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

STATE OF LOUISIANA, by and through its Attorney General, Jeff Landry, *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 3:21-CV-4370-TAD-KDM

DEFENDANTS' MOTION FOR LEAVE TO FILE MOTION TO DISMISS, OR IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT, IN EXCESS OF PAGE LIMITS

Defendants, various federal officials and agencies, respectfully request the Court's leave to file a Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, in excess of the 25-page limit set by the Local Rules. *See* LR7.8.

Plaintiffs commenced this action by filing a 234-paragraph complaint challenging an interim final rule regarding COVID-19 mitigation strategies in Head Start programs and requesting that the Court issue an injunction applicable to at least twenty-four states across the country. ECF No. 1. Defendants intend to file a single combined motion to dismiss, or in the alternative, motion for summary judgment. The Local Rules normally permit 25 pages for briefs in support of a motion. *See* LR7.8. The Government respectfully submits that a brief of up to 45 pages is appropriate under the circumstances given the length of Plaintiffs' complaint and the Government's intent to combine both a motion to dismiss and a motion for summary judgment, as well as the importance of the Government interests at stake involving the Government's response to the COVID-19 pandemic.

The Government does not intend to burden the Court with unduly lengthy briefing, but rather believes that a brief of the length requested herein is necessary to provide a comprehensive response to Plaintiffs' complaint and would aid the Court in its decisionmaking process.

For all these reasons, the Government requests that the Court grant leave for the Government to file a Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, of no more than 45 pages. On March 23, 2022, counsel for Defendants asked Plaintiffs' counsel whether Plaintiffs opposed the relief sought in this motion. As of the filing of this Motion, Plaintiffs had not responded with a position.

Dated: March 24, 2021

Respectfully submitted,

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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

[DRAFT] PROPOSED ORDER

On this day came to be considered Defendants' Motion for Leave to File Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, in Excess of Page Limits. After considering the motion and the pleadings of the parties filed herein, and finding that good cause has been shown for the relief requested:

It is hereby **ORDERED** that Defendants' Motion for Leave to File Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, in Excess of Page Limits is **GRANTED**. Defendants may file a Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, in Excess of Page Limits not to exceed 45 pages, excluding the table of contents and table of authorities.

IT IS SO ORDERED.

March ___, 2022

_____
THE HONORABLE TERRY A. DOUGHTY
UNITED STATES DISTRICT JUDGE

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' BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS, OR IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

COVID-19 has killed over 965,000 people and infected nearly 80 million in the United States alone. *See* Centers for Disease Control and Prevention ("CDC"), COVID Data Tracker (Mar. 14, 2022), https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://perma.cc/T9UT-QSXZ]. Those numbers continue to grow as the highly transmissible virus passes easily from person to person. As a result, the pandemic has been devastating for children and families alike. Fortunately, safe and effective vaccines are now approved or authorized for emergency use to protect against COVID-19. And now, the Supreme Court has confirmed that the "unprecedented circumstances" of the COVID-19 pandemic "provide no grounds for limiting the exercise of authorities [the Department of Health and Human Services] has long been recognized to have," and that such authorities may be used to impose vaccination requirements like the one challenged here. *See Biden v. Missouri*, 142 S. Ct. 647, 654 (2022) (per curiam).

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. Head Start students are five years old and younger, and thus most cannot be vaccinated. 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 have severe negative consequences beyond the classroom. In addition, a majority of Head Start children and personnel come from minority and low-income communities, which have been disproportionately impacted by COVID-19.

The Secretary of Health and Human Services (the "Secretary") reviewed the evidence and concluded that he must take urgent measures to protect Head Start students and those interacting with them from infection. Congress has assigned the Secretary a statutory responsibility to protect the health and safety of Head Start students and personnel. To carry out this statutory duty, the Secretary issued an Interim Final Rule, Vaccine and Mask Requirements to Mitigate the Spread of COVID 19 in Head Start Programs, 86 Fed. Reg. 68,052 (Nov. 30, 2021) (the "Rule"), requiring that those interacting with Head Start students be vaccinated for COVID-19, or otherwise qualify for an

exemption. These individuals were required to receive a single-shot vaccine or to obtain the second shot of a two-dose vaccine by January 31, 2022, or to request an exemption from this requirement from their employer. The Rule also requires masking, effective immediately, for all Head Start students over two years old and those Head Start personnel who have contact with students. Just as the Secretary did with the Supreme Court's approval in *Missouri*, 142 S. Ct. at 654, he issued the Rule on an emergency basis and waived a comment period in advance of publication due to an anticipated spike in COVID-19 cases in winter months and planned return to fully in-person services in January 2022. The Rule is therefore necessary to avoid further disruption to Head Start children's development and learning.

