No. 21-1463

In the Supreme Court of the United States

STATES OF MISSOURI, NEBRASKA, ALASKA, ARKANSAS, IOWA, KANSAS, NEW HAMPSHIRE, NORTH DAKOTA, SOUTH DAKOTA, AND WYOMING,

Petitioners,

v.

JOSEPH R. BIDEN, JR., *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

REPLY BRIEF

DOUGLAS J. PETERSON
Nebraska Attorney General
JAMES A. CAMPBELL
Solicitor General
OFFICE OF THE NEBRASKA ATTORNEY GENERAL
2115 State Capitol
Lincoln, NE 68509
(402) 471-2682

ERIC S. SCHMITT
Missouri Attorney General
D. JOHN SAUER
Solicitor General
Counsel of Record
MICHAEL E. TALENT
Deputy Solicitor General
OFFICE OF THE MISSOURI ATTORNEY GENERAL
Supreme Court Building
P.O. Box 899
Jefferson City, MO 65102
(573) 751-8870
John.Sauer@ago.mo.gov

Counsel for Petitioners

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REPLY BRIEF

On January 13, 2022, there was "no real dispute that this case merits our review." *Missouri* v. *Biden*, 142 S. Ct. 647, 655 (2022) (Thomas, J., dissenting). The only change since then is that the Government has now prevailed instead of losing below. This Court's review standards are not a one-way ratchet for the Government. Moreover, time and the Omicron variant have refuted the Mandate's most basic premise—*i.e.*, that the vaccines supposedly prevent infection and transmission of COVID-19. Even Dr. Fauci has grudgingly admitted that they do not. All that remains is a policy that forces thousands of healthcare workers—many of whom valiantly remained at their posts during the pandemic's outbreak, contracted COVID-19, and obtained natural immunity—to lose their jobs, with no discernible benefit to patients. The Court should grant the petition and invalidate the Mandate.

I. This Court's Stay Opinion Did Not Decide the Merits.

This case warrants review because a lower federal court "has decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). When it had lost below, the Government vigorously urged that the case warrants review because it presents "an issue of exceptional national importance." Stay App. 16. In fact, that was the principal ground on which the Government urged this Court to review the case and stay the injunction. *See id.* (citing Sup. Ct. R. 10(c)).

The Government argues that this Court's stay opinion "did not couch [its] holding in terms of likelihood of success." Br. in Opp. 11. But the Court

did not have to "couch its holding" using any particular phrasing. The Court's standards for granting a stay of injunction are well established, and they have been recently and repeatedly reaffirmed. *See, e.g., Merrill* v. *Milligan*, 142 S. Ct. 879, 879 (2022) (Kavanaugh, J., concurring); *Little* v. *Reclaim Idaho*, 140 S. Ct. 2616, 2616 (2020) (Roberts, C.J., concurring); *Teva Pharms. USA, Inc.* v. *Sandoz, Inc.*, 572 U.S. 1301, 1301 (2014); *Maryland* v. *King*, 567 U.S. 1301, 1302 (2012) (Roberts, C.J., in chambers); *Hollingsworth* v. *Perry*, 558 U.S. 183, 190 (2010). The stay "ruling means only that the Federal Government is likely to be able to show that this departure is lawful, not that it actually is so." *Missouri*, 142 S. Ct. at 659 (Alito, J., dissenting). A "stay order is not a ruling on the merits, but instead simply stays the District Court's injunction *pending a ruling on the merits*." *Merrill*, 142 S. Ct. at 879 (Kavanaugh, J., concurring). "To reiterate: The Court's stay order is not a decision on the merits." *Id.*

The Court's stay opinion did not purport to depart from these black-letter standards *sub silentio*. "This Court does not normally overturn, or so dramatically limit, earlier authority *sub silentio*." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 18 (2000). In *Missouri*, four dissenting Justices in two separate opinions noted that the ordinary stay standards applied, without any disagreement from the majority. *Missouri*, 142 S. Ct. at 655 (Thomas, J., dissenting); *id.* at 659 (Alito, J., dissenting). The Government itself, in its stay application, urged the Court to rely on these same factors. Stay App. 15 (citing *San Diegans for the Mt. Soledad Nat'l War Mem'l* v. *Paulson*, 548 U.S. 1301, 1302 (2006) (Kennedy, J., in chambers)).

