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

STATE OF LOUISIANA, *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 3:21-CV-04370-TAD-KDM

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF SANDY BRICK'S CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiff Sandy Brick challenges the Interim Final Rule, Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68,052-01 (Nov. 30, 2021) (the "Rule"), requiring that those interacting with Head Start students wear a mask and be vaccinated against COVID-19 or otherwise qualify for an exemption. The Rule also requires masking for all Head Start participants over the age of two.

Head Start, a federal grant program, provides funding to aid school readiness for infants, toddlers, and pre-school aged children from low-income families. The COVID-19 pandemic has hit Head Start students and families particularly hard. Many of these students rely on the programs not just for educational purposes, but also for everyday needs, so program closures due to COVID-19 outbreaks can have severe negative consequences beyond the classroom. In addition, most Head Start children and personnel come from minority and low-income communities, which have been disproportionately impacted by COVID-19.

Plaintiff challenges the Rule on statutory and constitutional grounds, but the Supreme Court has upheld a similar requirement to vaccinate participants in another federal spending program against COVID-19. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam) (upholding vaccination requirement for certain Medicare and Medicaid providers). Based on a straightforward application of that binding precedent, the Sixth Circuit recently upheld the Rule at issue here. "The statute creating the Head Start program gives the Secretary of HHS the power to promulgate regulations to promote the health and wellbeing of the children in the program." *Livingston Educ. Serv. Agency v. Becerra*, 35 F.4th 489, 491 (6th Cir. 2022), *reh'g denied*, No. 22-1257, 2022 WL 2286410 (6th Cir. June 21, 2022). For the reasons set forth in Defendants' Brief in Support of Their Motion to Dismiss, or in the Alternative, Motion for Summary Judgment ("Defs.' Br."), ECF No. 32-2, *Brick v. Biden*, No. 2:21-cv-04386-TAD-KK (W.D. La. Apr. 29, 2022), Plaintiff's challenges to the Rule fail. The Court should accordingly deny Plaintiffs' Motion for Summary Judgment, ECF No. 105.

BACKGROUND

Defendants incorporate the recitation of background facts from their Motion to Dismiss, or in the Alternative, Motion for Summary Judgment. *See* Defs.' Br. at 3–9.

On February 28, 2022, the Office of Head Start ("OHS"), within the Administration for Children and Families ("ACF") of the Department of Health and Human Services ("HHS") released a statement that it "is reviewing the new CDC recommendations" concerning mask usage and, "[w]hile reviewing the [guidelines], OHS will not evaluate compliance with the mask requirement in its program monitoring." OHS, *CDC Community Levels Recommendations and Mask Wearing*, https://tmsc.createsend.com/campaigns/reports/viewCampaign.aspx?d=j&c=3A108D6223F50AA6&ID=AB3F63F79F75CFE62540EF23F30FEDED&temp=False&tx=0&source=SnapshotHtml [https://perma.cc/Y7NW-SQTU]. On August 22, 2022, OHS released another statement reminding programs that they "will not be monitored for mask use given the updated CDC mask guidance." OHS, *Masks and Vaccines in Head Start Programs*, https://eclkc.ohs.acf.hhs.gov/blog/masks-vaccines-head-start-programs [https://perma.cc/3M4M-3AF2]. That monitoring policy regarding the mask requirement is still in effect today.

STANDARD OF REVIEW

A moving party is entitled to summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Challenges to agency decisions under the APA are properly resolved on motions for summary judgment . . . ." *Berry v. Esper*, 322 F. Supp. 3d 88, 90 (D.D.C. 2018); *see also Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1245 (E.D. Cal. 2013) ("Normally, APA cases are resolved on cross-motions for summary judgment . . . ."); *Smirnov v. Clinton*, 806 F. Supp. 2d 1, 21 n.16 (D.D.C. 2011) ("[M]ost APA cases[] [are resolved] through the consideration of cross motions for summary judgment . . . ."), *aff'd*, 487 F. App'x 582 (D.C. Cir. 2012).

ARGUMENT

I. The Secretary Had Authority to Promulgate the Rule.

Plaintiff's challenge to the Secretary's statutory authority fails under the reasoning of *Missouri*, 142 S. Ct. 647, which upheld a similar interim final rule requiring federally funded healthcare facilities to ensure that their staff were vaccinated against COVID-19. The only court of appeals to consider whether the Secretary had the authority to promulgate the Rule challenged here determined that he likely did, based in part on the reasoning in *Missouri*. *Livingston*, 35 F.4th at 491. This Court should follow suit because the Rule is authorized by statute and does not violate any provision of the Head Start Act.

A. The Rule is Authorized by Statute.

The vaccination requirement falls within the Secretary's "broad rule-making powers." *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969); *see also Nat'l Welfare Rts. Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976) (referencing Congress's "broad grant of power" to the Secretary). When analyzing an agency's construction of a statute, courts apply *Chevron* deference to the agency's interpretation. Plaintiff points to no case law to suggest that "*Chevron* deference is outdated," Pl.'s Mem. in Supp. of Cross-Mot. for Summ. J. at 14, ECF No. 111 ("Pl.'s Mem."), and the Government strongly contests that notion. Where, as here, "Congress has directly spoken to the precise question at issue," courts "must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Only "if the statute is silent or ambiguous with respect to the specific issue," does the court assess "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

Although this Court previously found a likelihood of success on the claim that HHS lacked statutory authority to implement the Rule, that opinion was issued before the Supreme Court made clear in *Missouri* that HHS had the statutory authority to enact a similar COVID-19 vaccine requirement that also derived from the federal government's authority to protect beneficiaries in a

federally funded program. *See Missouri*, 142 S. Ct. at 652. And since the Supreme Court issued the *Missouri* opinion, the Sixth Circuit held that the Rule's "vaccine requirement for Head Start program staff, contractors, and volunteers" was within HHS's statutory authority. *Livingston*, 35 F.4th at 491. After the Sixth Circuit issued its opinion, it denied the plaintiffs' petition for rehearing en banc, and no Sixth Circuit judge requested a vote. *Livingston*, 2022 WL 2286410, at *1.

1. The Plain Statutory Text Authorizes the Rule.

An analysis of an agency's statutory authority "begins with the statutory text"—and, when the text is clear, it "ends there as well." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018) (citation omitted). "The statute creating the Head Start program gives the Secretary of HHS the power to promulgate regulations to promote the health and well-being of the children in the program." *Livingston*, 35 F.4th at 491. Congress charged the Secretary with adopting, "as necessary," "standards relating to the condition . . . of [Head Start] facilities," as well as to address other "administrative . . . standards" necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress vested the Secretary with broad authority to issue "such other standards as the Secretary finds to be appropriate" for Head Start agencies and programs. *Id.* § 9836a(a)(1)(E). Binding Supreme Court case law confirms the extent of the Secretary's authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency "broad authority." *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 365 (1973). More specifically, "[w]here 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 Court held that "the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Id.* at 369 (quoting *Thorpe*, 393 U.S. at 280–81); *see also Livingston*, 2022 WL 660793, at *5. The same is true of statutes that authorize regulations as the Secretary finds to be "appropriate." *See, e.g.*, *Arkansas v. Oklahoma*, 503 U.S. 91, 105 (1992); *GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021), *vacated*

by 31 F.4th 1109 (9th Cir. 2022) (mem.) ("statutory language—'appropriate' and 'necessary and proper'—is a hallmark of vast discretion" (footnote omitted)).

