling on the traditional authority of the States to regulate public health within their borders, including the topic of compulsory vaccination. *Cf. Alabama Ass'n of Realtors*, 141 S. Ct. at 2489 ("[Supreme Court] precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property.").

372. By interfering with the traditional balance of power between the States and the federal government, and by acting pursuant to *ultra vires* federal action, CMS violated the Tenth Amendment and structural principles of federalism.

373. For all these reasons, the CMS vaccine mandate was adopted pursuant to an unconstitutional exercise of authority and must be invalidated.

COUNT TEN – UNCONSTITUTIONAL DELEGATION OF AUTHORITY

374. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

375. "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend.

X. The U.S. Constitution provides that "[a]ll legislative powers herein granted shall be vested in a Congress of the United States," not in the federal executive branch. U.S. Const. art. I, § 1.

376. "[A] statutory delegation is constitutional as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Gundy*, 139 S. Ct. at 2123 (plurality op.). Congress must offer "specific restrictions" that "meaningfully constrain[]" the agency's exercise of authority. *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Moreover, Congress must "speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2489.

377. As previously explained, the CMS vaccine mandate intrudes on the Plaintiff States' historic and traditional authority to regulate health and safety, including the topic of mandatory vaccination. The mandate implicates vast political considerations, perhaps the most contentious political issue of the day, and will significantly harm the ability of the Plaintiff States to continue to provide healthcare to their populations by jeopardizing the jobs of millions of healthcare workers.

378. Even if CMS has statutory authority to promulgate the vaccine mandate, such a delegation of authority would be unlawful. There is no intelligible principle to guide CMS, nor is there any limit or direction for how it is to exercise such power.

379. If Defendants are right that the Social Security Act grants CMS authority to mandate vaccination, both "the degree of agency discretion" and "the scope of the power congressionally conferred" are limitless. *Whitman*, 531 U.S. at 475. Congress, however, lacks authority to delegate "unfettered power" to an executive agency. *Tiger Lily, LLC v. HUD*, 5 F.4th 666, 672 (6th Cir. 2021).

380. Congress cannot delegate to agencies the "authority to decide major policy questions"—such as whether all healthcare workers must be vaccinated—because doing so would violate the nondelegation doctrine. *Paul v. United States*, 140 S. Ct. 342, 342 (2019) (statement of Justice Kavanaugh respecting the denial of certiorari); *see also Tiger Lily*, 5 F.4th at 672 ("[T]o put 'extra icing on a cake already frosted,' the government's interpretation of § 264(a) could raise a nondelegation problem."). In other words, under our Constitution, the answer to the question who decides a major policy question *cannot* be an unelected federal bureaucrat.

381. In short, if Congress truly granted CMS the authority to issue the vaccine mandate under the Social Security Act, the Act violates the nondelegation doctrine.

382. For all these reasons, the CMS vaccine mandate was adopted pursuant to an unconstitutional exercise of authority and must be invalidated.

COUNT ELEVEN – CHANGES IN CORE CIRCUMSTANCES

383. All preceding Paragraphs of this Complaint are hereby incorporated by reference.

384. The Supreme Court has recognized that courts reviewing agency action must vacate and remand that action to the agency when the "intervening facts" following that agency action "so change[] the complexion of the case" that it would be inequitable for the action to remain in effect. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 172 (1962). Indeed, in some cases "the equities of a situation militate in favor of returning a rule to an agency for further consideration in light of new evidence." *Am. Optometric Ass'n v. FTC*, 626 F.2d 896, 907 (D.C. Cir. 1980). This occurs when "there has been a change in circumstances, subsequent to administrative decision and prior to court decision, that is not merely material but rises to the level of a change in core circumstances, the kind of change that goes to the very heart of the case." *Id.* (cleaned up).

385. CMS adopted its vaccine mandate to address circumstances that existed when Delta was the prevailing variant. But Delta has been displaced by Omicron. That new variant presents a greatly reduced risk of severe health outcomes compared to Delta, and the available COVID-19 vaccines are ineffective in preventing transmission of Omicron. Given this significant change, and the other changes in core circumstances alleged herein, it would be inequitable to allow the CMS vaccine mandate to continue, particularly considering all the harm that the mandate is causing the healthcare community and imposing on people needing healthcare in the Plaintiff States.

386. Additionally, the legal and regulatory landscape has drastically changed since CMS issued its vaccine mandate. That mandate was initially designed to work in tandem with vaccine mandates on other types of employers. But those mandates have been stayed, enjoined, or withdrawn in full or in part. CMS did not consider the non-enforcement of the other vaccine mandates. Rather, the agency was deeply reliant on this collective patchwork of mandates that no longer exists.