In the end, the Government argues that the case warrants review only when the Government loses below, but not when it wins. Br. in Opp. 23. There is no basis in the Court's rules or case law for this lopsided standard, and the Court should not adopt it. Last January, the Government "succeeded in persuading" the Court "to accept [its] earlier position" that the case warrants review. *New Hampshire* v. *Maine*, 532 U.S. 742, 750 (2001). It is no less worthy of review now.

II. The Mandate Rests on "Stale Evidence," Not the States' Challenge to It.

The Government contends that the States' claims are based on "stale evidence." Br. in Opp. 19. This charge should be laid at the Government's feet.

According to the Government, the Mandate's fundamental premise that the vaccines prevent COVID-19 infection, and thus transmission to patients. *Id.* at 6. There was never much evidence to support this justification, as CMS admitted at the time. *See* 86 Fed. Reg. 61,615 ("[T]he effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] *not currently known*.") (emphasis added). And now, the Omicron variant has made very clear the vaccines' limited effectiveness in preventing infection and transmission of the virus.

Omicron "generated the largest waves of infection in" COVID-19, "even in countries with successful mass-vaccination campaigns." Ori Magen et al., *Fourth Dose of BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting*, NEW ENGLAND JOURNAL OF MEDICINE 2 (Apr. 13, 2022), https://www.nejm.org/doi/full/10.1056/NEJMoa2201688. Observers immediately noticed that Omicron

penetrated vaccine-induced immunity. As a recent study concluded, the vaccines' ability to stop infection and transmission of the Omicron variant is "negligible." Heba Altarawneh, et al., *Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections*, 387 NEW ENG. J. MED. 21 (June 15, 2022), *at* https://www.nejm.org/doi/pdf/10.1056/NEJMoa2203965 ("The effectiveness of vaccination with two doses of BNT162b2 and no previous infection was negligible").

The Omicron variant now accounts for all COVID-19 infections in the United States. *See* CDC COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (updated Sept. 7, 2022). Yet the Omicron variant "dramatically evades neutralizing antibody responses," and so it is able to infect those with prior vaccine-induced immunity. Jinyan Liu et al., *Vaccines Elicit Highly Conserved Cellular Immunity to SARS-CoV-2 Omicron*, 603 NATURE 493, 495 (2022). That, coupled with the waning of vaccine-mediated immunity over time, means that any vaccine-mediated immunity a person may have against Omicron largely disappears within six months of vaccination. *See, e.g.,* N. Andrews et al., *COVID-19 Vaccine Effectiveness Against the Omicron (B.1.1.529) Variant*, 386 NEW ENG. J. MED. 1532, 1537 (2022) (Pfizer vaccine's effectiveness against symptomatic Omicron infection went from 65.5 percent in the first month to 8.8 percent after six months); Neil Ferguson et al., *Report 49: Growth, Population Distribution and Immune Escape of Omicron in England*, at 8 (Dec. 16, 2021), https://spiral.imperial.ac.uk/handle/10044/1/93038 (finding "very limited" to "low protection" against Omicron from two-dose regimes); UK Health Sec.

Agency, *COVID-19 Vaccine Surveillance Report: Week 16*, at 3, 10, 11 tbl.3 (Apr. 21, 2022) (providing estimates showing that, after six months, vaccine efficacy against symptomatic infection was 0 to 20 percent, depending on vaccine). Even boosters, which the Mandate does not require, fail to provide long-term protection against infection and transmission. *See* Yinon M. Bar-On et al., *Protection by a Fourth Dose of BNT162b2 Against Omicron in Israel*, 386 NEW ENG. J. MED. 1712 (Apr. 5, 2022), *at* https://www.nejm.org/doi/full/10.1056/NEJMoa2201570 ("Protection against confirmed infection appeared short-lived" after "a fourth dose of BNT162b2 vaccine").