The vaccination and masking Rule "plainly falls within the Secretary's authority." *Livingston*, 2022 WL 660793, at *4. By requiring vaccines and masking for certain Head Start personnel and participants under certain circumstances and subject to exemptions, the Secretary was imposing an "administrative . . . standard" that was "necessary" for the safe management of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), and a standard "relating to the condition . . . of facilities," *id.* § 9836a(a)(1)(D). The Rule sought to improve indoor air quality at Head Start facilities by reducing transmission of the virus that causes COVID-19, "which spreads through the air via respiratory droplets."[1] *Livingston*, 2022 WL 660793, at *4. At a bare minimum, the Secretary was imposing a "standard[]" he found to be "appropriate" for the Head Start program. 42 U.S.C. § 9836a(a)(1)(E). As noted above, Congress created the Head Start program to provide a healthy and safe learning environment for low-income children across the country. This measure was "appropriate" to protect student health. While Plaintiff contends that no limiting principle governs Defendants' interpretation of the statute, *see* Pl.'s Mem. at 7, if the Rule is "appropriate" to further the Head Start program's purposes as set forth in 42 U.S.C. § 9831, the Rule is authorized. The agency reasoned that, as of that time, "[g]iven that children under age 5 years are too young to be vaccinated . . ., requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19."[2] 86 Fed.

[1] Plaintiff confusingly argues that "indoor air quality" cannot plausibly include viruses that spread through the air because "HHS's sister agency, the EPA" states on its website that "indoor air quality" refers to pollutants like "asbestos," "nitrogen dioxide," and "carbon dioxide." Pl.'s Mem. at 6 (quoting EPA, Introduction to Indoor Air Quality (Dec. 16, 2021), available at https://perma.cc/YJ7W-JKTR). But actually, that article, which Plaintiff only selectively quotes from, explains that, "Indoor Air Quality (IAQ) refers to the air quality within and around buildings and structures, *especially as it relates to the health . . . of building occupants*." *Id.* (emphasis added). The Secretary created the Rule specifically to protect the health of building occupants at Head Start facilities. Anyway, "IAQ" is clearly a term of art that EPA uses for its own unique purposes in this article, and the statutory text of the Head Start Act is not defined in relation to how the EPA might separately use that term.

[2] After the Rule was issued, the FDA authorized emergency use of both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for children six months and older

Reg. at 68,055. HHS further noted that, in addition to protecting individuals from COVID-19, the requirements will "reduce closures of Head Start programs, which can cause hardship for families, and support the Administration's priority of sustained in-person early care and education that is safe for children—with all of its known benefits to children and families." *Id.* at 68,053 (footnote omitted).

Plaintiff makes much of the supposed limits of the term "modify" in 42 U.S.C. § 9836a(a)(1), which directs that "[t]he Secretary shall modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs under this subchapter." *See* Pl.'s Mem. at 4–5. Plaintiff argues that the term cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. But Plaintiff offers no alternative definition. Required masking of children over age two and required staff vaccinations against a deadly and highly contagious disease were two "modifications" to a program whose purpose addresses all facets of students' readiness to succeed in an academic setting, including their health and safety (and that of their families). *See* 42 U.S.C. § 9831(2) ("It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development . . . through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.").

"In addition to that broad grant of authority, the statute also specifically provides how the Secretary may remedy 'health' risks to children in the program." *Livingston*, 35 F.4th at 492. The Secretary is charged with issuing deficiencies when programs fail to follow program performance standards. 42 U.S.C. § 9836a(e)(1). A "deficiency" is "a systematic or substantial material failure of an agency in an area of performance that the Secretary determines involves—(i) a threat to the health, safety, or civil rights of children or staff; [or] (iii) a failure to comply with standards related to early

in June 2022. *See* FDA, News Release, Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age (June 17, 2022), FDA, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children.

childhood development and health services." *Id.* § 9832(2)(A). By the statute's plain language, then, the Secretary can certainly establish "standards related to early childhood development and health services" and "the health . . . of children or staff" because he can issue deficiencies on failures to follow standards that are a threat to health and safety. *Id.*; *see Missouri*, 142 S. Ct. at 652 (explaining that a vaccination requirement "fits neatly within the language of [a] statute" addressed to the "health and safety of individuals" (internal quotation marks omitted)); *see also Livingston*, 2022 WL 660793, at *5 (discussing the Secretary's power to identify and correct "deficiencies").

Plaintiff argues that "the 'deficiencies' for which the Secretary can impose sanctions" do not "widen the scope of what 'performance standards' comprises." Pl.'s Mem. at 10 (quoting *Texas v. Becerra*, 577 F. Supp. 3d 527, 544 (N.D. Tex. 2021)). That begs the question, though; "performance standards" includes in its scope "the power to promulgate regulations to promote the health and well-being of the children in the program." *Livingston*, 35 F.4th at 492. In any case, since the district court issued the ruling in *Texas* on which Plaintiff relies, the Sixth Circuit has explained that 42 U.S.C. § 9836a(e)(1) provides that grant of authority related to identifying and correcting deficiencies. *See Livingston*, 35 F.4th at 492. And even if it were true that "it means that the deficiency needs to be egregious enough that it impacts health and safety to justify the federal government stepping in," Pl.'s Mem. at 11, a national pandemic that has killed over one million Americans alone plainly fits the bill.

2. The History of Past Head Start Regulations Confirms that HHS Has the Authority to Regulate Health and Safety Within Head Start Programs.

Even if the Court were to disagree with the Government's arguments as to the plain meaning of the statute and move to step two of the *Chevron* deference framework, the agency's interpretation, at a minimum, "is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. Plaintiff claims, though, that "[a]n agency is only entitled to deference in interpreting a silent statute when the statute delegated it discretion on the issue in the first place," Pl.'s Mem. at 14, and "there is nothing in the Head Start statute plausibly giving the Agency Defendants discretion on the issue of teacher and volunteers' health." *Id.* at 15. The only court of appeals to weigh in on this issue disagrees

with Plaintiff. "HHS's history of regulating the health of Head Start children and staff provides further evidence that the vaccine requirement does not exceed the agency's statutory authority." *Livingston*, 35 F.4th at 492. And the Supreme Court emphasized a similar "longstanding practice of [HHS] in implementing the relevant statutory authorities" in upholding a COVID-19 vaccine requirement for health care workers who treat Medicare and Medicaid patients. *Missouri*, 142 S. Ct. at 652. The Court rejected the state challengers' narrow reading of the statute at issue there because it was inconsistent with HHS's historical practice of imposing "conditions that address the safe and effective provision of healthcare, not simply sound accounting." *Id.*; *see also Livingston*, 35 F.4th at 492 (confirming that, contrary to Plaintiff's contention, *see* Pl.'s Mem. at 16, the history of Centers for Medicare and Medicaid Services ("CMS") regulations in *Missouri* is similar to that at issue with the Rule).