Plaintiffs, a collection of twenty-four states, challenge the Rule on statutory and constitutional grounds. As an initial matter, Plaintiffs—which do not directly receive Head Start funds to operate classrooms under 42 U.S.C. § 9836—lack standing to pursue their claims. Regardless, Plaintiffs have failed to state a claim for relief. The Secretary has express statutory authority to ensure that federal funds are used to protect the health and safety of Head Start students and personnel. He has exercised this authority for decades, including by promulgating regulations requiring Head Start participants to receive a slate of vaccinations, *see, e.g.*, 45 C.F.R. § 1304.3-4(2) (1975), and requiring staff to undergo health examinations and screenings, *see, e.g.*, Head Start Program, 61 Fed. Reg. 57,186, 57,210, 57,223 (Nov. 5, 1996). Similarly, here, the Secretary reasonably exercised that authority to arrive at the vaccination and mask Rule. He explained that the need to protect the health and safety of those in the Head Start program compelled him to act now. In exercising this authority Congress lawfully delegated to him under the Spending Clause, he did not run afoul of any Constitutional provision.

The Supreme Court upheld a similar Department of Health and Human Services vaccination requirement in *Missouri*, 142 S. Ct. 647, just last month. In light of that decision, a district court in the Eastern District of Michigan recently declined to issue a preliminary injunction of the Rule, holding that Plaintiffs were not likely to succeed on the merits of their claims because the Rule "plainly falls within the Secretary's authority." *Livingston Educ. Serv. Agency v. Becerra*, No. 22-cv-10127, 2022 WL

660793, at *4 (E.D. Mich. Mar. 4, 2022). For these reasons, this Court should dismiss the Complaint, or in the alternative, enter summary judgment in favor of Defendants.

BACKGROUND

I. The COVID-19 Pandemic Has Had Devastating Effects.

The novel coronavirus SARS-CoV-2 causes a severe acute respiratory disease known as COVID-19. 86 Fed. Reg. at 68,052. SARS-CoV-2 is primarily transmissible through exposure to respiratory droplets when one person is in close contact with another person who has COVID-19. As of March 2022, nearly 80 million COVID-19 cases and over 965,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://perma.cc/T9UT-QSXZ] (cited at 86 Fed. Reg. at 68,052 n.6). There can be no dispute that "COVID-19 is a highly contagious, dangerous, and . . . deadly disease." *Missouri*, 142 S. Ct. at 652. COVID-19 has had a disproportionate effect on low-income and minority communities. 86 Fed. Reg. at 68,054–56.

Because the virus that causes COVID-19 is highly transmissible, it readily spreads among unvaccinated individuals in classroom settings, even when infection control practices are followed. *Id.* at 68,053. Unvaccinated educators are at a much higher risk of infection and, therefore, pose a higher risk of transmitting the virus to young unvaccinated children in their care. *Id.* Studies have also shown that a lack of consistent mask usage in schools is associated with a higher risk of transmission.[1] Transmission of SARS-CoV-2 in child care settings often leads to infection and hospitalization in family members, including family members who are more susceptible to the effects of COVID-19 due to age or underlying condition. *Id.* at 68,055. When a child or staff member tests positive or is exposed to someone who has tested positive for SARS-CoV-2, classrooms and school programs often

[1] *See* 86 Fed. Reg. at 68,056 & nn.47–48 (citing Tracy Lam-Hine, Stephen A. McCurdy, Lisa Santora, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School—Marin County, California, May-June 2021, (Sept. 3, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1214, https://perma.cc/27TA-622J; Megan Jehn, J. Mac McCullough, Ariella P. Dale, et al. Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks—Maricopa and Pima Counties, Arizona, July-August 2021, (Sept. 24, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1372–73, https://perma.cc/Z9YT-3P28).

must be closed for days or weeks to allow time to receive test results and for quarantining. *Id.* Closures impose hardship on Head Start children and families by preventing in-person attendance in Head Start, thereby impairing early learning and development and diminishing the ability of parents to work. *Id.*

In June and July 2021, an especially contagious strain of SARS-CoV-2 known as the Delta variant drove dramatic increases in COVID-19 case and hospitalization rates throughout the United States. *Id.* at 68,052 & n.4 (citing CDC, Delta Variant: What We Know About the Science (updated Aug. 26, 2021), https://perma.cc/4YRA-UWSP). The Delta variant is associated with a higher risk of hospitalization in children: From June to mid-August 2021, weekly COVID-19-related hospitalizations among children and adolescents were nearly five times higher than in the preceding months. *Id.* at 68,054 & n.26 (citing Miranda J. Delahoy, Dawud Ujamaa, Michael Whitaker, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents—COVID-NET, 14 States, Mar. 1, 2020-Aug. 14, 2021, (Sept. 10, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1255–60, https://perma.cc/F535-GXNZ (noting also that hospitalization among children ages four and below increased tenfold)). Vaccination and mask usage remain effective mitigation strategies against the Delta variant. *Id.*