Even Dr. Fauci has grudgingly conceded that, "because of the high degree of transmissibility of this virus," the vaccines "don't protect overly well … against infection." *Fauci admits that COVID-19 vaccines do not protect 'overly well' against infection*, FOX NEWS (July 12, 2022), *at* https://www.foxnews.com/media/fauci-admits-covid-19-vaccines-protect-overly-well-infection. Thus, if anything rests on "stale evidence," Br. in Opp. 19, it is the Mandate itself.

In any event, the Government's claim that the States' arguments rest on "stale evidence" is baseless. The States seek review of the case based on the evidence they submitted to the district court in support of the judgment under review, which is the evidence that is properly before the Court on appeal. *See* Sup. Ct. R. 26.1; Fed. R. App. P. 10(a). The Government had a full and fair opportunity to dispute the States' 30 declarations before the district court, but it chose not to do so. The district court, therefore,

was entitled to credit the States' evidence, and it explicitly did so. App. 40a-45a.

In fact, the district court made a long series of specific factual findings based on the States' uncontested evidence. It found that this evidence "shows the harm to the physical health and well-being of the states' citizens if the mandate is not enjoined." App. 40a. It found that the evidence "demonstrate[s] that the mandate will more than likely exacerbate the already-existing staffing problem." *Id.* It found that the Mandate would cause "a cascade of consequences," such as "decreas[ing] the quality of care provided at facilities, compromis[ing] the safety of patients, and plac[ing] even more stress on the remaining staff." App. 41a. The district court also found that staffing losses "will diminish entire areas of care within a facility that inevitably implicate others." App. 42a. "Facilities in rural locations … will have to evaluate what healthcare services they could still safely provide, if any at all, in the region they serve." *Id.* The court next found that there would be "an especially hard impact to emergency services in rural areas." App. 42a-43a. And it found that "the loss of staffing in many instances will result in *no care at all*, as some facilities will be forced to close altogether." App. 43a. All these specific factual findings of the district court are soundly rooted in the States' evidence, which the Government chose not to dispute at the time. There is no basis to revisit any of them on appeal.

Nevertheless, the Government belatedly attempts to discredit Plaintiffs' 30 sworn declarations by citing a single hearsay-based Politico article printed months later that provides almost no specific information about conditions in the Plaintiff States. Br. in Opp.

19 & n.4 (quoting Megan Messerly, *Rural Hospitals Stave Off Mass Exodus of Workers to Vaccine Mandate*, POLITICO (Feb. 22, 2022), https://www.politico.com/news/2022/02/22/rural-hospitals-workers-vaccine-mandate-00010272).[1] If the Court wishes to consider *post-judgment* evidence of the Mandate's harms, it should not consider the unsworn hearsay of this Politico article; instead, it should consider the five additional sworn declarations the States submitted to Eighth Circuit on March 2, 2022, in support of their motion to expedite this appeal. C.A. Mot. to Expedite, Exs. B–F (Bollin, McClain, Schrage, Stalcup, and Ribordy Declarations). These March 2022 declarations post-date and contradict the Politico article's narrative, and they directly support the district court's factual findings and predictions. *See id.*

Among other things, these subsequent declarations attest to: a wave of closures of much-needed long-term care facilities in rural Missouri caused by the Mandate, Bollin Decl. ¶ 8, McClain Decl. ¶ 12; critical staffing shortages at remaining facilities, directly attributable to the Mandate, McClain Decl. ¶ 10; the imposition of "crisis staffing standards" at facilities in rural Kansas, with "staff … exhausted and overworked, which has reduced the quality of care that we can provide our patients," Stalcup Decl. ¶¶ 12, 15; rural facilities on a "path [that] is not financially sustainable" due to desperate

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[1] Even the Politico article admits that "[h]ospital officials in Arkansas, Colorado, Indiana, Maine, Montana, Nebraska, Nevada, North Dakota, South Dakota, Tennessee, Virginia, West Virginia and Wyoming said they are still facing significant staffing shortages." *Id.*

stopgap measures to fill staffing shortages, *id.* ¶ 14; skilled nursing facilities "barley able to staff our facilities" and forced to limit admissions of new patients, Ribordy Decl. ¶ 13; and a state of emergency for all rural healthcare facilities in the State of Nebraska. Neb. Exec. Order 22-02 (March 15, 2022).