"HHS has a history of regulating the health of Head Start staff in order to protect the children in the program." *Livingston*, 35 F.4th at 492; *see also Missouri*, 142 S. Ct. at 653 (explaining that numerous health and safety regulations fall within the grant of authority to CMS). These include measures like the vaccine requirement at issue here, and Plaintiff has never objected to any of these past similar measures. These health and wellness standards apply specifically to staff, who are required to have "an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate." 45 C.F.R. § 1302.93(a). In addition, all Head Start personnel are required to meet the childcare standards of the states in which they operate. 42 U.S.C. § 9837(c)(1)(E)(iii); *see also id.* § 9832(2)(A)(vi) (defining a program deficiency in part as the "failure to meet any other Federal or State requirement that the agency has shown an unwillingness or inability to correct"); 45 C.F.R. § 1304.5(a)(2)(viii) (specifying that failure to abide by applicable state requirements is a ground for termination).

Head Start Programs also have a responsibility to "ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program." *Id.*

§ 1302.93(a). As explained in the Government's Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, numerous other regulations, both in that past and present, have governed the health and safety of staff and program participants alike. *See* 45 C.F.R. § 1302.42(b)(1)(i)-(ii); *id.* § 1302.42(e)(2); *id.* § 1302.47(b)(4)(i)(A) & (b)(7)(iii); *id.* § 1304.3-3(b)(4)–(6) (1975); *id.* § 1304.3-3(b)(8) (1975); *id.* 45 C.F.R. § 1304.3-4(a)(2) (1975); *id.* § 1308 App'x (2015); 61 Fed. Reg. at 57,210, 57,223; Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,357, 61,433 (Sept. 6, 2016); *see also* Defs.' Br. at 16–18. As in *Missouri*, this history is a strong indication that the Head Start Act confers broad authority on the Secretary and that the Rule was a permissible exercise of that authority.

Additionally, the Supreme Court has rejected Plaintiff's argument that "the unprecedented nature of the Rule counsels against interpreting the Head Start statute as authorizing it," Pl.'s Mem. at 12; *see also id.* at 15. *Missouri* recognizes that the federal government may exercise longstanding powers in new ways when faced with new challenges. The Court found it unsurprising that HHS's "vaccine mandate [went] further than what [HHS] has done in the past to implement infection control" because HHS "has never had to address an infection problem of [the] scale and scope" of the COVID-19 pandemic. *Missouri*, 142 S. Ct. at 653; *accord Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1749 (2020) ("[T]he fact that a statute has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity; instead, it simply demonstrates the breadth of a legislative command" (cleaned up)). That reasoning equally applies here. *See Livingston*, 2022 WL 660793, at *7. It is thus immaterial that HHS had not previously required Head Start personnel to be vaccinated. *See id.*; *see also PennEast Pipeline Co. v. New Jersey*, 141 S. Ct. 2244, 2261 (2021) ("[T]he non-use[] of a power does not disprove its existence." (citation omitted)). What matters is that HHS had previously exercised its rulemaking authority to promulgate similar requirements to respond to novel challenges, and the exercise of that authority had never before been challenged.

Plaintiff's reliance on *Alabama Ass'n of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is also misplaced. There, the Supreme Court held that a CDC eviction moratorium

exceeded CDC's authority to "prevent the [interstate] introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a). The Court held that the language's scope was informed by the next sentence, which "illustrat[ed] the kinds of measures that could be necessary," such as "fumigation" or "pest extermination." 141 S. Ct. at 2488. Those measures "directly relate to preventing the interstate spread of disease," whereas the eviction moratorium "relate[d] to interstate infection" only "indirectly," through the "downstream connection between eviction" and possible spread of COVID-19 by evicted individuals moving "from one State to another." *Id.*

Here, the connection between the vaccine requirement and student and personnel health is direct: By requiring program personnel to take the measure that most effectively reduced the risk of contracting and spreading COVID-19, the Secretary sought to reduce the risk that Head Start students and personnel would contract the virus. *Cf. Florida v. U.S. Dep't of Health & Hum. Servs.*, 19 F.4th 1271, 1287–88 (11th Cir. 2021); *see generally Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537–38 (D.C. Cir. 2020) (distinguishing an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" from a valid rule with "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs"). Moreover, a COVID-19 outbreak in a Head Start program hampers students' ability to learn and benefit from the numerous ways in which Head Start supports children and families. The Secretary is simply exercising long-recognized and common-sense authority to adopt health and safety conditions for federally-funded programs for personnel who are already subject to extensive conditions of employment.

3. The Major Questions Doctrine and Federalism Canon Do Not Apply Here.

Like the plaintiffs in *Missouri*, Plaintiff here asserts that the Rule violates the major questions doctrine.[3] Those arguments did not persuade the Supreme Court, and they are even less persuasive here. Whereas the interim final rule at issue in *Missouri* affected more than ten million staff at

[3] *Compare* Pl.'s Mem. at 12–13, with Response to Application for a Stay, *Biden v. Missouri*, No. 21A240, 2021 WL 8946189, at *22–24 (U.S. Dec. 30, 2021), and Response to Application for a Stay Pending Appeal, *Becerra v. Louisiana*, Nos. 21A240, 21A241, 2021 WL 8939385, at *22–24, *26–28 (U.S. Dec. 30, 2021).

healthcare facilities, *see Missouri*, 142 S. Ct. at 655 (Thomas, J., dissenting), the Rule at issue here affected just 273,000 Head Start workers, 86 Fed. Reg. at 68,077, and a share of the approximately one million volunteers who interact with children in certain in-person settings, *see id.* at 68,068. Plaintiff's comparison to the OSHA rule at issue in *National Federation of Independent Business v. Department of Labor*, 142 S. Ct. 661 (2022) ("*NFIB*") (per curiam), is misplaced. The Supreme Court deemed the OSHA requirement overbroad in "imposing a vaccine mandate on 84 million Americans." *Id.* at 665. And whereas the Supreme Court found that the OSHA requirement was not statutorily authorized because the threat was "untethered, in any causal sense, from the workplace," *id.* at 666, the threat here existed with full force in a classroom environment with children who were too young to be vaccinated at the time the Rule was issued and where social distancing was often not possible. The Head Start context was more akin to health care facilities, where, the *NFIB* Court recognized, COVID-19 "poses a special danger because of the particular features of an employee's job or workplace" such as "particularly crowded or cramped environments." *Id.* at 665–66. Therefore, "targeted regulations are plainly permissible." *Id.* at 666. In other words, the analogous case is *Missouri*, where the Court held that a vaccination requirement "fits neatly within the language of the statute." *Missouri*, 142 S. Ct. at 652; *see also Livingston*, 2022 WL 660793, at *6 (discussing *NFIB* and *Missouri*).

