In the Supreme Court of the United States

XAVIER BECERRA., SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

APPLICANTS,

v.

STATE OF LOUISIANA, ET AL.

On Application for A Stay of the Injunction Issued by the United States District Court for the Western District of Louisiana Pending Appeal to the United States Court of Appeals for the Fifth Circuit and Further Proceedings in this Court

MOTION FOR LEAVE TO FILE AND BRIEF OF SERVICE EMPLOYEES INTERNATIONAL UNION, AMERICAN FEDERATION OF TEACHERS, AND AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES AS AMICI CURIAE IN SUPPORT OF APPLICANTS

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MOTION FOR LEAVE TO FILE

Proposed *amici curiae* Service Employees International Union (SEIU) et al. respectfully move for leave to file a brief in support of the federal government and its stay application and to file the enclosed brief without 10 days' advance notice to the parties of amici's intent to file. *See* Sup. Ct. R. 37.2(a). Respondents do not oppose the filing of this brief, and the federal applicants take no position on it.¹

INTERESTS OF MOVANTS

SEIU is a labor organization representing approximately two million working men and women in the United States, Canada, and Puerto Rico. SEIU represents hundreds of thousands of healthcare workers, and has advocated since the beginning of the Covid-19 pandemic for safe working conditions that allow SEIU members to deliver quality care to their patients. The preliminary injunction issued by the district court, by preventing implementation of a Medicaid and Medicare participation requirement designed to protect patients in advance of the winter surge of Covid-19 cases, endangers healthcare workers in hospitals, skilled nursing facilities, clinics, and other health facilities throughout the country.

The American Federation of Teachers (AFT), an affiliate of the AFL-CIO, was founded in 1916. The AFT represents 200,000 healthcare workers, as well as other essential frontline workers in public services,

¹ No counsel for any party authored this amicus brief in whole or in part, and no person or entity other than amici curiae, its members, or its counsel made a monetary contribution intended to fund the brief's preparation or submission. Sup. Ct. R. 37.6.

K-12 education and higher education, totaling 1.7 million members who have worked tirelessly during the Covid-19 pandemic. Healthcare workers and the patients they serve are endangered by the preliminary injunction issued by the district court, which prevents implementation of a vaccine mandate for staff of participants in the Medicaid and Medicare programs.

The American Federation of State, County and Municipal Employees, AFL-CIO (AFSCME) is a labor organization of 1.4 million working people who provide vital public services around the nation. AFSCME represents workers across the full range of healthcare occupations, including nurses, doctors, EMTs, therapists, CNAs and more, in all types of medical, nursing, mental and behavioral health facilities and centers, many of which participate in the Medicaid and Medicare programs. AFSCME members have been on the front lines of the Covid-19 pandemic, and the district court's preliminary injunction needlessly jeopardizes its members' safety.

Proposed amici have a strong interest in the outcome of this litigation and respectfully submit that their perspective will aid this Court's deliberations.

Given the expedited consideration of this matter of urgent and national concern, proposed amici also respectfully request leave to file the enclosed brief without 10 days' advance notice to the parties of intent to file. The court of appeals denied the federal government's emergency motion for a stay on December 15, 2021. The application to this Court for a stay was filed on December 16, 2021. On December 17, 2021, the Court set a deadline of 4 p.m. on December 30, 2021, for Respondents' brief. Further, in light of the expedited nature of this matter, proposed amici are providing electronic page proofs of this motion and attached brief to counsel for the parties on December 21, with printed booklets to follow via overnight mail on December 22, 2021.

For the foregoing reasons, SEIU et al. respectfully request that the Court grant leave to file the enclosed brief in support of the stay application.

