No. 21-3725

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

STATE OF MISSOURI, et al.,
Plaintiffs-Appellees,
v.

JOSEPH R. BIDEN, JR., in his official capacity as President of the United States of America, et al.,
Defendants-Appellants.

RELIANT CARE MANAGEMENT COMPANY, L.L.C.,
Amicus Curiae,
AMERICAN ACADEMY OF FAMILY PHYSICIANS, et al.,
Amici on Behalf of Appellant(s).

On Appeal from the United States District Court
for the Eastern District of Missouri

REPLY BRIEF FOR APPELLANTS

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INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs urge this Court to affirm the preliminary injunction that the Supreme Court stayed in this case. Pl. Br. 56. Their brief reiterates the arguments that they made unsuccessfully in the Supreme Court.

Contrary to plaintiffs' contention, this Court is not free to disregard the Supreme Court's decision. That decision—issued after the Supreme Court took the extraordinary measure of hearing oral argument on the stay applications—conclusively rejected plaintiffs' challenges to the Interim Final Rule (IFR) on the merits. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam). There is nothing tentative or preliminary about the Supreme Court's reasoning. Accordingly, this Court should vacate the preliminary injunction and remand to the district court with instructions to enter judgment in the federal government's favor.

ARGUMENT

I. The Supreme Court's Decision Fully Resolved Plaintiffs' Challenges To The IFR.

A. The Supreme Court's Reasoning Was Not Tentative Or Preliminary.

The IFR required healthcare facilities that accept federal funding under the Medicare or Medicaid programs to develop and implement

policies to ensure that their covered staff were fully vaccinated against COVID-19, or had claimed an exemption, by January 4, 2022. *See* 86 Fed. Reg. 61,555, 61,573 (Nov. 5, 2021). The district court in this case issued a preliminary injunction that blocked the IFR's enforcement against facilities within the 10 plaintiff States, and this Court declined to stay that injunction. In *Louisiana v. Becerra*, -- F. Supp. 3d --, No. 3:21-CV-03970, 2021 WL 5609846 (W.D. La. Nov. 30, 2021), the district court issued a preliminary injunction that blocked the IFR's enforcement against facilities nationwide (carving out only the 10 States already covered by the injunction in this case). The Fifth Circuit stayed the injunction as applied to facilities outside the 14 plaintiff States but denied a stay of the injunction as applied to facilities within those States.

The government filed emergency applications asking the Supreme Court to stay the injunctions in their entirety. After hearing oral argument, the Supreme Court issued a decision conclusively resolving the challenges to the IFR on the merits, rather than relying on other factors such as the balance of harms. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam). Soon thereafter, the Centers for Medicare & Medicaid Services (CMS) indicated, as a matter of enforcement discretion, that it would monitor and

enforce compliance with the IFR for facilities within the plaintiff States under a timeline in which covered employees would receive their first vaccine shot, or claim an exemption, by February 14, 2022, and non-exempt employees would receive a second shot by March 15, 2022. *See* CMS, *External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule*, https://perma.cc/PUW4-Y39E (last updated Jan. 20, 2022).

Plaintiffs are manifestly wrong to argue that the Supreme Court's decision leaves this Court free to declare unlawful the same IFR that the Supreme Court upheld in this very case. Plaintiffs invoke the general principle that a "'stay order is not a decision on the merits.'" Pl. Br. 26 (quoting *Merrill v. Milligan*, 142 S. Ct. 879, 879 (2022) (Kavanaugh, J., concurring in grant of stay applications)). That general principle does not apply here, however, because the Supreme Court chose to resolve the merits of the dispute.

The Supreme Court's opinion was not tentative or preliminary. For the detailed reasons that it set forth, the Supreme Court definitively held that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Biden v. Missouri*, 142 S. Ct. at 652. The Court did not merely conclude that the Secretary was "likely" to succeed on that

issue. Likewise, the Supreme Court explained that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered below." *Id*. at 653. The Supreme Court held that "the interim rule is not arbitrary and capricious," *id*., and that plaintiffs' "[o]ther statutory objections to the rule fare no better," including their procedural claims, *id*. at 654.

Plaintiffs cannot plausibly equate the Supreme Court's opinion in this case with the ruling in *Merrill* on which they rely. There, the Supreme Court merely granted a stay without providing any explanation. *See Merrill*, 142 S. Ct. at 879. Here, by contrast, the Supreme Court held oral argument and issued an opinion providing extensive reasoning that conclusively rejected plaintiffs' challenges to the IFR on the merits. Accordingly, this Court should vacate the preliminary injunction and remand with instructions to enter judgment for the federal government.