Moreover, Head Start grants are discretionary, *see* HHS, Grants Policy Statement, at I-1, I-3 to I-4 (Jan. 1, 2007), https://perma.cc/PME5-9724 ("Grants Policy Statement"), and Head Start programs cover only a small fraction of children under age six, *see* 86 Fed. Reg. at 68,077 (estimated number of children enrolled in Head Start programs); Forum on Child & Family Statistics, POP1 Child Population: Number of Children (in Millions) Ages 0-17 in the United States by Age, 1950-2020 and Projected 2021-2050, https://perma.cc/8EU9-V2HA (last visited Sept. 13, 2022) (projected number of children under the age of six). If a particular grantee is unwilling or unable to comply with the Head Start program standards, it is free to relinquish its grant and provide early childhood services through a non-Head Start program instead. The Rule does not "intrude on state police powers" any

more than do "the long-standing rules conditioning federal funds on requiring that Head Start personnel do not 'pose a significant risk' 'of communicable disease.'" *Livingston*, 2022 WL 660793, at *10 (quoting 45 C.F.R. § 1302.93(a)).

The recently decided case of *West Virginia v. EPA*, 142 S. Ct. 2587 (2022), does not alter the inapplicability of the major questions doctrine. *See* Pl.'s Mem. at 12–13. HHS did not find "a newfound power" in an "ancillary provision" of a statute, as the Supreme Court found the EPA had done with the Clean Power Plan. *See West Virginia*, 142 S. Ct. at 2602, 2613 (concluding that EPA had identified for its regulation a statutory "backwater" that had been "used . . . only a handful of times since the enactment of the statute"). To the contrary, as already discussed, Congress expressly granted the Secretary the authority to promulgate rules like the Rule at issue here, and HHS has used its authority to issue similar rules regulating health and safety for decades. If anything, *West Virginia* confirms that the major questions doctrine applies only "in certain extraordinary cases" when a regulatory action involves "major policy decisions." *Id.* at 2609. A regulation that concerns only Head Start programs and has affected just 273,000 staff, 86 Fed. Reg. at 68,077, and a share of the approximately one million volunteers, *see id.* at 68,068, nationwide is not such an "extraordinary case."

The federalism canon also does not apply here, notwithstanding Plaintiff's two-sentence argument that it does simply because it can "often travel together" with the major questions doctrine. *See* Pl.'s Mem. at 13–14 (quoting *West Virginia*, 142 S. Ct. at 2621 (Gorsuch, J., concurring)). That claim is so far afield from the text and purpose of this Rule that the Supreme Court did not even address such an argument in *Missouri*, which dealt with a similar vaccine requirement that was broader than the one at issue here, even though both the *Louisiana* and *Missouri* plaintiffs argued the federalism canon should apply. *See Becerra v. Louisiana*, Resp. to Appl. for Stay Pending Appeal, 21A240, 21A241, 2021 WL 8939385, at *22–24 (U.S. Dec. 30, 2021); *Biden v. Missouri*, Resp. to Appl. for Stay Pending Appeal, 21A240, 2021 WL 8946189, at *20–21 (U.S. Dec. 30, 2021). And following *Missouri*, the *Livingston* district court held that the Rule does not "intrude on state police powers" any more than do

"the long-standing rules conditioning federal funds on requiring that Head Start personnel do not 'pose a significant risk' 'of communicable disease.'" *Livingston*, 2022 WL 660793, at *10 (quoting 45 C.F.R. § 1302.93(a)). The Sixth Circuit adopted that reasoning. *See Livingston*, 35 F.4th at 491.

There is also no reason to think that Congress—which granted the Secretary broad authority to protect Head Start students and personnel precisely because it could not foresee all future threats to participant health and safety—would have regarded a vaccine requirement as a matter requiring clear congressional authorization. *See* 153 Cong. Rec. S14375-02, S14376 (daily ed. Nov. 14, 2007) (statement of Sen. Kennedy) (Head Start "provides the starting point for a child's day, with a healthy meal each morning and a promise to parents that while they are at work and balancing two jobs, their children will see a doctor and dentist, and receive immunizations."). To the contrary, "[v]accination requirements are a common feature of the provision of healthcare in America," *Missouri*, 142 S. Ct. at 653, and have had particular prominence in the education context, *see, e.g.*, *Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021); *see also Jacobson v. Massachusetts*, 197 U.S. 11, 25–35 (1905) (identifying vaccine requirements in the United States and other Western countries in the early 1800s). Thus, "when it comes to vaccination mandates, there was no reason for Congress to be more specific than authorizing the Secretary to make regulations." *Florida*, 19 F.4th at 1288 (in the context of the Secretary's rulemaking on Medicare and Medicaid facilities). At a minimum, the Secretary reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See Northport Health Servs. of Ark., LLC v. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021), *pet. for cert. filed*, No. 21-1455 (U.S. May 17, 2022).

In any event, to the extent that either the major questions doctrine or the federalism canon applies, for the aforementioned reasons, Congress spoke clearly by authorizing the Secretary to impose, *inter alia*, "standards relating to the condition . . . of [Head Start] facilities," as well as to address other "administrative . . . standards" necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress gave the Secretary the authority

to adopt any "other standards as the Secretary finds to be appropriate." *Id.* § 9836a(a)(1)(E). "Congress could have limited [the Secretary's] discretion in any number of ways, but it chose not to do so." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020), *remanded sub nom.*, *Pennsylvania v. Pres., U.S.*, 816 F. App'x 632 (3d Cir. 2020). And courts may not "impos[e] limits on an agency's discretion that are not supported by the text." *Id.* at 2381. Indeed, the Supreme Court recently rejected a similar effort to "offer a narrow[] view" of "seemingly broad [statutory] language," where "the longstanding practice of" HHS "in implementing the relevant statutory authorities [told] a different story." *Missouri*, 142 S. Ct. at 652.

B. The Rule is Not Contrary to Law.

Plaintiff wrongly alleges that the Rule violates 42 U.S.C. § 9836a(2)(A), which requires that the Secretary "shall consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs." *See* Pl.'s Mem. at 24–25. Plaintiff states that Defendants "admitted their failure to do this because the Rule does not list all these required experts," *id.*, but this is baseless. The Rule explains that the Secretary consulted with "experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA." 86 Fed. Reg. at 68,054. Absent from 42 U.S.C. § 9836a(a)(2) is any requirement that the Secretary identify by name the specific experts with whom he consulted. And Plaintiff does not point to any authority requiring such specificity. *Cf.* 5 U.S.C. § 553(c) (requiring only "a concise general statement of [a final rule's] basis and purpose"). The personnel who work in the Office of Head Start who created the Rule are of course, themselves, experts in the other listed fields. In any event, even if the Secretary had failed to comply with the statute's consultation requirement, "consultation during the deferred notice-and-comment period is permissible." *Missouri*, 142 S. Ct. at 654 (rejecting a similar argument to that which Plaintiff makes here).

II. The Rule Does Not Violate the APA's Notice-and-Comment Requirement.

An agency may issue a rule without advance notice and comment when the agency "for good cause finds" that it is "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This exception can be invoked when "delay could result in serious harm." *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004); *see also Haw. Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (good cause upheld when there was a "concern about" [a] threat to public safety").