387. Under these drastically altered conditions, where the core circumstances that the mandate addresses have changed, the Court should vacate the IFR and remand to CMS "for further consideration in the light of the changed conditions." *Burlington Truck Lines*, 371 U.S. at 172; *see also Am. Optometric Ass'n*, 626 F.2d at 917 ("suspend[ing] the operation of the rule . . . until such time as the Commission has completed its reconsideration").

388. Moreover, to the extent that CMS has statutory authority to create rules that further the health and safety of patients, it has an ongoing statutory obligation to ensure that its rules further those interests. The existence of "conditions forging the . . . link between [CMS] regulations" and patient health is "essential to their continuing operation." *Geller v. FCC*, 610 F.2d 973, 980 (D.C. Cir. 1979). CMS "is statutorily bound to determine whether that linkage now exists."

Id. "[T]he agency cannot sidestep a reexamination of particular regulations when abnormal circumstances make that course imperative." *Id.* at 979.

389. Now that the Omicron variant has displaced Delta and other core circumstances have changed, CMS must reexamine its vaccine mandate to determine whether it still furthers patient health and safety. As explained above, CMS's adoption of the rule was driven by Delta, and it makes no sense to continue the mandate now that Delta has effectively disappeared. As a result, the mandate should be vacated, and the matter sent back to the agency for further consideration.

PRAYER FOR RELIEF

Wherefore, the Plaintiff States ask this Court to issue an order and judgment:

A. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate is arbitrary and capricious and unlawful under the APA;

B. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate is contrary to law and in excess of statutory authority under the APA;

C. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate violates APA procedural requirements;

D. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate violates the Social Security Act's procedural requirements;

E. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate violates 42 U.S.C. § 1395z because CMS failed to consult with appropriate state agencies;

F. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate violates 42 U.S.C. § 1302(b)(1) because CMS failed to prepare a regulatory impact analysis;

G. Declaring, pursuant to 28 U.S.C. § 2201, that the CMS vaccine mandate violates the Spending Clause, the anti-commandeering doctrine, the Tenth Amendment, and the nondelegation doctrine;

H. Declaring, pursuant to 28 U.S.C. § 2201, that the change in core circumstances requires that the CMS vaccine mandate be vacated and remanded to the agency;

I. Setting aside the CMS vaccine mandate;

J. Preliminarily and permanently enjoining Defendants from imposing the CMS vaccine mandate;

K. Preliminarily and permanently enjoining Defendants from imposing the CMS vaccine mandate without first following the required notice-and-comment procedures of the APA and the Social Security Act;

L. Tolling any relevant compliance deadlines pending judicial review; and

M. Granting any and all other relief the Court deems just and proper.

Dated: November 23, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on November 23, 2022, a true and correct copy of the foregoing and any attachments were filed electronically through the Court's CM/ECF system, to be served on counsel for all parties by operation of the Court's electronic filing system and to be served on those parties that have not appeared who will be served in accordance with the Federal Rules of Civil Procedure by mail or other means agreed to by the party.

/s/ *Michael E. Talent*
Counsel for Plaintiffs

EXHIBIT

A

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF MISSOURI ex rel. ERIC S. SCHMITT, Attorney General, and STATE OF LOUISIANA ex rel. JEFFREY M. LANDRY, Attorney General, *Plaintiffs*, v. JOSEPH R. BIDEN, JR., in his official capacity as President of the United States, *et al.*; *Defendants*.	Case No. 3:22-cv-01213

DECLARATION OF DR. JAYANTA BHATTACHARYA

I, Dr. Jayanta Bhattacharya, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my knowledge, education, and experience.

2. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 161 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 13,000 times.

3. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions.

I have studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals with "natural immunity"). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

4. I have served as an expert witness in many cases involving challenges to COVID-19 restrictions such as mask mandates and lockdowns, including as an expert on behalf of the Missouri Attorney General's Office. My writings on COVID-19-related issues has appeared in both scientific journals (like the *Journal of the American Medical Association* and the *International Journal of Epidemiology*) and in the popular press around the world (including the *Wall Street Journal*, *Newsweek*, *the Telegraph*, *the Spectator*, and many other outlets). I have appeared as a invited guest on national and international news programs, including Fox News, BBC, CNN, NPR, Sky News, NewsMax, GB News, and other stations in the US, the UK, Australia, and elsewhere.

5. Because of my views on COVID-19 restrictions, I have been specifically targeted for censorship by federal government officials.