B. Plaintiffs' Brief Reiterates The Arguments They Made To The Supreme Court.

Plaintiffs' brief simply reiterates the arguments that they and the plaintiffs in the parallel *Louisiana* case made unsuccessfully to the Supreme Court. The Supreme Court explicitly rejected plaintiffs' central arguments,

holding that the IFR was within the Secretary's statutory authority, that it was not arbitrary and capricious, and that the Secretary had good cause to issue the IFR without advance notice and comment.

Plaintiffs cannot circumvent the Supreme Court's decision by urging this Court to accept subsidiary arguments that the Supreme Court regarded as too insubstantial to warrant separate discussion. For example, in their Supreme Court brief, plaintiffs argued:

> The district court identified five reasons why the mandate is arbitrary and capricious: (1) CMS's lack of evidence regarding most of the covered healthcare facilities; (2) CMS's improper rejection of alternatives; (3) the mandate's irrationally broad scope; (4) CMS's pretextual change in course; and (5) CMS's failure to consider or properly weigh reliance interests and the risk that this failure will impose devastating consequences on healthcare services. App.18a-27a. To prevail on appeal, the Secretary must refute all five reasons. But he cannot rebut even one.

Response To Application For A Stay at 25, *Biden v. Missouri*, No. 21A240 (U.S. Dec. 30, 2021). Plaintiffs then went on to defend each of the five subsidiary reasons offered by the district court for declaring the IFR arbitrary and capricious. *See id.* at 25-32.

Nonetheless, the Supreme Court expressly held that "the interim rule is *not* arbitrary and capricious." *Biden v. Missouri*, 142 S. Ct. at 653 (emphasis added). "Given the rulemaking record," the Supreme Court

rejected the contention that "the Secretary failed to 'examine the relevant data and articulate a satisfactory explanation for' his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of employees with 'natural immunity' from prior COVID–19 illness; and (3) depart from the agency's prior approach of merely encouraging vaccination." *Id.* at 653-54 (first quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983); and then citing 86 Fed. Reg. at 61,583, 61,559-61, 61,614). The Supreme Court likewise rejected the contention that "the Secretary 'entirely failed to consider' that the rule might cause staffing shortages, including in rural areas." *Id.* at 654 (first quoting *State Farm*, 463 U.S. at 43; and then citing 86 Fed. Reg. at 61,566, 61,569, 61,607-09).

Plaintiffs emphasize that the Supreme Court did not specifically discuss their "pretext[]" and "reliance" arguments. Pl. Br. 24. That is irrelevant because the Supreme Court explained that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered below." *Biden v. Missouri*, 142 S. Ct. at 653. In other words, none of the arguments presented by either set of plaintiffs had persuaded the Supreme Court.

C. Plaintiffs' Constitutional Challenges To The IFR Are Foreclosed By The Supreme Court's Decision In This Case And By Other Supreme Court Precedent.

Plaintiffs' constitutional claims are foreclosed by both the Supreme Court's decision in this case and by other Supreme Court precedent.

Plaintiffs emphasize that the district court did not reach their constitutional claims. Pl. Br. 42. However, the district court in the *Louisiana* case addressed the constitutional challenges to the IFR, and the *Louisiana* plaintiffs urged the Supreme Court to uphold that injunction on the basis of those challenges. *See* Response To Application For A Stay Pending Appeal at 26, *Becerra v. Louisiana*, Nos. 21A240 & 21A241 (U.S. Dec. 30, 2021). The *Louisiana* plaintiffs urged the Supreme Court that, "[i]f Congress authorized the Mandate, it is unconstitutional under both the Spending Clause and the Non-Delegation Doctrine." *Id.* In advancing the Spending Clause argument, they claimed that their state-run facilities did not have constitutionally sufficient notice of the vaccination requirement and that, "even if they had notice, the condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds." *Id.* at 27. They also argued that, if any statutory provision "authorizes the Secretary to legislate the vaccination

schedules of 10.4 million healthcare workers, it is an unconstitutional delegation of legislative authority." *Id.* And they urged the Supreme Court that, "[a]t a minimum, those constitutional concerns warrant construing [the statute] to avoid them." *Id.*; *see also id.* at 27-28 (emphasizing that "statutes should be construed to avoid constitutional questions if such a construction is fairly possible" (quoting *Boos v. Barry*, 485 U.S. 312, 333 (1988))).

The Supreme Court was unpersuaded and upheld the IFR as a valid condition of federal funding. The Supreme Court reasoned that the "vaccination requirement" was "a straightforward and predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose" on facilities that accept federal funds under Medicare or Medicaid. *Biden v. Missouri*, 142 S. Ct. at 653. The Supreme Court concluded that this funding condition was "not a surprising one." *Id.*

That reasoning forecloses plaintiffs' constitutional claims. Plaintiffs' assertion that the vaccination requirement "is a surprising and unprecedented requirement that no informed reader of the relevant statutes—including CMS itself—could have reasonably anticipated," Pl.