While the courts in *Louisiana* and *Texas* previously found that the Secretary had not properly invoked the good cause exception, *see Louisiana v. Becerra*, 577 F. Supp. 3d 483, 498 (W.D. La. 2022); *Texas*, 577 F. Supp. 3d at 547, since then, the Supreme Court has made clear that good cause can be properly shown in the COVID-19 vaccination context when "something specific" justifies it. *Missouri*, 142 S. Ct. at 654 (citation omitted). And the Sixth Circuit determined that "HHS likely did not violate the [APA] when it promulgated the vaccine requirement through an interim final rule instead of notice-and-comment rulemaking." *Livingston*, 35 F.4th at 491.

In *Missouri*, the Supreme Court held that "the Secretary's finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths" constituted the "something specific" that is "required to forgo notice and comment." *Missouri*, 142 S. Ct. at 654 (citation omitted). The Secretary found good cause here for similar reasons, *see* 86 Fed. Reg. at 68,058–59, including the prospect of flu season and returning to fully in-person programs in January 2022, *id.* at 68,059. The Supreme Court also expressly rejected the argument Plaintiff advances here, Pl.'s Mem. at 23—that the Secretary's delay in promulgating the Rule undercuts his ability to invoke the good cause exception. *Missouri*, 142 S. Ct. at 654 ("[W]e cannot say that in this instance the two months the agency took to prepare a 73-page rule constitutes 'delay' inconsistent with the Secretary's finding of good cause.").

Plaintiff attempts to distinguish *Missouri* because that case involved CMS, which "has expertise in regulating public health." Pl.'s Mem. at 24. But the Court did not rely on any agency expertise in

concluding that the HHS Secretary—the same official who promulgated the Rule at issue here—had demonstrated emergency circumstances sufficient to forgo notice and comment. *See generally Missouri*, 142 S. Ct. at 654. Plaintiff also claims *Livingston* is unpersuasive because it held that the Rule is similar to the one upheld by the Supreme Court in *Missouri*. Pl.'s Mem. at 24. But it is persuasive for exactly that reason—the Sixth Circuit in *Livingston* recognized the similarities between the two rules and faithfully applied Supreme Court precedent. *See Livingston*, 35 F.4th at 491 ("Given the similarity between the interim final rule at issue here and the rule that the Supreme Court upheld in *Missouri*, the plaintiffs are unlikely to prevail on their claim that the lack of notice-and-comment rulemaking violated the Administrative Procedure Act."). In short, "[t]he interim final rule contains ample discussion of the evidence in support of a vaccine requirement and the Secretary's justifications for enacting the requirement." *Livingston*, 35 F.4th at 491.

III. The Rule Is Not Arbitrary and Capricious.

Plaintiff's claims that the Rule is arbitrary-and-capricious fare no better. Agency action must be upheld in the face of an arbitrary-and-capricious challenge so long as the agency "articulate[s] a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor*, 140 S. Ct. at 2383 (citation omitted). A court's review is "narrow," and the court "is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Ky. Coal Ass'n v. Tenn. Valley Auth.*, 804 F.3d 799, 801 (6th Cir. 2015) (APA standard is not an "invitation for judicial second-guessing"). Under this "deferential" standard, a court "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Critically, "mere policy disagreement is not a basis for a reviewing court to declare agency action unlawful." *N.C. Fisheries Ass'n v. Gutierrez*, 518 F. Supp. 2d 62, 95 (D.D.C. 2007).

Furthermore, the Court's review of Plaintiff's APA claims should be confined to the record

before the Secretary. "[T]he focal point for judicial review should be the administrative record already in existence [on the basis of which the Secretary's determination was made], not some new record made initially in the reviewing court." *La. Env't Soc'y, Inc. v. Dole*, 707 F.2d 116, 119 (5th Cir. 1983) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). What matters, therefore, is the evidence that was available and considered by the Secretary at the time the Rule was issued. *See id.*; *see also Lee Mem'l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 46–47 (D.D.C. 2015) (remarking that the administrative record "consists of all documents and materials directly or indirectly considered by agency decision-makers"). "[W]hen a party seeks review of agency action under the APA . . . , the district judge sits as an appellate tribunal." *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). Thus, the Court's review "is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously." *Id.*

Here, the Secretary adopted a reasonable Rule after considering the relevant issues. The fifty-page Rule reasonably explains the Secretary's decision, setting forth the justifications, weighing costs and benefits, considering alternative approaches, and providing an economic impact analysis. *See generally* 86 Fed. Reg. at 68,052. Although this Court previously stated that some of the APA claims raised "interesting issues," PI Order at 28, the Supreme Court has since rejected similar arbitrary-and-capricious claims against the CMS vaccine requirement, *see Missouri*, 142 S. Ct. at 653–54, and other courts have found that the Rule is not arbitrary and capricious, *see Livingston*, 2022 WL 660793, at *8; *see also Livingston*, 35 F.4th at 491 ("adopt[ing] the reasoning of the district court" as to the reasons why "plaintiffs have not shown that they will likely prevail on the merits," including as to their arbitrary-and-capricious claim).

First, contrary to Plaintiff's assertion, *see* Pl.'s Mem. at 17–18, the agency considered whether to tie requirements to community transmission rates. 86 Fed. Reg. at 68,066. However, given the number of Head Start grant recipients and the fact that many serve entire states or cross state lines, the agency concluded that such an approach "would be burdensome for" grant recipients operating

over a large area. *Id.* It is not arbitrary or capricious for the agency to recognize that "children benefit from routine and predictability"[4] and to "prioritiz[e] a clear and transparent policy that is easy for grantees to follow across their service areas." *Id.* And an agency's action should be upheld where it acts within the "zone of reasonableness." *Prometheus Radio Project*, 141 S. Ct. at 1158; *see also Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214 (D.C. Cir. 2013) ("An agency has wide discretion in making line-drawing decisions and the relevant question is whether the agency's [determination is] within a zone of reasonableness, not whether [it is] precisely right." (cleaned up)).[5]

Plaintiff points to a pre-Rule CDC statement "celebrat[ing] the success of Head Start programs adjusting to COVID based on their locality." Pl.'s Mem. at 17. But at that time, OHS had no requirements whatsoever, and as explained below, the onset of the Delta variant and the move towards in-person classes immediately preceding the issuance of this Rule necessitated, in the Secretary's reasoned judgment, a new approach. Plaintiff also says that the Rule interferes with "Head Start programs' liberty or the liberty of the individuals." *Id.* at 18. But Head Start is a discretionary grant program; no one is entitled to receive a Head Start grant or to attend a Head Start program, and all participants necessarily agree to abide by the standards HHS sets when they voluntarily join the program. *See* Grants Policy Statement. And in any event, it was not arbitrary and capricious for the Secretary to prioritize the health and safety of participants and the need to prevent program closures.