6. On October 4, 2020, I and two colleagues—Dr. Martin Kulldorff, a professor of medicine, biostatistician, and epidemiologist at Harvard University; and Dr. Sunetra Gupta, an epidemiologist with expertise in immunology, vaccine development, and mathematical modeling of infectious diseases at the University of Oxford—published online the "Great Barrington Declaration."[1]

7. The Great Barrington Declaration questioned the then-prevailing governmental policies of responding to COVID-19 with lockdowns, school shutdowns, and similar restrictions. It stated:

[1] Great Barrington Declaration, https://gbdeclaration.org/.

"As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection." *Id.*

8. The Declaration called for an end to economic lockdowns, school shutdowns, and similar restrictive policies on the ground that they disproportionately harm the young and economically disadvantaged while conferring limited benefits. The Declaration stated: "Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice." *Id.*

9. It asserted that "[k]eeping these measures in place until a vaccine is available will cause irreparable damage, with the underprivileged disproportionately harmed. … We know that vulnerability to death from COVID-19 is more than a thousand-fold higher in the old and infirm than the young. Indeed, for children, COVID-19 is less dangerous than many other harms, including influenza." *Id.*

10. The Declaration endorsed an alternative approach called "Focused Protection," which called for strong measures to protect high-risk populations while allowing lower-risk individuals to return to normal life with reasonable precautions: "The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection." *Id.*

11. The Declaration stated, "Those who are not vulnerable should immediately be allowed to resume life as normal. Simple hygiene measures, such as hand washing and staying home when sick should be practiced by everyone to reduce the herd immunity threshold. Schools and universities should be open for in-person teaching. Extracurricular activities, such as sports, should be resumed. Young low-risk adults should work normally, rather than from home. Restaurants and other businesses should open. Arts, music, sport and other cultural activities should resume. People who are more at risk may participate if they wish, while society as a whole enjoys the protection conferred upon the vulnerable by those who have built up herd immunity." *Id.*

12. At the time of its publication on October 4, 2020, the Great Barrington Declaration was co-signed by 43 medical and public health scientists and medical practitioners. Since its publication, the online version of the Declaration has been co-signed by 930,528 people, including 15,883 medical and public health scientists, 47,037 medical practitioners, and 867,612 concerned citizens, as of the morning of June 4, 2022.

13. The Great Barrington Declaration received an immediate backlash from senior government officials who were the architects of the lockdown policies, such as Dr. Anthony Fauci; World Health Organization Director-General Tedros Adhanom Ghebreyesus; and the United Kingdom's health secretary, Matt Hancock.

14. Because it contradicted the government's preferred response to COVID-19, the Great Barrington Declaration was immediately targeted for suppression by federal officials. On October 8, 2020, four days after the Declaration's publication, then-Director of NIH, Dr. Francis Collins, emailed Dr. Anthony Fauci and Cliff Lane at NIH/NIAID about the Great Barrington Declaration. This email stated: "Hi Tony and Cliff, See: https://gbdeclaration.org/. This proposal from the three

fringe epidemiologists who met with the Secretary seems to be getting a lot of attention – and even a co-signature from Nobel Prize winner Mike Leavitt at Stanford. There needs to be a quick and devastating published take down of its premises. I don't see anything like that online yet – is it underway? Francis." This email was produced over a year later in response to FOIA requests.[2]

15. To my knowledge, no "quick and devastating *published* take down" of the Declaration's "premises" ever appeared—at least, none by any qualified scientist. (Dr. Fauci, instead, would refer to a criticism published by a journalist at Wired magazine.) Instead, what followed was a relentless *covert* campaign of social-media censorship of our dissenting view from the government's preferred message.

16. After the publication of the Great Barrington Declaration, I and my colleagues, Dr. Kulldorff and Dr. Gupta, and our views, were repeatedly censored on social media. Soon after we published the Declaration, Google deboosted search results for the Declaration, pointing users to media hit pieces critical of it, and placing the link to the actual Declaration lower on this list of results.[3] A prominent online discussion site, Reddit, removed links to the Declaration from COVID-19 policy discussion fora.[4] In February 2021, Facebook removed the Great Barrington Declaration page without explanation before restoring it a week later.[5]

17. On March 18, 2021, Dr. Scott Atlas of Stanford University, Dr. Kulldorff, Dr. Gupta, and I participated in a two-hour roundtable discussion with Governor Ron DeSantis of Florida. During

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[2] Wall Street Journal Editorial Board. (2021) "How Fauci and Collins Shut Down Covid Debate" *Wall Street Journal*. Dec. 21, 2021. https://www.wsj.com/articles/fauci-collins-emails-great-barrington-declaration-covid-pandemic-lockdown-11640129116