Dated: December 22, 2021 Respectfully submitted,

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141 S. Ct. 2485 (2021)	13, 16
Alexander v. Sandoval, 532 U.S. 275 (2001)	12
Ali v. Fed. Bureau of Prisons, 552 U.S. 214 (2008)	16
Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019)	15
<i>Diamond v. Chakrabarty,</i> 447 U.S. 303 (1980)	17
FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)	13
Gonzales v. Oregon, 546 U.S. 243 (2006)	16
Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242 (2010)	10
Harris Tr. & Sav. Bank v. Salomon Smith	
Barney, Inc., 530 U.S. 238 (2000)	12
<i>King v. Burwell</i> , 576 U.S. 473 (2015)	13

Lewis v. City of Chicago, Ill., 560 U.S. 205 (2010)15
Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania, 140 S. Ct. 2367 (2020)17, 18
Mourning v. Fam. Publications Serv., Inc., 411 U.S. 356 (1973)17
Rasulis v. Weinberger, 502 F.2d 1006 (7th Cir. 1974)
Ross v. Blake, 578 U.S. 632 (2016)12
Sabri v. United States, 541 U.S. 600 (2004)15, 16
United States Forest Serv. v. Cowpasture River Pres. Ass'n, 140 S. Ct. 1837 (2020)13
Utility Air Regulatory Group v. EPA, 573 U.S. 302 (2014)
Watt v. Energy Action Educ. Found., 454 U.S. 151 (1981)
Yates v. United States, 574 U.S. 528 (2015)
Statutes
42 U.S.C. § 1302
42 U.S.C. § 1395bbb9

42	U.S.C. §	1395eee	9
42	U.S.C. §	1395d	8, 9
42	U.S.C. §	1395hh	8
42	U.S.C. §	1395i-3	9, 11
42	U.S.C. §	1395i-4	9
42	U.S.C. §	1395x	.8, 9, 10, 11
42	U.S.C. §	1395rr	10
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Regulations

42	C.F.R. §	482.42			•••••	.13
51	Fed. Re	g. 22,010-01	(1986)		13,	14
86	Fed. Re	g. 61,555-01	(Nov. 5, 202	21)2,	8, 10,	13

Other Authorities

Aaron Richterman et al., Hospital-Acquired	
SARS-CoV-2 Infection: Lessons for	
Public Health, JAMA (Nov. 13, 2020),	
https://jamanetwork.com/journals/jama/f	
ullarticle/2773128	4

Alyson M. Cavanaugh et al., COVID-19
Outbreak Associated with a SARS-CoV-2
R.1 Lineage Variant in a Skilled
Nursing Facility After Vaccination
Program — Kentucky, March 2021 (Apr.
21, 2021), https://
www.cdc.gov/mmwr/volumes/70/wr/mm7
017e2.htm?s_cid=mm7017e2_w5
Jessica Ibiebele et al., Occupational
COVID-19 exposures and secondary
cases among healthcare personnel, Am.
J. of Infection Control (Aug. 8, 2021),
https://www.ncbi.nlm.nih.gov/pmc/articl
es/PMC8349432/
Eric C. Schneider et al., The U.S. COVID-
19 Vaccination Program at One Year:
How Many Deaths and Hospitalizations
Were Averted?, The Commonwealth
Fund (Dec. 14, 2021),
https://www.commonwealthfund.org/pub
lications/issue-briefs/2021/dec/us-covid-
19-vaccination-program-one-year-how-
many-deaths-and
Lost on the frontline: Thousands of US
healthcare workers died fighting Covid-
19. We counted them and investigated
why, The Guardian (Apr. 8, 2021),
https://www.theguardian.com/us-
news/ng-interactive/2020/aug/11/lost-on-
the-frontline-covid-19-coronavirus-us-
healthcare-workers-deaths-database
nearmeare workers acams aatabase