Second, Plaintiff argues that the agency did not sufficiently explain why it departed from its previous guidance that merely promoted vaccination. Pl.'s Mem. at 18–19. That argument lacks merit. The Rule notes, among other considerations, that "the advent of the Delta variant and the potential for new variants," and the "return to fully in-person services" in January 2022, justified a more robust

[4] Plaintiff says it "makes no sense" to say that a nationwide Rule, as opposed to one based on community-transmission levels, promotes routine and predictability because children attend the same Head Start program every day. Pl.'s Mem. at 18. But transmission levels within a community can change over time, so a rule that varied with transmission level could see masks required on a fluctuating and unpredictable basis.

[5] Notably, the CMS rule at issue in *Missouri* also did not differentiate between localities. *See Missouri*, 142 S. Ct. at 653–54 (upholding the CMS rule).

approach at that time, particularly given that "uptake of vaccination among Head Start staff ha[d] not been as robust as hoped for and ha[d] been insufficient to create a safe environment for children and families." 86 Fed. Reg. at 68,054. In addition, on November 10, 2021, the CDC "issued updated guidance to early childhood education and child care (ECE) programs," which, among other things, recommended "universal indoor masking for ECE programs for everyone aged 2 years and older." *Id.* The changed circumstances, including the emergence of the Delta variant and the updated CDC recommendations shortly before the Secretary issued the Rule, justified the change in course. This is not unusual. "[A]gencies are expected to reevaluate the wisdom of their policies in response to changing factual circumstances." *COMPTEL v. FCC*, 978 F.3d 1325, 1335 (D.C. Cir. 2020). Contrary to Plaintiff's suggestion, there is no heightened standard when an agency changes its policy so long as the agency shows that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). That Plaintiff would have reached a different conclusion does not mean that the agency acted arbitrarily or capriciously. *See N.C. Fisheries Ass'n*, 518 F. Supp. 2d at 95 ("[M]ere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.").

Plaintiff's allusion to "reliance interests," Pl.'s Mem. at 19, is unavailing. None of Plaintiff's interests implicates reliance in the traditional sense, *i.e.*, Plaintiff does not allege that she or other staff and volunteers undertook actions to their detriment because of representations that the Secretary had made to them. Plaintiff also says it was unreasonable for the Secretary to consider the potential for future variants on the grounds that there may be no new variants, or they may be innocuous. *Id.* That argument should be rejected both because it was reasonable for the Secretary to consider potential risks even if there is a chance they do not come to fruition, and because the post-Rule emergence of the Omicron variant proved that the risk was real. And the fact that some programs operated in

person before the Rule was issued, Pl.'s Mem. at 19, does not mean it was unreasonable for the Secretary to issue a Rule that would encourage more programs to return to in-person instruction.

Third, contrary to Plaintiff's argument, *see* Pl.'s Mem. at 19–20, HHS did consider alternatives to the vaccine requirement, including a testing alternative. Indeed, the Rule has an entire section outlining several options the agency considered but rejected. 86 Fed. Reg. at 68,066. HHS considered "screening and diagnostic testing" as one such alternative approach but ultimately decided to require vaccinations and mask use instead because those were two of the most effective mitigation strategies, as supported by numerous studies cited by the agency, and because those requirements aligned with the program performance standards already in place for the Head Start program. *Id.*

The fact that OSHA issued a rule requiring different standards is beside the point. *See* Pl.'s Mem. at 19–20. There is no rule that an agency acts arbitrarily and capriciously merely because a different agency has adopted a different approach to address a common health risk in a different context. To the contrary, it is a "well known" principle of administrative law that regulations "are not arbitrary just because they fail to regulate everything that could be thought to pose any sort of problem." *Pers. Watercraft Indus. Ass'n v. Dep't of Com.*, 48 F.3d 540, 544 (D.C. Cir. 1995). As the Rule explains, the OSHA rule, which covered over eighty million employees nationwide, was promulgated pursuant to a different statutory authority from the Rule and covered a far broader array of workplace contexts. 86 Fed. Reg. at 68,061, 68,069. It is thus not surprising or in any way improper that the two agencies determined that different standards were appropriate for different situations.[6]

Fourth, Plaintiff also takes issue with the fact that there is no end date to the mask requirement, Pl.'s Mem. at 20, although she does not raise this issue in the Amended Complaint.[7] Again, the Rule provides a reasoned explanation: "[C]hildren benefit from routine and predictability. ACF determined

[6] To the extent Plaintiff incorporates arguments by reference to the Plaintiff States' briefs, Pl.'s Mem. at 20, Defendants incorporate their corresponding responses to those arguments.

[7] As discussed above, HHS is not currently monitoring programs for compliance with the masking requirement. *See supra* Bkgrd.

that the best course of action was not to provide an end date on the" masking requirement and testing requirement for vaccine-exempt adults at this time. 86 Fed. Reg. at 68,066; *see Prometheus Radio Project*, 141 S. Ct. at 1158 (stating that the agency only needs to have "reasonably considered the relevant issues and reasonably explained the decision"). Additionally, the Secretary invited comments on this decision regarding an end date, indicating a willingness to adjust course if needed when it finalizes the Rule.[8]

Plaintiff also says that Defendants failed to "consider science that undermines the Rule's rationale," pointing to record evidence that "[v]accinated people can spread COVID" and thus, she says, "forcing preschool teachers to get vaccinated to slow the spread is nonsensical." Pl.'s Mem. at 20. The scientific literature on which the Rule is based recognized that breakthrough infections in vaccinated persons were possible and that such infected persons could spread SARS-CoV-2. However, the evidence available at the time also showed that the risk of developing COVID-19 was higher for unvaccinated than for vaccinated people, and therefore unvaccinated persons were more likely to transmit the virus. 86 Fed. Reg. at 68,059 & n.74. Studies also showed that, at the time the Rule was published, vaccinated people with breakthrough infections were potentially less infectious than unvaccinated individuals with primary infections. *Id.* at 68,055 (citing Ashley Fowlkes, Manjusha Gaglani, Kimberly Groover, et al., Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021, (Aug. 27, 2021), MMWR Morb. Mortality Wkly. Rep. 2021; 70:1167–69, https://perma.cc/5YKH-QYR4). Indeed, the Supreme Court acknowledged the efficacy of vaccines as necessary to "reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients." *Missouri*, 142 S. Ct. at 652 (citing Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,557–58 (Nov. 5, 2021)).

[8] The CMS rule at issue in *Missouri* also did not provide an end date. *See Missouri*, 142 S. Ct. at 653–54 (upholding the CMS rule).