[3] Fraser Myers (2020) "Why Has Google Censored the Great Barrington Declaration?" *Spiked Online*. October 12, 2020. https://www.spiked-online.com/2020/10/12/why-has-google-censored-the-great-barrington-declaration/

[4] Ethan Yang (2020) "Reddit's Censorship of The Great Barrington Declaration" *American Institute for Economic Policy Research*. Oct. 8, 2020. https://www.aier.org/article/reddits-censorship-of-the-great-barrington-declaration/

[5] Daniel Payne (2021) "Facebook removes page of international disease experts critical of COVID lockdowns" *Just the News*. February 5, 2021. https://justthenews.com/nation/technology/facebook-removes-page-international-disease-experts-who-have-been-critical-covid?utm_source=breaking-newsletter&utm_medium=email&utm_campaign=newsletter

the discussion, the participants (including me) questioned the efficacy and appropriateness of requiring children to wear face masks, including in school. For example, Dr. Kulldorff stated, "children should not wear face masks, no. They don't need it for their own protection and they don't need it for protecting other people either." I stated that requiring young children to wear face masks is "developmentally inappropriate and it just doesn't help on the disease spread. I think it's absolutely not the right thing to do." Dr. Atlas stated, "There's no scientific rationale or logic to have children wear masks in schools." (These are all views that are strongly supported by scientific research, both before and since we made these comments.)

18. The video of the March 18, 2021 roundtable discussion was promptly censored on social media.[6] YouTube removed the video, claiming that it "contradicts the consensus of local and global health authorities regarding the efficacy of masks to prevent the spread of COVID-19." Notably, the efficacy of masks, especially cloth masks, has been widely questioned by scientists and public health authorities.

19. In the wake of the Great Barrington Declaration and Dr. Collins' October 8, 2020 email to Dr. Fauci, my colleague Dr. Kulldorff also experienced extensive censorship on social media.

20. Dr. Kulldorff has publicly summarized the online and social-media censorship experienced by the Great Barrington Declaration and its co-authors after its publication. As he stated, "We got together and we wrote the Great Barrington Declaration—a one-page thing. We argued for better focused protection of older, high-risk people, at the same time, as we let children and young adults

[6] Wall Street Journal Editorial Board. (2021) "YouTube's Assault on Covid Accountability" *Wall Street Journal*. April 8, 2021. https://www.wsj.com/articles/youtubes-assault-on-covid-accountability-11617921149

live near normal lives so as to minimize the collateral public health damage from these lockdowns and other measures."[7]

21. As Dr. Kulldorff recounted, after its publication, "there was sort of an organized campaign against the Great Barrington Declaration with various sort of strange accusations, that it was let-it-rip, which is the opposite. We thought that we were like exorcism, eugenics, clowns, anti-vaxxers, that we did financial gains, even though the opposite is true. We were accused of threatening others, which none of us have done, Trumpian, libertarian and Koch funded, pseudo scientists, and that we received a free lunch when we were at Great Barrington writing this declaration." *Id.*

22. In particular, the Great Barrington Declaration was censored online. This included suppression in searches by Google, the parent company of YouTube: "when the Great Barrington Declaration came up, at the very beginning, it comes up at the top in the search engine in Google, but then suddenly it wasn't there. Instead, what was there was those who criticized it. Other search engines had it at the top, but not Google…." *Id.*

23. The Great Barrington Declaration was also censored on social media. As Dr. Kulldorff reported, "There were some issues with … Twitter, Facebook, YouTube, and LinkedIn." *Id.*

24. Among other things, the Declaration was censored on Facebook based on a flimsy rationale: "Facebook, they took down the Great Barrington Declaration page for a week, no explanation. The offending post was that we argued that, with the vaccines, which at that time had just come out, we should prioritize giving it to the older, high-risk people. That's what caused Facebook to close it down." *Id.*

[7] The Epoch Times (2021), "Censorship of Science, with Dr. Martin Kulldorff, Dr. Scott Atlas, and Dr. Jay Bhattacharya," May 2, 2021. https://www.theepochtimes.com/live-censorship-of-science-with-dr-martin-kulldorff-dr-scott-atlas-and-dr-jay-bhattacharya_4343061.html.