Our key findings about US healthcare worker	
deaths in the	
pandemic's first year, The Guardian (Apr.	
8, 2021),	
https://www.theguardian.com/us-news/ng-	
interactive/2020/dec/22/lost-on-the-	
frontline-our-findings-to-date	3, 4
Brenda Goodman and Andy Miller, A	
Disturbing Number of Hospital Workers	
Still Unvaccinated, GPB News (June 29,	
2021), https://www.gpb.org/news/2021/0	
6/29/disturbing-number-of-hospital-	
workers-still-unvaccinated	4
Long H. Nguyen et al., Risk of COVID-19	
among frontline healthcare worker and	
the general community; a prospective	
cohort study, medRxiv (May 25, 2020),	
https://www.ncbi.nlm.nih.gov/pmc/articl	
es/PMC7273299/.	3
Roni Caryn Rabin, An unvaccinated worker set	
off an outbreak at a U.S. nursing home where	
most residents were	
<i>immunized</i> , New York Times (Apr. 21, 2021),	
https://www.nytimes.com/2021/04/21/health/	
vaccine-nursing-homes-infections.html	5

INTERESTS OF AMICI CURIAE

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Amici have a strong interest in the outcome of this litigation and respectfully submit that their perspective will aid this Court's deliberations.

INTRODUCTION

Amici submit this brief to highlight the real-life experiences of healthcare workers on the frontlines of the Covid-19 pandemic who have experienced the dangers of under-vaccination firsthand and who strongly support vaccination for staff members at healthcare facilities. Amici also underscore the importance of respecting the statutory authority vested in the Center for Medicare and Medicaid Services (CMS) to promulgate a Rule that protects the health and safety of Medicare and Medicaid patients. See Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555-01 (Nov. 5, 2021). The district court injunction substitutes that court's views on epidemiology for the considered and reasoned judgment of CMS, the very agency Congress charged with establishing minimum necessary requirements

to ensure the health and safety of individuals who receive health services at facilities participating in the federal Medicare and Medicaid programs.

ARGUMENT

1. The Rule Protects Workers As Well As Patients.

A. Under-Vaccination Poses Severe Risks to Healthcare Workers.

The Covid-19 pandemic has placed an unprecedented strain on the healthcare industry, and on healthcare workers in particular. It has been understood since the early months of the pandemic that healthcare workers face heightened risk of contracting Covid-19 relative to the general population.² More than 3,600 healthcare workers in the U.S. died during the first year of the pandemic.³ More than half of those workers were younger than 60 years old; more than half were people of color; more than half worked in healthcare facilities other than hospitals; and the highest number of those who died were nurses and healthcare support staff, many of whom are lower-paid relative to other medical staff.⁴

coronavirus-us-healthcare-workers-deaths-database.

Footnote continued on next page

² Long H. Nguyen et al., *Risk of COVID-19 among frontline healthcare worker and the general community; a prospective cohort study*, medRxiv (May 25, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7273299/.

³ Lost on the frontline: Thousands of US healthcare workers died fighting Covid-19. We counted them and investigated why, The Guardian (Apr. 8, 2021), https://www.theguardian.com/usnews/ng-interactive/2020/aug/11/lost-on-the-frontline-covid-19-

⁴ Our key findings about US healthcare worker deaths in the pandemic's first year, The Guardian (Apr. 8, 2021), https://www.theguardian.com/us-news/ng-

Many of the risks to healthcare workers come from lax policies that fail to adequately protect both workers and patients, and the greatest transmission risks in hospitals often come from workers in facilities without sufficient enforcement of safety protocols.⁵ This is true even where universal masking policies have been implemented. For example, at one provider in North Carolina, "unmasked exposure to another health care worker rather than exposure to known infected patients resulted in the most [Covid-19] cases among staff after implementation of universal masking."⁶ Recent research has similarly suggested that healthcare workers are more likely to contract Covid-19 from co-workers than from patients.⁷

In the more recent months of the pandemic, outbreaks have often been tied to under-vaccination among healthcare workers. This past summer, during an outbreak at a Maine hospital, four of the first five staff members to test positive had not been fully vaccinated.⁸ And at a nursing home in Kentucky, 26

⁷ Jessica Ibiebele et al., Occupational COVID-19 exposures and secondary cases among healthcare personnel, Am. J. of Infection Control (Aug. 8, 2021),

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8349432/.

⁸ Brenda Goodman and Andy Miller, *A Disturbing Number* of Hospital Workers Still Unvaccinated, GPB News (June 29, 2021), https://www.gpb.org/news/2021/06/29/disturbingnumber-of-hospital-workers-still-unvaccinated.

interactive/2020/dec/22/lost-on-the-frontline-our-findings-to-date.