Fifth, Plaintiff argues that the Rule overlooked that staff might leave the program due to the vaccine requirement, thereby diminishing the "quality and quantity of Head Start services," *see* Pl.'s Mem. at 20–22, an argument that again Plaintiff did not raise in her Amended Complaint. In any event, the Secretary explicitly considered that the Rule might result in staff vacancies and stated that "[t]o value the countervailing risk of staff vacancies, [the Secretary] adopt[s] an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks." 86 Fed. Reg. at 68,091. The Secretary also explained that, "[f]or each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings." *Id.* One of the primary goals of the Rule was to reduce instances in which a positive case of COVID-19 in the classroom resulted in program closures and service interruptions. *See id.* at 68,054. Thus, the Secretary considered that some personnel and students might voluntarily leave the Head Start program over the new requirements, but nevertheless determined that those costs would be outweighed by the benefits of reducing COVID-19 transmission based on the evidence available at the time. *See La. Env't Soc'y, Inc.*, 707 F.2d at 119. Additionally, the Rule provides exemptions from the vaccine requirement for personnel "who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance." 86 Fed. Reg. at 68,061 (footnote omitted). There is no evidence that the vaccine requirement would result in widespread program closures; indeed, half of the country (in which no injunction has been entered) has operated under the Rule for over half a year, and Plaintiff does not point to any such closures in those states. The Secretary's determination that the hours of time saved by issuing the Rule outweighed the cost of staff departures is not arbitrary and capricious. Courts are not to "second-guess[]" an agency's "weighing of risks and benefits" associated with a rulemaking. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019).

Sixth, the Secretary's rationale for the Rule—to mitigate the spread of COVID-19 in Head Start programs—was not pretextual. *Contra* Pl.'s Mem. at 22–23. The thorough explication in the fifty-page Rule of the Secretary's justifications and reasons rebuts any accusation that his reasons were

pretextual. And, of course, to the extent that the Rule was part of a broader focus by the administration to protect the health and safety of Americans, there is nothing unusual or unlawful about this. "[A] court may not set aside an agency's policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities." *Dep't of Com.*, 139 S. Ct. at 2573. Unlike in *Department of Commerce v. New York*, here there was not a "significant mismatch between the decision the Secretary made and the rationale he provided." *Id.* at 2575. Given the copious evidence available at the time the Rule was published about the effectiveness of vaccines in reducing the spread of COVID-19, *e.g.*, 86 Fed. Reg. at 68,059, it is not at all surprising that other federal agencies, like OSHA or CMS, may have concluded it was vital to their own missions to require vaccination of individuals that participated in their programs or that were regulated by them. Plaintiff's references to *NFIB* and *BST Holdings, LLC* are unavailing; neither case concluded that the OSHA rule at issue in those cases violated the APA. *See generally NFIB*, 142 S. Ct. 661 (not conducting any APA analysis); *BST Holdings, LLC v. OSHA*, 17 F.4th 604 (5th Cir. 2021) (same).

IV. The Rule Does Not Violate the Nondelegation Doctrine.

Plaintiff contends that the Head Start Act lacks an intelligible principle because, along with authorizing the Secretary to issue "standards relating to the condition . . . of [Head Start] facilities," as well as to address other "administrative . . . standards" necessary for safely carrying out day-to-day operations of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), (D), it permits him to adopt "such other standards as the Secretary finds to be appropriate" for Head Start agencies and programs, *id.* § 9836a(a)(1)(E). *See* Pl.'s Mem. at 25–26. But many statutes use similar terminology, and Plaintiff has "not identified a single case which finds one of those statutes to be in violation of" the nondelegation doctrine. *Livingston* 2022 WL 660793, at *9. It is not the case that "'appropriate' could mean anything" Defendants want it to, Pl.'s Mem. at 26, because any standard promulgated by the Secretary must be consistent with the Head Start Act's purpose of promoting the school readiness of Head Start participants by providing them with health, education, social and other services. *See* 42

U.S.C. § 9831(2); *see also supra* Section I.A.1. The Secretary's authority in § 9836a(a)(1)(E) meets the "minimal standard" required for the nondelegation doctrine. *Livingston* 2022 WL 660793, at *9.

V. The Rule Does Not Violate the Commerce Clause.

Plaintiff argues that because this Rule involves a vaccine requirement, just as the OSHA Rule did, the Fifth Circuit's holding that the OSHA Rule violated the Commerce Clause should also apply here. Pl.'s Mem. at 26. But as Defendants explained, *see* Defs.' Br. at 25, the Head Start Act was passed pursuant to Congress's authority under the Spending Clause, not the Commerce Clause. Plaintiff's mistaken belief that there exists a "mismatch between mask and vaccine mandates and the Head Start Program's goals," Pl.'s Mem. at 27, does not negate Congress's power to enact a spending program such as the Head Start Act. And because Congress lawfully exercised its Spending Clause authority, *BST Holdings*, which addressed the Commerce Clause, does not apply.

VI. The Rule Does Not Violate the Tenth Amendment.

The Rule does not violate the Tenth Amendment. The Head Start Act was passed pursuant to Congress's Spending Clause authority, and when "a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York v. United States*, 505 U.S. 144, 156 (1992). The Secretary issued the Rule pursuant to the authority that Congress delegated to him in the Head Start Act. *See supra* Section I. And even if the Rule displaces state law as to the entities that accept Head Start funds, Pl.'s Mem. at 24, the federal government does not "invade[] areas reserved to the States by the Tenth Amendment simply because it exercises its authority" under the Constitution, even "in a manner that *displaces* the States' exercise of their police powers." *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291 (1981) (emphasis added).

While Plaintiff argues that *Missouri* is distinguishable because states have traditionally had a role in education, *see* Pl.'s Mem. at 27, Congress's Spending Clause authority applies even when Congress legislates "in an area historically of state concern." *Sabri v. United States*, 541 U.S. 600, 608

n.* (2004). Because the Rule rests on authority specifically delegated to the federal government, it does not violate the Tenth Amendment. *See Brackeen v. Haaland*, 994 F.3d 249, 310 (5th Cir. 2021) ("[T]he Federal Government, when acting within a delegated power, may override countervailing state interests, whether those interests are labeled traditional, fundamental, or otherwise." (citation omitted)), *cert. granted*, 142 S. Ct. 1205 (2022).

VII. Any Relief Granted to Plaintiff Should Be Limited in Scope.

Finally, if the Court finds that Plaintiff is entitled to summary judgment (and it should not), any relief should be limited in scope. If the Court decides to set aside any part of the Rule under the APA, that relief should be no broader than necessary to remedy any demonstrated irreparable harms of the specific Plaintiff in this case. "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018). Plaintiff's decision to bring APA claims does not necessitate a nationwide remedy. *See, e.g.*, *Louisiana v. Becerra*, 20 F.4th 260, 263–65 (5th Cir. 2021) (vacating nationwide scope of injunction in APA challenge). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiff.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiff's Cross-Motion for Summary Judgment.