The overseer of 13 skilled nursing facilities in rural Kansas stated: "Our facilities were stretched thin before the pandemic, but now we cannot find people to hire regardless of pay increases and bonuses we offer. Imposition of the [Mandate] is exasperating our already desperate situation." Ribordy Decl. ¶ 13. Like Politico, CMS simply ignored the concerns of these declarants and dozens of others like them. The fact that the Mandate exacerbates the "desperate situation" of rural healthcare facilities, *id.*, is a powerful factor favoring this Court's review.

III. CMS Did Not Believe Its Own Predictions of Doom.

In its opposition brief, the Government again emphasizes CMS's predictions that "hundreds" or "thousands" of deaths could occur per month without the Mandate. Br. in Opp. 9. As noted above, these baleful predictions never had a convincing scientific basis. *Supra* Part II. What is worse, CMS's subsequent actions demonstrate that CMS did not believe its own forecasts of doom.

This Court granted a stay of the preliminary injunction on January 13, 2022. *Missouri*, 142 S. Ct. at 650. The next day, January 14, 2022, CMS issued a memorandum *delaying the full implementation of the Mandate for another three months.* Department of Health & Human Services, Mem. QSO-22-09-ALL, *Guidance for the Interim Final Rule - Medicare and*

Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination 3-4 (Jan. 14, 2022). This delay pushed the Mandate's full effective date to April 15, 2022—well past the "winter spike" and "anticipated winter surge" that the Government had just emphasized in its stay briefing. Stay App. 2, 5. In QSO-22-09, CMS admitted that mere partial compliance with the Mandate—such as 80 percent staff-vaccination levels—typically would *not* "pose a threat to patient health and safety." *Id.* at 3, 4.

There is no evidence that delaying the Mandate resulted in a single additional injury or death to any patient, and the Government cites none. The Secretary did not behave as if he believed his own predictions of "hundreds" or "thousands" of deaths. When the rubber hit the road, the Secretary was evidently not quite so worried about preventing COVID-19 transmission from unvaccinated healthcare workers to patients. *See id.*

Unlike the Mandate itself, the Secretary's decision to *delay* the Mandate's full effect was perfectly rational. The Government contends that, in the Mandate, "the Secretary "explained that, *unless appropriate protections are implemented*, the virus can spread among healthcare workers and from workers to patients." Stay App. 9 (emphasis added). But, in the Mandate, the Secretary also conceded that "appropriate protections" had *already* been "implemented" prior the Mandate in the vast majority of facilities. *Id.* As CMS noted, "highly effective" precautions against transmission "have been *essentially universal in the health care sector during all of 2021*." 86 Fed. Reg. 61,557, 61,612 (emphasis added); *see also* Mo. Stay App. 45a, 99a, 103a.

The Secretary's actions speak louder than words. CMS adopted the Mandate, not out of concerns for patient safety, but because the President directed CMS to do so, for reasons unrelated to staff-to-patient transmission—*i.e.*, because he wanted to compel the vaccination of as many Americans as he could possibly reach. Pet. 4-5, 27-30. The Mandate targeted unvaccinated healthcare workers, not to protect their patients, but because they constituted a segment of millions of Americans that arguably lay within the reach of a federal power. *See id.* The Mandate is pretextual to its core.

IV. The Government's Other Arguments Lack Merit.

The Government's various other arguments lack merit. For one, the Government urges that medical organizations have recommended *private* vaccine requirements for healthcare workers. Br. in Opp. 7-8. But these organizations do not speak for small, rural, community-based healthcare systems, which attest urgently that they and their patients face devastation from the Mandate. Mo. Stay App. 35a-139a. Moreover, there is a great difference between private vaccination requirements, and the Government-imposed, mandatory, nationwide Mandate. The former can be disregarded or tailored to meet individual needs; the latter cannot.