⁵ Aaron Richterman et al., *Hospital-Acquired SARS-CoV-2* Infection: Lessons for Public Health, JAMA (Nov. 13, 2020), https://jamanetwork.com/journals/jama/fullarticle/2773128.

⁶ Id. (quoting Sonali Advani et al., Are we forgetting the "universal" in universal masking? current challenges and future solutions, Infection Control & Hospital Epidemiology (July 16, 2020)).

patients and 20 healthcare workers were infected in an outbreak set off by a single unvaccinated worker.⁹ As one group of researchers put it, "[t]o protect [nursing home] residents, it is imperative that [healthcare workers], as well as ... residents, be vaccinated."¹⁰

Covid-19 vaccines are extraordinarily effective. One study estimated that the U.S.'s vaccination program had prevented more than 10.3 million hospitalizations, and more than 1.1 million additional deaths by November 2021.¹¹ Without vaccines, daily deaths could have jumped to as high as 21,000 per day—more than 5.2 times the level of the record peak.¹² As of October 2021, rates of hospitalization among unvaccinated adults were nearly 12 times the rates for fully vaccinated adults.¹³ Nonetheless, as the study's authors noted, "[e]ven the 2.6 million COVIDrelated hospitalizations that occurred during 2021

⁹ Roni Caryn Rabin, An unvaccinated worker set off an outbreak at a U.S. nursing home where most residents were immunized, New York Times (Apr. 21, 2021),

https://www.nytimes.com/2021/04/21/health/vaccine-nursing-homes-infections.html.

¹⁰ Alyson M. Cavanaugh et al., COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021 (Apr. 21, 2021),

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e2.htm?s_ci d=mm7017e2_w.

¹¹ Eric C. Schneider et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?*, The Commonwealth Fund (Dec. 14, 2021), https://www.commonwealthfund.org/publications/issue-

briefs/2021/dec/us-covid-19-vaccination-program-one-year-how-many-deaths-and.

 $^{^{12}}$ Id.

 $^{^{13}}$ Id.

placed an enormous strain on hospitals, with many staff lost not only to the virus but also to exhaustion and burnout."¹⁴ The study concluded that "[a]s the Omicron variant begins to spread and the Delta variant surge continues," vaccination has "tremendous power . . . to reduce disease and death from COVID-19."¹⁵

B. Frontline Healthcare Workers Support the Rule.

Toni, an SEIU 1199NE New England union member, has been a Certified Nurse's Aide at St. Joseph's Center, a Medicare- and Medicaid-certified facility in Trumbull, Connecticut, for thirty-one years. She recalls that before Covid-19 vaccines were available, her facility faced terrible conditions-the virus "hit [her] floor drastically," and dozens of residents died from Covid-19. The staff were not safe: Toni herself was one of the first people to contract Covid-19, and then many other employees also got sick. Tragically, some staff members carried Covid-19 home to their families, and some family members died from the virus. For Toni, the lack of vaccines during that difficult time meant that she had to go months at a time without seeing her children and grandchildren. for fear of spreading the virus.

Toni strongly supports requiring healthcare staff to be vaccinated. She explains that relying solely on personal protective equipment is dangerous because it is a strain, hard to wear, and does not provide complete protection. After Connecticut set vaccine requirements for long-term care facilities, 100% of her co-workers are now vaccinated. Toni says

 $^{^{14}}$ Id.

requiring vaccination is a "no-brainer," because she has seen the terrible effects of under-vaccination: "The proof was in the pudding: we saw people dying."

Colley, SEIU 1199 Sophia an United Healthcare Workers East union delegate and officer. has been a Certified Nursing Assistant at Titusville Rehab & Nursing Center, a Medicare- and Medicaidcertified facility in Titusville, Florida, for more than thirty years. She explains that earlier in the pandemic, especially after the death of a staff member from Covid-19, many co-workers were "scared to come to work," and many stayed away entirely out of fear of contracting Covid-19 at work and passing it on to their families. When vaccines became available, many staff members were still afraid. But as vaccination rates have risen at the facility, more and more workers have felt safe to return to work and care for their patients.