Dated: September 14, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Michael P. Clendenen
CHRISTOPHER D. EDELMAN (DC Bar No. 1033486)
MICHAEL P. CLENDENEN (DC Bar No. 1660091)

MADELINE M. MCMAHON (DC Bar No. 1720813)
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street N.W.
Washington, DC 20005
Phone: (202) 305-0693
michael.p.clendenen@usdoj.gov

Attorneys for Defendants

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

STATE OF LOUISIANA, *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 3:21-CV-04370-TAD-KDM

DEFENDANTS' RESPONSE TO PLAINTIFF SANDY BRICK'S STATEMENT OF MATERIAL FACTS IN SUPPORT OF HER CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 56.1, Defendants hereby submit this response to Plaintiff Sandy Brick's Statement of Material Facts in Support of her Cross-Motion for Summary Judgment, ECF No. 105-1, numbers 1–13. Defendants note that because this case arises under the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, the "generally applicable" Rule 56 standard does not apply, and the Court reviews the challenged agency action to determine "whether[,] as a matter of law, the evidence in the administrative record permitted the agency to make the decision it did." *Triplett v. Fed. Bureau of Prisons*, No. 3:08-cv-1252-K 2009 WL 792799, at *7 (N.D. Tex. Mar. 24, 2009) (quoting *Tex. Comm'n on Nat. Res. v. Van Winkle*, 197 F. Supp. 2d 586, 595 (N.D. Tex. 2002)); *see Boston Redevelopment Auth. v. Nat'l Park Serv.*, 838 F.3d 42, 47 (1st Cir. 2016). Defendants object generally to reliance on statements of undisputed material facts to resolve the legal questions presented in this case. "[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. By Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The Court must rely upon "'the full administrative record that was

before the [agency] at the time' it took the action under review." *SIH Partners LLLP v. Commissioner of Internal Revenue*, 923 F.3d 296, 302 (3d Cir. 2019) (quoting *C.K. v. N.J. Dep't of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996))).

1. A July 14, 2021, OHS webinar on "staff wellness" included this statement by OHS Deputy Director Ann Linehan: "The final thing that we want to say, we want to recognize, . . . that we understand receiving the vaccination is a personal decision. We want to make sure everything that you're doing everything you can to make sure that your staff and families have reliable information and resources to help them make this decision and in consultation with their doctor." *Mental Health and Staff Wellness: Emotionally Strong Together*, HHS/OHS webinar, July 14, 2021.

   Response: Statement not disputed.

2. On July 23, 2021, the White House acknowledged that imposing vaccine mandates is "not the role of the federal government; that is the role that institutions, private-sector entities, and others may take . . . . [W]e're going to continue to work in partnership to fight misinformation. And we're going to continue to advocate and work in partnership with local officials and—and trusted voices to get the word out." Jen Psaki, White House Press Briefing (July 23, 2021).

   Response: Statement not disputed.

3. Yet, on September 9, 2021, President Biden reversed course, announcing "a new plan to require more Americans to be vaccinated, to combat those blocking public health." *Remarks by President Biden on Fighting the COVID-19 Pandemic*, White House (Sept. 9, 2021). He stressed that: "we must increase vaccinations among the unvaccinated with new vaccination requirements." *Id.* He noted: "The bottom line: We're going to protect vaccinated workers from unvaccinated co-workers." *Id.*

   Response: Statement not disputed.

4. The President indicated that he was "frustrated with the nearly 80 million Americans who are still not vaccinated" *id.*, claimed that unvaccinated persons "can cause a lot of damage" *id.*, and noted that he would not allow the unvaccinated, for whom his "patience is wearing thin," *id.*, "to stand in the way of protecting the large majority of Americans who have done their part . . . ." *Id.*

   Response: Statement not disputed.

5. The President announced that the federal government would issue five new COVID-19 vaccine mandates: an emergency temporary standard from the Occupational Safety & Health Administration ("OSHA") on all companies with 100 or more employees; an emergency rule from the Centers for Medicare & Medicaid Services ("CMS") for all healthcare employees working at facilities that accept Medicare or Medicaid patients; an executive order for all executive branch federal employees; an executive order for employees of federal contractors; and this Head Start Rule. AR 0001, 01057, 01211, 01284, 01288.

   Response: Statement not disputed.

6. The same day, the director of the Office of Head Start at HHS sent a letter to Head Start providers introducing "a new requirement for Head Start programs. All Head Start employees must be vaccinated against COVID-19." The letter promised "rulemaking to implement this policy."

   Response: Statement not disputed.

7. On Monday, November 30, 2021, the Office of Head Start ("OHS") and Administration for Children & Families ("ACF") and HHS published an interim final rule imposing a vaccination mandate on all staff, student-facing contractors, and all volunteers to have received the second shot by January 31, 2022, and a universal mask mandate on all Head Start participants over age two. The Rule stated it would be immediately implemented without notice-and-comment.

AR 00001, 00008; 86 Fed. Reg. 68,052, 68,059.

Response: Statement disputed to the extent it asserts that the Rule requires a two-dose vaccination series. The Rule also allows for a single dose of vaccines for which only one does is required, *i.e.*, the Johnson & Johnson vaccine. Statement also disputed as to its statement of the scope of the vaccination requirement; the vaccination requirement applies to Head Start staff, volunteers, and contractors whose activities involve contact with or providing direct services to children and families in classrooms.

8. The Rule cites 42 U.S.C. § 9836a(a)(1)(C)–(E) as the basis for Defendants' statutory authority. AR 00001; 86 Fed. Reg. 68,052.

Response: Statement not disputed.

9. The Rule departed from President Biden's September 9, 2021, plan in at least two major ways: President Biden had said nothing about mandating vaccines for all Head Start volunteers—nearly 1.1 million people—and had made no mention of requiring program participants to wear masks.

Response: Statement disputed to the extent it suggests that the President's September 9, 2021 statement set out all of the details of the anticipated actions. Statement also disputed to the extent that it misstates the scope of the vaccination requirement; the vaccination requirement applies to Head Start staff, volunteers, and contractors whose activities involve contact with or providing direct services to children and families in classrooms.

10. Plaintiff works as a teacher for a school serving federal Head Start students in Kinder, Louisiana. Decl. of Sandy Brick ("Brick Decl.") ¶ 3.

Response: Statement not disputed.

11. Subsequent to the Rule's publication, and only because of the Rule, Plaintiff's employing Head Start agency informed her that she must either submit proof of vaccination or have an

exemption approved by January 28, 2022. Brick Decl. ¶ 4. Her employer also warned that if she failed to meet either the vaccination requirement or receive an exemption, she would be subject to termination. Brick Decl. ¶ 4.

Response: Statement disputed. Defendants have no knowledge as to whether or not Plaintiff's employing Head Start program has an independent requirement for its staff to be vaccinated against COVID-19.

12. Plaintiff does not wish to take the COVID-19 vaccine and filed this lawsuit on December 22, 2021, to protect her job. Brick Decl. ¶ 6.

Response: Statement not disputed.

13. Shortly after federal courts enjoined the Head Start federal vaccine mandate in Louisiana, Plaintiff 's employer informed her that the vaccination policy was not being enforced because a court had blocked the federal Head Start vaccine mandate from going into effect. Brick Decl. ¶ 7. Since then, her employer has not required staff to take the COVID-19 vaccine or required them to wear masks. Brick Decl. ¶ 7.

Response: Statement not disputed.

Dated: September 14, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Michael P. Clendenen
CHRISTOPHER D. EDELMAN (DC Bar No. 1033486)
MICHAEL P. CLENDENEN (DC Bar No. 1660091)
MADELINE M. MCMAHON (DC Bar No. 1720813)
Trial Attorneys

U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street N.W.
Washington, DC 20005
Phone: (202) 305-0693
michael.p.clendenen@usdoj.gov

Attorneys for Defendants