Br. 42, cannot be squared with the Supreme Court's conclusion that the vaccination requirement was a "predictable" and "not . . . surprising" exercise of the Secretary's statutory authority, *Biden v. Missouri*, 142 S. Ct. at 653.

Likewise, because the Supreme Court upheld the vaccination requirement as a condition of federal funding, plaintiffs' contention that the IFR is "coercive" or "commandeers" state-run facilities necessarily fails. *See* Pl. Br. 46 (arguing that the vaccination requirement "is unconstitutionally coercive for the reasons discussed in the anti-commandeering section below"). Although "the Federal Government may not compel the States to enact or administer a federal regulatory program," *Printz v. United States*, 521 U.S. 898, 933 (1997) (quoting *New York v. United States*, 505 U.S. 144, 188 (1992)), it is well settled that valid conditions on federal funds are not commandeering. *See New York*, 505 U.S. at 167, 173 (contrasting funding conditions with commandeering); *Printz*, 521 U.S. at 936 (O'Connor, J., concurring). Furthermore, "[t]he anticommandeering doctrine does not apply when Congress evenhandedly regulates an activity in which both States and private actors engage." *Murphy v. National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1478 (2018). Here, the IFR applies

evenhandedly to state-run facilities and privately-run facilities, which forecloses plaintiffs' claim that the IFR coerces or commandeers state-run facilities. And the anti-commandeering doctrine has no application whatsoever to the vast number of Medicare- and Medicaid-participating facilities that are run by private entities.

Plaintiffs' Tenth Amendment "police power" claim (Br. 49) is equally groundless and adds nothing to their other arguments. The Supreme Court has long acknowledged—and the Constitution expressly provides—that "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). The Supreme Court has also long recognized that when Congress acts pursuant to its Spending Clause power, it may do so in ways that serve objectives traditionally thought of as within the police power of the States. *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (upholding a state minimum drinking age as a condition on the acceptance of federal funds). Congress's power to impose conditions on the acceptance of federal funds applies regardless of whether Congress legislates "in an area historically of state

concern." *Sabri*, 541 U.S. at 608 n.*. Plaintiffs' constitutional challenges to the IFR are thus foreclosed by Supreme Court precedent.

D. Plaintiffs Cannot Circumvent The Supreme Court's Decision By Asserting That The Omicron Variant Made The IFR "Obsolete."

Plaintiffs' argument regarding the balance of harms is legally irrelevant because the Supreme Court resolved the merits of their challenges to the IFR in the federal government's favor. In any event, plaintiffs' equitable arguments simply rehash the arguments that they made unsuccessfully to the Supreme Court.

Plaintiffs cannot circumvent the Supreme Court's decision by asserting that the Omicron variant rendered the IFR "obsolete." Pl. Br. 56. The Supreme Court was well aware of the Omicron variant, which was discussed in the Supreme Court briefing. In upholding the IFR, the Supreme Court applied the bedrock administrative-law principle that the validity of the rule is determined based on the record that was before the agency when the rule was issued, "not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam). Furthermore, the Supreme Court admonished that the district courts had erred by substituting their views of the data for the Secretary's expert

judgment. *Biden v. Missouri*, 142 S. Ct. at 654. By asserting that vaccines are ineffective in preventing the transmission of Omicron, plaintiffs invite this Court to replicate the error that the Supreme Court identified.

More generally, the forum for a "changed circumstances" argument is the agency, not the district court. The Supreme Court has long held that when a party affected by a rule believes that changed circumstances warrant a change, "[t]he proper procedure for pursuit of [that] grievance is set forth explicitly in the APA: a petition to the agency for rulemaking, § 553(e), denial of which must be justified by a statement of reasons, § 555(e), and can be appealed to the courts, §§ 702, 706." *Auer v. Robbins*, 519 U.S. 452, 459 (1997) (citing 5 U.S.C. §§ 553(e), 555(e), 702, 706). The question whether evolving pandemic conditions warrant a change in policy is quintessentially a matter for the Secretary. Likewise, it is for the Secretary to evaluate the empirical evidence regarding the effects of the IFR's implementation on staffing. *See, e.g.*, Megan Messerly, *Rural Hospitals Stave Off Mass Exodus of Workers to Vaccine Mandate*, Politico (Feb. 22, 2022), https://perma.cc/BKS6-8T8W (reporting, based on interviews with "[n]early two dozen rural hospital officials and state hospital association

leaders," that predictions that "the mandate would lead to a workforce crisis and limit care, particularly in rural areas, have not been borne out").