25. The co-authors of the Great Barrington Declaration also experienced personal social-media censorship. Dr. Kulldorff recounts several examples, including an instance where Twitter censored his tweet stating that "Thinking that everyone must be vaccinated is as scientifically flawed as thinking that nobody should. COVID vaccines are important for older, higher risk people and their caretakers, not those with prior natural infection or for children." *Id.* He also recounts being locked out of Twitter for three weeks "because I tweeted about masks, saying that, 'By claiming that masks are a good protection, some older people will sort of believe that, and they will go and do things and get infected, thinking that it protects the way it doesn't. That's not so good. So, they might die because of this misinformation about the masks.'… For three weeks, I had no access to Twitter because of this tweet." *Id.*

26. Twitter also censored Dr. Kulldorff's speech arguing that healthcare facilities should emphasize hiring workers with natural immunity instead of firing them, because they have the best protection from COVID-19: "Here, another one… [N]ot even I was allowed to read this tweet, they removed it completely. I was arguing that since the people who have recovered from COVID, they're the ones who have the best immunity, better than those who are vaccinated. So, they are the ones who are least likely to spread it to others. So, hospitals should hire nurses like that or doctors like that and use them for the most frail, oldest patients at the geriatric ward or the ICUs because they're least likely to infect these patients." *Id.*

27. Dr. Kulldorff also recounted YouTube's censorship of our roundtable with Governor DeSantis: "On YouTube, we did a round table in April with Governor Ron DeSantis in Florida. It was me and Dr. Scott Atlas, Dr. Jay Bhattacharya, and Dr. Sunetra Gupta. And we talked, for example, about the fact that children don't need to have masks. And we argued against vaccine passport; there was some rumbling starting about vaccine passport. So, then, we sort of thought,

'Let's try to argue against that from the very beginning before it sort of takes off.' So, that was removed by YouTube, which is owned by Google." *Id.*

28. Dr. Kulldorff also experienced censorship on LinkedIn, which is a common vehicle for speech among professionals. As he stated, "LinkedIn, which is owned by Microsoft, they also censor. So, this was an article… It was an interview I did with The Epoch Times on the dangers of vaccine mandates…. [LinkedIn said], 'Only you can see this post.' So, I could still read my post, but nobody else could." *Id.* He also recounted "another one. I actually didn't write anything. I just reposted a LinkedIn post by a guy from Iceland and what he did, he just cited what the Icelandic chief epidemiologist had said, which is sort of the equivalent of the CDC director in the U.S. So, this is the official public health authority in Iceland, but that was censored." *Id.*

29. LinkedIn also censored our public criticism of government officials, such as Dr. Fauci. As Dr. Kulldorff stated, "Together with Dr. Bhattacharya, we wrote a Newsweek article about how Fauci fooled America with the various things about public health, and LinkedIn took that away also." *Id.*

30. As Dr. Kulldorff notes, LinkedIn eventually terminated his account for posting about the benefits of natural immunity: "Later on, LinkedIn actually closed down my account.… [T]his was the last post before suspension, 'By firing staff with natural immunity after COVID recovery, hospitals got rid of those least likely to infect others.'" *Id.*

31. As Dr. Kulldorff noted in his public comments, social-media censorship has not focused solely on the co-authors of the Great Barrington Declaration, but has swept in many other scientists as well: "Twitter, LinkedIn, YouTube, Facebook, they have permanently suspended many accounts—including scientists." *Id.* These censorship policies have driven scientists and others to self-censorship, as scientists like Dr. Kulldorff restrict what they say on social-media platforms to

avoid suspension and other penalties: "I have continued to speak up, but I have since self-censored myself. Because these are important channels of communication, so I don't want to be removed. So, I'm careful with what I say." *Id.* "[C]ensoring, it leads to self-censoring. And also, it leads to self-censoring of people … are victims of these censoring because they see that somebody else is censored. 'Okay. I don't want to be suspended. So, I better be careful with what I say.' And of course, that's the purpose of authoritarians and the purpose of those things. And sometimes, where they sort of kind of randomly select who they censor, what they sensor, because they want people to be uncertain about what they can and cannot say." *Id.*

32. Having observed and lived through the government-driven censorship of the Great Barrington Declaration and its co-authors, it is clear to me that these attacks were politically driven by government actors. As I stated, in remarks alongside those of Dr. Kulldorff, "One of the motivations for that was a motivation to create a consensus within the public that… an illusion of consensus within the public that there was no scientific dissent against lockdowns. The reason why the Great Barrington Declaration, they reacted that way…. [W]e got this viral attention, [that] was a problem for this group [*i.e.*, Dr. Collins, Dr. Fauci, and other government officials]. It posed a political problem for them because they wanted to tell the public that there was no dissent. And so, they had to destroy us. They had to do a devastating takedown. It was a political problem they were solving… I think that's the immediate context for why they did what they did." *Id.*

33. Dr. Kulldorff aptly summarized our experiences: "it has been really stunning to be a scientist during these last two years. It's kind of been absurd. We have NIH Director Collins and NIAID Director Fauci thinking that you promote science by silencing scientists through published takedowns. It's pretty absurd. We have a geneticist and a virologist thinking they know

epidemiology better than epidemiologists at Oxford, Harvard and Stanford, and calling them instead fringe epidemiologists." *Id.*

I swear or affirm under penalty of perjury that the foregoing is true and correct.