In Sophia's view, from working at her facility and speaking with other healthcare workers, vaccine mandates have an extremely important role to play alongside PPE policies, one-on-one conversations, encouragement, and education—in making skilled nursing facilities safe and effective in the face of an ongoing pandemic. As she says, getting vaccinated protects your co-workers as well as "the residents that you're taking care of." She is proud of her facility, where 98 percent of staff are now vaccinated.

II. The Rule Is Well Within CMS's Authority.

A. The Statutory Text Is Clear.

The district court's injunction is based on speculations about Congressional intent without *any* grounding in the actual, relevant statutory text. Indeed, the district court virtually ignores Congress's text in conducting its cursory statutory interpretation. But that text leaves no doubt that Congress granted CMS the authority to issue the Rule.

With respect to both the Medicare and Medicaid programs, Congress has commanded the Secretary of Health and Human Services to "make and publish such rules and regulations . . . as may be necessary to the efficient administration of the functions with which [he] is charged[.]" 42 U.S.C. § 1302(a). Similarly, Congress requires the Secretary to "prescribe such regulations as may be necessary to carry out the administration of [Medicare] insurance programs[.]" 42 U.S.C. § 1395hh(a)(1).

More specifically, Congress has instructed the Secretary to set health and safety standards for providers and suppliers who participate in the Medicare and Medicaid programs. For example, Congress has provided that any "hospital" that participates in the Medicare program must "meet[] such ... requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." 42 U.S.C. § 1395x(e)(9); see also id. § 1395d(a); Rasulis v. Weinberger, 502 F.2d 1006, 1010 (7th Cir. 1974) (noting that Congress has "explicitly empowered" the Secretary to establish health and safety standards to protect hospital patients).

As carefully discussed in the Rule, *see* 86 Fed. Reg. at 61,567, 61,575–61,583, Congress has granted the Secretary this same or similar authority with respect to all of the participating providers included within the Rule's scope. *See* 42 U.S.C. § 1395x(f)(2) (same authority for participating psychiatric

id. hospitals): §§ 1395x(o), 1395bbb(b)(same authority for participating home health agencies); id. § 1395x(p)(4)(A)(v) (same authority for participating and rehabilitation agencies providing clinics outpatient physical therapy); id. § 1395x(aa)(2)(k) (same authority for participating rural health clinics); 1395x(dd)(2)(G)id. (same authority for hospice id. participating programs): § 1395x(ff)(3)(B)(iv) (same authority for participating community mental health centers); *id.* § 1395eee(f)(4)(same authority for participating programs of allinclusive care for the elderly); *id.* 1395x(cc)(2)(J) (same authority for participating comprehensive outpatient rehabilitation facilities, including express set health and safety authority to standards "concerning qualifications of personnel in these facilities"); id. 1395i-3(d)(4)(B), (f)(1) (authority to set standards relating to the "health, safety, and wellbeing of residents" for participating long-term care (skilled nursing) facilities); id. § 1396d(h)(1)(A) (same certain psychiatric residential authority for treatment facilities participating in Medicaid); id. § 1396d(*l*) (same authority for rural health clinics participating in Medicaid); id. § 1396d(o) (same authority for hospice programs participating in Medicaid); id. § 1396r(d)(4)(B) (same authority for nursing facilities participating in Medicaid); id. § 1396u-4(f)(4) (same authority for programs of allfor the elderly participating inclusive care in Medicaid): § 1396d(d)(1) id. (authority to set standards for participating intermediate care facilities for individual with intellectual disabilities); *id.* \$1395i-4(e)(3) (authority to set criteria for critical participating access hospitals): id. § 1395x(iii)(3)(D)(i)(IV) (authority to set requirements for participating home infusion therapy suppliers); *id*.