The Government argues that the States already raised their arguments about reliance interests, pretext, and the Mandate's unconstitutionality. Br. in Opp. 17-18. On the contrary, within the compressed limits of the stay-stage briefing, the States raised their claim about pretext in one paragraph, Stay Opp. 27; their claim about reliance interests in two pages,

id. at 27-28; and their constitutional claims not at all.[2] Within the constraints of emergency-stay briefing, these meritorious claims received only limited attention, and no specific consideration in this Court's opinion. *See Missouri*, 142 S. Ct. 647.

The Government contends that "CMS had never adopted any formal or informal policy *against* vaccination requirements." Br. in Opp. 18. But the Government concedes that CMS (1) never imposed *any* vaccination requirement on healthcare workers in over 50 years of its existence; (2) explicitly considered whether to impose such a requirement earlier in the COVID-19 pandemic, and decided not to do so; but then (3) was ordered by the President to adopt one. *See* 86 Fed. Reg. 61,567, 61,568, 61,583. Having a decades-old practice of not mandating vaccines, and reconsidering and reaffirming that practice in the specific context of the COVID-19 pandemic, qualifies as a "formal or informal policy" to most speakers of ordinary English. Indeed, after denying that CMS had any "formal or informal policy," the Government admits in its next sentence that "[t]he agency … *changed course*" in imposing the Mandate. Br. in Opp. 18 (emphasis added). But "[w]hen an agency *changes course*, … it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Dep't of Homeland Sec.* v. *Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020) (emphasis added)

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[2] The *Missouri* district court failed to reach the States' constitutional claims, and the States did not raise them in the stay-stage briefing. The Government cites the *Louisiana* Plaintiffs' brief to argue that the constitutional claims were presented to this Court. *See* Br. in Opp. 20.

(quotation marks omitted). "It would be arbitrary and capricious to ignore such matters. Yet that is what [CMS] did." *Id.* (citations and quotation marks omitted).

The Government also contends that "the Secretary considered *the relevant staffing issues*." Br. in Opp. 18 (emphasis added). But merely considering "staffing issues" is not the same as considering legitimate *reliance* interests. It is one thing to consider staffing shortfalls in a vacuum, and quite another to consider staffing crises that *CMS itself caused* by inducing healthcare facilities to rely on its 50-year-old policy of not mandating vaccinations. *Regents*, 140 S. Ct. at 1913; *see also* Pet. 12-14; Mo. Stay App. 78a, 95a-96a, 119a. CMS was required to consider the latter, not just the former. *Id.*

The Governments' other arguments are meritless as well. The case presents questions of national importance that warrant this Court's review.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

DOUGLAS J. PETERSON
Nebraska Attorney General
JAMES A. CAMPBELL
Solicitor General
OFFICE OF THE NEBRASKA ATTORNEY GENERAL
2115 State Capitol
Lincoln, NE 68509
(402) 471-2682

ERIC S. SCHMITT
Missouri Attorney General
D. JOHN SAUER
Solicitor General
Counsel of Record
MICHAEL E. TALENT
Deputy Solicitor General
KENNETH C. CAPPS
Assistant Attorney General
OFFICE OF THE MISSOURI ATTORNEY GENERAL
Supreme Court Building
P.O. Box 899
Jefferson City, MO 65102
(573) 751-8870
John.Sauer@ago.mo.gov

Additional Counsel:

TREG R. TAYLOR
Attorney General of Alaska

LESLIE RUTLEDGE
Attorney General of Arkansas

JEFFREY S. THOMPSON
Solicitor General of Iowa

DEREK SCHMIDT
Attorney General of Kansas

JOHN M. FORMELLA
New Hampshire Attorney General

DREW H. WRIGLEY
North Dakota Attorney General

JASON R. RAVNSBORG
South Dakota Attorney General

BRIDGET HILL
Attorney General of Wyoming