Dated: June 4, 2022 Signed: */s/ Jayanta Bhattacharya*

EXHIBIT

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF MISSOURI ex rel. ERIC S. SCHMITT, Attorney General, and STATE OF LOUISIANA ex rel. JEFFREY M. LANDRY, Attorney General, *Plaintiffs*, v. JOSEPH R. BIDEN, JR., in his official capacity as President of the United States, *et al.*; *Defendants*.	Case No. 3:22-cv-01213

DECLARATION OF DR. MARTIN KULLDORFF

I, Dr. Martin Kulldorff, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my knowledge, education, and experience.

2. I am an epidemiologist, a biostatistician and a former Professor of Medicine at Harvard University and Brigham and Women's Hospital, from 2015 to November 2021. Before that, I was Professor of Population Medicine at Harvard University from 2011 to 2015. I hold a Ph.D. from Cornell University. I have published over 200 scholarly articles in peer-reviewed journals in the fields of public health, epidemiology, biostatistics and medicine, among others. My research has been cited in the peer-reviewed scientific literature more than 25,000 times.

3. I have dedicated my professional career to the development and implementation of new disease surveillance systems, including the early detection and monitoring of disease outbreaks;

and the post-market evaluation of the safety and efficacy pharmaceutical drugs and vaccines, including the early detection of drug and vaccine adverse reactions.

4. I have served on multiple governmental scientific advisory boards, including the World Health Organization's Disease Mapping Advisory Group; the Scientific Advisory Board for the Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe; the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee; the New York State Department of Health Environmental Public Health Tracking Project; the New York City Department of Health and Hygiene's Advisory Board for Augmenting Statistical Methods for Public Health Syndromic Surveillance System; the National Cancer Institute's Best Practices in Spatial Analysis Working Group; the Centers for Disease Control and Prevention's (CDC) Vaccine Safety Datalink Project, the CDC's MMRV Vaccine Safety Working Group; and CDC's COVID-19 Vaccine Safety Technical Sub-Group; among others. In April 2021, I was abruptly removed from the latter after publishing an op-ed in The Hill against the CDC instituted pause on the one-dose Johnson & Johnson Covid vaccine, arguing that it should not be withheld from older high-risk Americans. As such, I am probably the only scientist that has been fired by CDC for being too pro-vaccine. (Four days after removing me from the working group, CDC reversed itself and lifted the pause.)

5. I have extensively studied and commented on the necessity and safety of vaccine requirements for different population groups with different benefit-risk profiles, including COVID-19 recovered individuals with natural immunity. I am intimately familiar with the data sources and the medical literature on this topic, as it pertains to both clinical practice and government health policy.

6. My writings on COVID-19-related issues have appeared in both scientific journals (like *Emerging Infectious Diseases, The Lancet* and *Annals of Epidemiology*) and in the popular press around the world (including the *Wall Street Journal*, *Newsweek, CNN, The Hill, the Telegraph, the Spectator, the Toronto Sun, Aftonbladet, Dagens Nyheter*, and many other). I have appeared as an invited guest on national and international news and debate programs in the United States, the United Kingdom, Ireland, Sweden, Germany, France, Spain, India, Mexico, Chile, Argentina and Uruguay, among other countries, including Fox News, Democracy Now, Munk Debates, NewsMax, GB News, Hindustan Times and Infobae.

7. As part of my professional work, I communicate scientific information not only through scientific journals, but also through social media. I have maintained a Twitter account since May 2014, and a LinkedIn account for approximately the same amount of time. I currently have 250,800 followers on Twitter and 13,400 contacts and followers on LinkedIn. Some of these followers reside in Missouri and Louisiana.

8. As a public health scientist, I have experienced censorship on social media platforms due to my views on the appropriate strategy for handling the COVID-19 pandemic. Since April 2020, I have argued for better focused protection of older, high-risk people, at the same time, as we should let children go to school and let young adults live near normal lives so as to minimize the collateral public health damage from these lockdowns and other measures.[1]

9. On October 4, 2020, two other epidemiologists and I published the "Great Barrington Declaration" online.[2] My co-authors were Dr. Jayanta Bhattacharya of Stanford University, and Dr. Sunetra Gupta of the University of Oxford.

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[1] The Epoch Times (2021), "Censorship of Science, with Dr. Martin Kulldorff, Dr. Scott Atlas, and Dr. Jay Bhattacharya," May 2, 2021. https://www.theepochtimes.com/live-censorship-of-science-with-dr-martin-kulldorff-dr-scott-atlas-and-dr-jay-bhattacharya_4343061.html.