1395rr(b)(1)(A) (authority to set requirements for participating end-stage renal disease facilities); *id.* 1395k(a)(2)(F)(i) (authority to specify "health, safety, and other standards" for participating ambulatory surgical centers).

Certainly, statutory provisions allowing the Secretary to establish health and safety requirements for participating facilities authorize this Rule. See Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242, 251 (2010) ("We must enforce plain and unambiguous statutory language according to its terms."). CMS explained at great length in the Rule why requiring staff working for Medicare and Medicaid providers to be vaccinated against Covid-19 is both "necessary to the efficient administration" of these programs, see 42 U.S.C. § 1302(a), and, more specifically, "necessary in the interest of the health and safety of individuals" receiving Medicare and Medicaid services from these providers, see, e.g., id. § 1395x(e)(9). CMS reviewed evidence demonstrating that requiring staff vaccination is critical to protecting Medicare and Medicaid recipients, because "[f]ewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients[.]" 86 Fed. Reg. at 61,558. For example, CMS discussed data showing that "residents of [long-term care] facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable COVID-19." Id. And beyond avoidable Covid-19 transmission from unvaccinated staff. CMS identified many other risks to patient health and safety that warranted implementation of the Rule, including reports that fear of infection from unvaccinated staff leads patients to forgo seeking medically necessary care, and evidence that "illnesses deaths associated with COVID-19 and are

exacerbating staffing shortages across the health care system." Id. at 61,558-61,559. CMS concluded that "[h]igher rates of vaccination...in health care settings will contribute to a reduction in the transmission of SARS-CoV-2 and associated morbidity and mortality across providers and communities, contributing to maintaining and increasing the amount of healthy and productive health care staff, and reducing risks to patients, resident, clients, and PACE program participants." Id. at 61.560.

In short, CMS drew a strong, direct, and evidencelink between provider staff based vaccine requirements and the health and safety of program recipients. There can be no serious argument that the Rule does not fall within the broad grants of statutory authority enacted by Congress, which, inter alia, make it "the duty and responsibility of the Secretary to assure that requirements which govern the provision of care ... are adequate to protect the health, safety, welfare, and rights of residents[.]" 42 U.S.C. § 1395i-3(f)(1) (standard for participating nursing homes); see also, e.g., id. \S 1395x(e)(9) (participating hospitals must "meet∏ such ... requirements as the Secretary finds necessary in the interest of the health and safety" of patients).

Neither the plaintiff states nor the district court or court of appeals engage with the plain text of the statutory authority Congress granted to CMS. Indeed, the district court did not even quote or cite the key Congressional language, and instead rested its injunction on its wholly conclusory assertion that "[n]one of these statutes give the Government Defendants the 'superpowers' they claim." Memorandum Ruling, *Louisiana v. Becerra*, No. 21cv-03970 (W.D. La. Nov. 30, 2021) ("District Court Order") at 20. This atextual approach to statutory interpretation has no basis in any decision of this Court. It is well established that, "in any case of statutory construction, [the Court's] analysis begins with the language of the statute. And where the statutory language provides a clear answer, it ends there as well." Harris Tr. & Sav. Bank v. Salomon Smith Barney, Inc., 530 U.S. 238, 254 (2000) (internal quotation and formatting omitted); see also Alexander v. Sandoval, 532 U.S. 275, 288 (2001) ("We have never accorded dispositive weight to context shorn of text.... [L]egal context matters only to the extent it clarifies text."). The district court erred out of the gate by making "no attempt to ground its analysis in the [statutory] language." Ross v. Blake, 578 U.S. 632, 638 (2016).

Here, there *is* no way to ground the district court's injunction in the statutory text. Congress gave CMS vital authority to set health and safety standards for providers who choose to participate in CMS's programs. The Rule is a lawful exercise of that unambiguous authority.

B. This Court's Major Questions Precedents Do Not Apply.

Instead of beginning its statutory interpretation with the text, the district court began—and ended with the idea that it could make its own assessment of whether the questions presented by the Rule were politically significant, such that it could ignore common rules of statutory construction.