Such questions could not properly be addressed by a court in the first instance. A court has authority only to review—not to make—agency policy. As the Supreme Court emphasized in this case: "[T]he role of courts in reviewing arbitrary and capricious challenges is to 'simply ensur[e] that the agency has acted within a zone of reasonableness.'" *Biden v. Missouri*, 142 S. Ct. at 654 (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).[1]

II. Plaintiffs' Argument About The Role Of State Survey Agencies Has No Bearing On The IFR And Is, In Any Event, Meritless.

Plaintiffs alternatively contend that CMS cannot "forc[e] their state surveyors to enforce the CMS vaccine mandate." Pl. Br. 44; *see also id.* at 47. That argument has no bearing on the validity of the IFR itself and could not be a basis to affirm the preliminary injunction.

The argument also fails on its own terms. "State survey agencies" are state agencies that choose to enter into agreements with CMS to inspect

[1] Plaintiffs' letter of March 3, 2022 noted a Senate resolution disapproving the IFR, but a Senate resolution cannot amend existing law.

facilities for compliance with the conditions of Medicare and Medicaid funds. As the government explained in the Supreme Court, a State's decision to enter into a survey agreement with CMS is voluntary. *See* Gov't Appl. Reply Br. at 17 n.5, *Becerra v. Louisiana*, Nos. 21A240 & 21A241 (U.S. Jan. 3, 2022) (quoting 42 U.S.C. § 1395aa(a)) (providing that "[t]he Secretary shall make an agreement with any State which is able and *willing* to do so") (emphasis added in the Supreme Court reply brief).

A State that wishes to do so enters into an agreement (known as a "Section 1864 Agreement") with the federal government under which its survey agency is paid to conduct periodic surveys to determine whether providers meet conditions of Medicare and Medicaid participation. *See* 42 U.S.C. § 1395aa(a); *see also* 42 C.F.R. § 488.10(a). A state survey agency that enters into a Section 1864 Agreement with the federal government agrees to survey providers for compliance with all of the applicable standards of the Medicare and Medicaid conditions of participation, including (but not limited to) the IFR.

CMS has explained that, if a state survey agency were not to fulfill that agreement, CMS would reduce the state agency's payments for survey activities by an amount "commensurate with the impact of the State actions

and the federal resources needed to provide appropriate oversight of providers and suppliers." CMS, *State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement* at 2 (Feb. 9, 2022), https://go.cms.gov/34PVy24. That statement reflects the unremarkable fact that a state survey agreement is a contract, and CMS provides funds to the state survey agency in exchange for its performance of a contractual agreement to conduct surveys.

Because state survey agreements are voluntary, they cannot be the basis for a commandeering claim. In any event, this Court could not properly adjudicate at this juncture a hypothetical dispute arising out of state survey activities. As noted above, this issue has no bearing on the validity of the IFR and could not be a basis to affirm the preliminary injunction. Assuming that one or more state survey agencies in the plaintiff States refuse to conduct survey activities, and assuming that CMS reduces the payment to those state survey agencies as a result, the state survey agencies could challenge the payment reduction at that time.[2]

[2] We note that plaintiffs mischaracterize the role of state survey agencies. *See* Pl. Br. 47. State survey agencies report their findings to CMS; enforcement action is the responsibility of CMS alone. *See* 42 C.F.R.

CONCLUSION

The Court should vacate the preliminary injunction and remand to the district court with instructions to enter judgment for the federal government.

Respectfully submitted,

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§§ 488.11, 488.12; 488.20(b). Moreover, a state survey agency's failure to survey providers does not disqualify the providers from program participation. All Medicare and Medicaid certified facilities are allowed to continue participation until a survey makes an initial finding of a violation because enforcement remedies are imposed only on the basis of survey findings showing violations. *See id.* §§ 488.28; 488.402(b). Even then, the facility generally would remain certified while it has the opportunity to correct any violations by submitting a plan of correction to CMS. *See Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 21-22 (2000) (noting that terminations are rare and reserved for the "most egregious and recidivist" facilities); 42 C.F.R. § 488.412(a)(2) (affording CMS discretion to delay termination for up to six months while facility attempts to correct violations under a plan of correction).

CERTIFICATE OF COMPLIANCE

This reply brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,210 words. This reply brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

Pursuant to Circuit Rule 28A(h)(2), I further certify that the brief has been scanned for viruses, and the brief is virus free.

/s/ Laura E. Myron
Laura E. Myron

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2022, I electronically filed the foregoing reply brief with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Laura E. Myron
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