When the Secretary issued the Rule, there were troubling indications of a resurgence of the virus in the forthcoming winter months. *Id.* at 68,058; CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://perma.cc/T9UT-QSXZ]. Respiratory viruses, like SARS-CoV-2, typically circulate more easily in cold weather, and the United States experienced a large spike in COVID-19 cases during the winter of 2020. 86 Fed. Reg. at 68,058.

II. Safe and Effective Vaccines and Masks Are Widely Available in the United States.

Currently, three manufacturers offer vaccines approved or authorized for emergency use in the United States by the Food and Drug Administration ("FDA"). *See* 86 Fed. Reg. at 68,052. These vaccines are manufactured by Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson), respectively. *Id.* On October 29, 2021, the FDA authorized the Pfizer-BioNTech vaccine for use in

children ages five and up. *Id.* at 68,059.[2] There is currently no vaccine available in the United States for children under the age of five. *Id.*

These vaccines are highly effective at preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. *Id.* at 68,054–55. The available evidence indicates that these vaccines offer strong protection against all known variants of the virus, including the Delta variant—particularly against hospitalization and death. *Id.* at 68,054. Other studies indicate that the vaccines are 80% effective in preventing SARS-CoV-2 infection among frontline workers—more effective in practice than other protocols, such as regular testing. *Id.* at 68,059 & n.74 (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. Mortal Wkly. Rep. 2021; 70:1167–69, https://perma.cc/5YKH-QYR4).

Like all vaccines, COVID-19 vaccines are not 100% effective at preventing infection, and some breakthrough cases are expected among people who are fully vaccinated. However, the risk of developing COVID-19 remains much higher for unvaccinated than for vaccinated people, and therefore the presence of unvaccinated personnel is expected to lead to higher rates of transmission to other Head Start personnel and students. *Id.* at 68,055 & n.74. Vaccinated people with breakthrough COVID-19 cases are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19. *Id.* at 68,059 (citing Fowlkes, et al., *supra*). Studies have also shown that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer opportunities for transmission. *Id.*

Because children under age five cannot receive a COVID-19 vaccine at this time, masking remains an important mitigation strategy, along with vaccination among older individuals with whom

[2] After the Rule was issued, the FDA also authorized the Moderna COVID-19 vaccine for use in individuals eighteen years of age and older. *See* "Spikevax and Moderna COVID-19 Vaccine," U.S. Food & Drug Administration, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.

young children come in contact. *Id.* at 68,055.

III. The Head Start Act Grants the Secretary the Authority to Issue Performance Standards Related to Health and Safety of Participants and Employees in Head Start.

Head Start is a federal discretionary grant program that promotes school readiness in low-income children up to age five. 42 U.S.C. § 9831. Children under age three are eligible for the related Early Head Start program. *Id.* § 9840a. The Head Start program began as a summer program and demonstration grant in 1964, and in 1974 the Headstart–Follow Through Act made it a permanent program. Headstart, Economic Opportunity, & Community Partnership Act of 1974, Pub. L. No. 93-644, 88 Stat. 2291. The Head Start program is administered by the Office of Head Start ("OHS"), within the Administration for Children and Families ("ACF") of the Department of Health and Human Services ("HHS"). Head Start is a direct federal-to-local grant that does not pass through the state.

The Headstart–Follow Through Act required the Secretary of Health, Education, and Welfare (predecessor to HHS) to issue regulations prescribing standards for Head Start grantees. Pub. L. No. 93-644, § 8(a), 88 Stat. 2291, 2300. Since 1975, these standards, known as the Head Start Performance Standards, have included comprehensive health screening for children. 45 C.F.R. §§ 1304.3-3(b)(4)–(5), 1304.3-4(2) (1975). Over the years, additional health-related performance standards have been added. And in 1996, HHS added health screenings for staff and regular volunteers. 61 Fed. Reg. at 57,210, 57,223.