This Court has recognized that an agency's exercise of regulatory authority may sometimes be of such extraordinary or "vast economic and political" significance that a court should hesitate before concluding that Congress intended to house such sweeping authority in an ambiguous statutory provision. See Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2489 (2021); King v. Burwell, 576 U.S. 473, 485–486 (2015); Utility Air Regulatory Group v. EPA (UARG), 573 U.S. 302, 324 (2014); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000). The Court has similarly required a clear statement from Congress before interpreting a statute to "significantly alter the balance between federal and state power and the power of the Government over private property." United States Forest Serv. v. Cowpasture River Pres. Ass'n, 140 S. Ct. 1837, 1850 (2020).

As an initial matter, on its face, CMS's Rule is not the sort of extraordinary exercise of authority that should prompt judicial skepticism. As discussed above, the Rule comfortably falls within a precise grant of Congressional authority-the authority to set health and safety standards for providers participating in the Medicare and Medicaid programs. It is difficult to imagine a regulation that is more concerned with patient health and safety than a regulation requiring the staff serving those patients to receive a highly effective vaccine against a virus that has caused more than 800,000 deaths in less than two years-"the deadliest disease in American history." 86 Fed. Reg. at 61,556. CMS has longstanding and unquestioned authority to set health and safety standards in operating these multibillion-dollar programs, and indeed already sets such standards related to controlling the spread of infectious disease. See, e.g., 42 C.F.R. § 482.42; see Medicare and Medicaid Programs; Conditions of Participation for Hospitals, 51 Fed. Reg. 22,010-01,

22,027 (1986) (placing "accountability on hospitals to prevent, control, and report hospital infections and communicable diseases").

Thus, this is a case in which a federal agency is regulating: (i) recipients of Medicare and Medicaid funding that are already subject to a detailed regulatory scheme administered by this same agency; (ii) in an area (controlling the spread of infectious disease) in which the agency has regulated these same entities for decades; (iii) under statutes that the agency regularly relies upon to regulate on the same topic. These circumstances bear no resemblance to those in which an agency has unduly stretched a narrow statutory provision to "bring about an enormous and transformative expansion in [its] regulatory authority," UARG, 573 U.S. at 324.

The fact that CMS has not had reason in the past to issue the precise regulation at issue here—a requirement that provider staff be vaccinated against a particular virus—in no way changes the analysis. CMS has never issued such a regulation because CMS has never before faced a situation in which high rates of non-vaccination among provider staff posed a major risk to the health and safety of Medicare and Medicaid patients. Congress obviously could not have foreseen this precise situation when it enacted the governing Medicare statutory provisions and Medicaid, but it did not need to, since it gave the Secretary broad authority to set health and safety standards. See Watt v. Energy Action Educ. Found., 454 U.S. 151, 162 (1981) ("If Congress meant to restrain the Secretary ['s] discretion in experimenting with the various [policy options], we can expect the statute to reflect that intent."). And neither the plaintiff states nor the courts below offered any interpretation of the text to explain why a regulation regarding vaccines falls outside the statutory grant of authority but CMS's numerous other health and safety regulations do not. Put simply, the statute cannot be read to contain a carve-out for regulations related to vaccines. *See Lewis v. City of Chicago, Ill.*, 560 U.S. 205, 215 (2010) ("It is not for us to rewrite the statute so that it covers only what we think is necessary to achieve what we think Congress really intended.").

In reaching its conclusion that Congress could not have intended to authorize the Rule, the district court reasoned that CMS has "used general authority statutes to mandate COVID-19 vaccines for over 10.3 million healthcare workers." District Court Order at 20. But CMS relied not only on its general authority to administer the Medicare and Medicaid programs, but also on its specific authority to set health and safety standards-statutory text that the district court completely failed to engage with. Similarly, the district court opined that "mandating a vaccine to 10.3 million healthcare workers is something that should be done by Congress, not a government agency." Id. at 21. But there is no legal authority for that assertion, and in any event the district court completely failed to explain why the Rule is different in kind from other regulations affecting large numbers Americans. or why the of Rule is unauthorized in the context of the federal government's spending on Medicare and Medicaid.¹⁶