[2] Great Barrington Declaration, https://gbdeclaration.org/.

10. In the Great Barrington Declaration, we stated: "As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection." *Id.* The Declaration criticized current lockdown policies to respond to COVID-19, stating: "Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice." *Id.*

11. The Great Barrington Declaration was publicly co-signed by 43 medical and public health scientists and practitioners, including a former chair of the Department of Epidemiology at Harvard School of Public Health. It has subsequently been co-signed by over 930,000 people, including over 15,000 medical and public-health scientists, and over 47,000 medical practitioners.

12. On October 8, 2020, four days after the Declaration's publication online, then-Director of National Institutes of Health, Dr. Francis Collins, emailed Dr. Anthony Fauci and Cliff Lane at NIH/NIAID about the Great Barrington Declaration. This email stated: "Hi Tony and Cliff, See: https://gbdeclaration.org/. This proposal from the three fringe epidemiologists who met with the Secretary seems to be getting a lot of attention – and even a co-signature from Nobel Prize winner Mike Leavitt at Stanford. There needs to be a quick and devastating published take down of its premises. I don't see anything like that online yet – is it underway? Francis." This email was produced over a year later in response to FOIA requests.[3]

[3] Wall Street Journal Editorial Board. (2021) "How Fauci and Collins Shut Down Covid Debate" *Wall Street Journal*. Dec. 21, 2021. https://www.wsj.com/articles/fauci-collins-emails-great-barrington-declaration-covid-pandemic-lockdown-11640129116

13. In a recent speech I gave on May 2, 2022, I summarized many of the instances of social-media censorship that I experienced after publishing the Great Barrington Declaration.[4]

14. After the Great Barrington Declaration was published, I noted that there was an organized campaign against the Great Barrington Declaration with various sorts of strange accusations. By other scientists, we were equated with 'exorcism', 'eugenics', 'clowns', 'anti-vaxxers', 'Trumpian', 'libertarian', 'Koch funded' and 'pseudo scientists'. We were accused of writing the Declaration for financial gains, even though the opposite is true. We were accused of threatening others, which none of us have done.

15. Soon after the Great Barrington Declaration was published, it was censored on social media in an apparent attempt to prevent it from (in Dr. Collins' words) "getting a lot of attention." This included Google deboosting search results for the Declaration within a few days of Dr. Collins' email to Dr. Fauci. In the first few days after its publication, the Great Barrington Declaration came up at the top in the search engine in Google, but then suddenly it wasn't there. Instead, what was there was those who criticized it. Other search engines still had it at the top, but not Google.

16. The Declaration was later censored on Facebook: They took down the Great Barrington Declaration page for about a week, with no explanation. The offending post was a pro-vaccine post arguing that we should prioritize giving the vaccines to older, high-risk people.

17. I also experienced extensive censorship on social media on my personal accounts. For example, in March 2021 Twitter censored my tweet stating that "Thinking that everyone must be vaccinated is as scientifically flawed as thinking that nobody should. COVID vaccines are

[4] The Epoch Times (2021), "Censorship of Science, with Dr. Martin Kulldorff, Dr. Scott Atlas, and Dr. Jay Bhattacharya," May 2, 2021. https://www.theepochtimes.com/live-censorship-of-science-with-dr-martin-kulldorff-dr-scott-atlas-and-dr-jay-bhattacharya_4343061.html.

important for older, higher risk people and their caretakers. Those with prior natural infection do not need it. Nor children."

18. I was also censored by Twitter for two tweets about masks. In one I wrote that, "Naïvely fooled to think that masks would protect them, some older high-risk people did not socially distance properly, and some died from #COVID19 because of it. Tragic. Public health officials/scientists must always be honest with the public." For three weeks starting in May 2021, I had no access to Twitter because of this tweet.

19. On November 5, 2021, I posted a direct quote from Dr. Roberto Strongman, an Associate Professor of Black Studies at the University of California-Santa Barbara. In a recent essay, he had reflected on the historical use of enforced mask use among enslaved populations. My tweet simply quoted his words that: "Masks are symbols of submission / Masks are the lurid fetish of power / Masks lead to the erasure of personhood / Masks promote a culture of fear / Masks are deterrents of solidarity," in quotation marks with an attribution to Dr. Strongman. Twitter censored this tweet by labeling it "Misleading" and preventing it from being replied to, shared, or liked.