¹⁶ The Medicare program alone spends \$700 billion every year. Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808 (2019). The Constitution and this Court's precedents recognize Congress' authority under the Spending Clause "to appropriate Footnote continued on next page

There is also a deeper problem with the plaintiffs' (and the district court's) major questions analysis. This Court has never suggested that courts should (or could) impose limitations on Congressional delegations of authority when those limitationsbased on courts' own perceptions of the political sensitivities of a particular issue—have no basis in the statutory text. See Alabama Ass'n of Realtors, 141 S. Ct. at 2489 (major questions precedents apply "if the text [is] ambiguous"); UARG, 573 U.S. at 324 (same). This Court has certainly never conducted the sort of free-floating, anti-textual analysis that produced the injunction below. The Court has invoked considerations of "economic and political significance" in deciding between competing to assist interpretations of a statute, not to "create ambiguity where the statute's text and structure suggest none," Ali v. Fed. Bureau of Prisons, 552 U.S. 214, 227 (2008). See, e.g., Brown & Williamson, 529 U.S. at 133-161 (carefully analyzing the statutory scheme and rejecting the agency's "strained understanding" of the statutory language); UARG, 573 U.S. at 322 (rejecting interpretation that "would be inconsistent with-in fact. would overthrow-the Act's structure and design"); Gonzales v. Oregon, 546 U.S. 243, 267 (2006) (rejecting interpretation of agency authority that was "incongruous with the statutory purposes and design").

The plaintiffs' sole attempt to paint CMS's statutory authorization as ambiguous is an argument that the statutory text instructing the Secretary to set

federal moneys to promote the general welfare," and to place conditions on the acceptance of federal funds, even in areas that are historically of state concern. *Sabri v. United States*, 541 U.S. 600, 605 (2004).

health and safety standards is relatively broad. But Congress knows how to write statutes narrowly or broadly, and it is black-letter law that a statute's use of broad language does *not* render it ambiguous per se. Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980) ("Broad general language is not necessarily ambiguous when congressional objectives require broad terms."); Yates v. United States, 574 U.S. 528, 564 (2015) ("[W]hen words have a clear definition, and all other contextual clues support that meaning, the canons cannot properly defeat Congress's decision to draft broad legislation."); see also Mourning v. Fam. Publications Serv., Inc., 411 U.S. 356, 369 (1973) ("Where the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'... the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation."").

For instance, in Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2379-2380 (2020), this Court interpreted a provision of the Affordable Care Act that required employers to provide "such additional preventive care ... as provided for in comprehensive guidelines supported by [the Health Resources and Services Administration (HRSA)]." The Court held that this provision authorized HRSA to exempt employers with religious or "sincerely held moral" objections from the general obligation to provide contraceptive coverage. Id. at 2380-82. While two Justices doubted that Congress would have delegated this particular task to HRSA, see id. at 2406 (Ginsburg, J., dissenting), the Court held that "folur analysis begins and ends with the text," id. at 2380 (majority op.). The Court

explained that "[o]n its face ... the provision grants sweeping authority to HRSA to craft [its] standards." *Id.* at 2380. "Congress could have limited HRSA's discretion in any number of ways, but it chose not to do so"—and "[i]t is a fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts." *Id.* at 2380–81 (internal quotation and formatting omitted). The Court emphasized that courts cannot "impos[e] limits on an agency's discretion that are not supported by the text." *Id.* at 2381.

The plaintiff states ask this Court, "[b]y introducing a limitation not found in the statute, to alter, rather than to interpret," the Medicare and Medicaid statutes. *Id.* And to the extent the states' position is fueled by disagreement with the wisdom of the Rule, "a policy concern cannot justify supplanting the text's plain meaning." *Id.* CMS followed Congress's clear instructions to set health and safety standards for providers participating in its federal programs.

CONCLUSION

For the foregoing reasons, the federal government's application for a stay should be granted.

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