20. Twitter is an important venue for communicating accurate public health information to the public. Because of the censoring, and the suspension of other scientists, I have had to self-censor myself on the platform. Sometimes by not posting at all and sometimes through imaginative phrasing. Here is one example of such a tweet: "Having been censored by Twitter, I must be careful what I write about masks: If you do surgery, please wear a surgical mask. It protects your patients."

21. On March 18, 2021, I participated in a two-hour roundtable discussion with Governor Ron DeSantis in Florida, along with Dr. Sunetra Gupta at Oxford, Dr. Jay Bhattacharya at Stanford and Dr. Scott Atlas at Stanford. In this discussion, we made remarks critical of COVID-19 restrictions, including mask mandates on children. I stated that "children should not wear face masks, no. They

don't need it for their own protection, and they don't need it for protecting other people either." Dr. Bhattacharya stated that "children develop by watching other people" and that it is "developmentally inappropriate" to require young children to wear face masks. Dr. Atlas pointed out that "there's no scientific rationale or logic to have children wear masks in schools." Dr. Gupta stated that "to force [children] to wear masks and distance socially, all of that to me is in direct violation of our social contract." In the same roundtable, we also argued against vaccine passports. 'Let's try to argue against that from the very beginning before it sort of takes off.' Unfortunately, the video of the roundtable was removed by YouTube, which is owned by Google.

22. I have also experienced censorship on LinkedIn, which is a popular communications platform among scientists and other professionals. In August 2021, LinkedIn censored a post where I linked to an interview I did with The Epoch Times on the dangers of vaccine mandate. LinkedIn said that 'Only you can see this post.' So, I could still read my own post, but nobody else could, which defeats the whole purpose.

23. The same week, LinkedIn also censored me when I reposted a LinkedIn post by a colleague from Iceland where he cited what the Icelandic chief epidemiologist had said. I did not add any text to the repost, so in this case LinkedIn censored the words of a government public health official: Iceland's equivalent of the CDC director in the U.S.

24. In October 2021, LinkedIn censored a post where I defended health care jobs, pointing out that natural immunity from covid infection is stronger than vaccine induced immunity, so that hospitals should hire rather than fire nurses and other health care providers with natural immunity, and use them for the patients that are the most vulnerable to Covid-19.

25. In November 2021 I wrote a Newsweek op-ed together with Dr. Jay Bhattacharya were we criticized the official Covid-19 response as formulated by Dr. Anthony Fauci. When I posted a

quote from and a link to the Newsweek article, it was removed by LinkedIn, which is owned by Microsoft. Ironically, Microsoft News (msn.org) republished the same Newsweek op-ed verbatim.

26. In January 2022, LinkedIn terminated my account for posting about the benefits of natural immunity. My last post before suspension was: "By firing staff with natural immunity after COVID recovery, hospitals got rid of those least likely to infect others." LinkedIn restored my account after my termination received media attention, but I now have to be very careful with what I write.

27. Twitter and LinkedIn are important venues for communicating accurate public health information to other scientists and to the public. Because of the censoring, and the suspension of other scientists, I have had to self-censor myself on both platforms. Sometimes by not posting important public health information. At other times, I have had to express my thoughts indirectly through imaginative phrasing. For example, on March 15, 2022, I tweeted: "Having been censored by Twitter, I must be careful what I write about masks: If you do surgery, please wear a surgical mask. It protects your patients." This, obviously, was a very indirect and oblique way of communicating the limited utility of wearing masks and expressing my criticism of mask mandates, including the widespread use of cloth masks.

28. Social-media censorship has not focused solely on the co-authors of the Great Barrington Declaration but has swept in many other scientists as well. These censorship policies have driven scientists and others to self-censor, as scientists like me restrict what we say on social-media platforms to avoid suspension and other penalties. In fact, the most devastating consequence of censoring is not the actual posts or accounts that are censored or suspended, but the reluctance of scientists to openly express and debate scientific questions using their varied scientific expertise. Without scientific debate, science cannot survive.

29. It can sometimes appear random who are being censored, but that serves the purpose of the censors. They cannot monitor every post from every user. By censoring a variety of individuals, some scientists and some non-scientists, some journalists, some private individuals, some anonymous accounts, some after warnings and others suddenly without a warning and some account with many followers and other accounts with few followers, the censors are able to make everyone scared and make everyone self-censor.

30. It has been stunning to be a scientist during these last two years. We have NIH Director Collins and NIAID Director Fauci thinking that you promote science by silencing scientists through published takedowns. It is absurd. We have a geneticist and a virologist thinking they know epidemiology better than epidemiologists at Oxford, Harvard and Stanford, calling us "fringe epidemiologists."

I swear or affirm under penalty of perjury that the foregoing is true and correct.

Dated: June 8, 2022 Signed: */s/ Martin Kulldorff*