Because of the discretionary nature of Head Start grants, all participants necessarily agree to abide by the standards HHS sets when they voluntarily seek to join the program. *See* HHS, Grant Policy Statement, at I-1, I-3 to I-4 (Jan. 1, 2007), https://perma.cc/PME5-9724. No one is entitled to a Head Start grant or to attend a Head Start program. As a discretionary grant, the federal government maintains the authority to choose which entities receive grants. *See id.* Any entity that chooses to apply for and receives a Head Start grant agrees that it will meet the performance standards HHS imposes, even if those entities are school districts or educational institutions. *See id.*

Head Start is not a universal program, nor does it dominate early childhood care in the United

States. Of the 24.6 million children ages five and under in the United States, *see* Forum on Child and Family Statistics, https://perma.cc/8EU9-V2HA (last visited Dec. 23, 2021), only 864,289 are currently enrolled in Head Start programs, 86 Fed. Reg. at 68,077. Many alternative pre-kindergarten programs are available to families that object to the Head Start Performance Standards. For example, many school districts provide, in the same schools, both Head Start pre-K services and non-Head Start pre-K services, the latter of which are not subject to the Head Start standards or the Rule. *See* Decl. of Jami Jo Thompson ¶ 2, Pls.' Ex. C, ECF No. 2-4; Decl. of Arthur M. Joffrion, Pls.' Ex. P, ECF No. 2-17. Alternative options are also available to entities that object to the Head Start Performance Standards, including health standards such as the Rule. For instance, before the COVID-19 pandemic began, one Maryland school system determined that it could no longer maintain the standards set for Head Start, so it relinquished its grant and provided services through its own non-Head Start pre-K program instead. *See* Donna St. George, *Head Start Expands in Md. County Where Scandal Flared Two Years Ago*, Washington Post (Sept. 12, 2018), https://perma.cc/RB7C-YP5B.

IV. Recent Developments Have Revealed an Urgent Need for Further Action to Protect the Health of All Involved in Head Start.

As noted above, the emergence of the Delta variant over the summer months led to a dramatic spike in cases, hospitalizations, and deaths caused by COVID-19, a resurgence that has been driven by the spread of infection among the unvaccinated population. The Secretary's initial policy approach after vaccines became available to the general population during the early months of 2021 was to encourage, rather than require, vaccination. 86 Fed. Reg. at 68,054. However, as the agency eventually determined, "uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families." *Id.* The vaccination rate among Head Start personnel was estimated to be 77.1% on November 10, 2021. *Id.* at 68,070. In September 2021, the President announced his COVID-19 Action Plan, which set out a series of regulatory actions that federal agencies were planning to undertake in response to the pandemic. As relevant here, the announcement described HHS's plans to require vaccinations for teachers and personnel in Head Start programs. The White House, Path Out of the Pandemic,

https://perma.cc/M4GG-HB2Q. On November 10, 2021, the CDC issued updated guidance to early childhood education and child care programs, which, among other things, recommended universal indoor masking for children ages two and older in these programs. 86 Fed. Reg. at 68,054 & n.28 (citing CDC, "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs," updated Nov. 10, 2021, https://perma.cc/6VRE-FRTR).

V. The Secretary Issued the Vaccination and Masking Rule to Protect the Health and Safety of All Involved in Head Start from the Transmission of SARS-CoV-2 in Head Start Facilities.

On November 30, 2021, ACF published the interim final rule at issue here. The Rule adds to the Head Start Performance Standards that all Head Start staff, volunteers, and contractors whose activities involve contact with or providing direct services to children and families in classrooms (collectively, "Head Start personnel") must be fully vaccinated for COVID-19. 86 Fed. Reg. at 68,060. Under the Rule, all non-exempt personnel must receive the second dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine by January 31, 2022. *Id.* at 68,052. Non-exempt individuals must provide documentation of their vaccination status. *Id.* at 68,061. Exemptions from the vaccination requirement will be given to individuals "who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance." *Id.* Each Head Start program must establish a process for reviewing and reaching a determination regarding exemption requests. *Id.* The Rule provides that exempt individuals must be tested for COVID-19 on a weekly basis. *Id.* at 68,053.

The Rule also adds to the Head Start Performance Standards a universal masking requirement. *Id.* at 68,060. All individuals ages two and over must wear a mask indoors in any setting where Head Start services are provided and inside any vehicle owned, leased, or arranged by the Head Start program. *Id.* Exceptions are permitted for individuals when they are eating or drinking, for children when they are napping, and for certain individuals who cannot wear a mask due to a disability. *Id.* Unvaccinated individuals are also required to wear a mask outdoors in crowded settings or during activities that involve sustained close contact with other people. *Id.* The masking requirement became

effective immediately upon publication of the Rule. *Id.*[3] The Secretary also concluded that there was good cause to waive the notice-and-comment process in rulemaking. *Id.* at 68,058–59.

VI. The Present Controversy

Plaintiffs challenge the Rule, asserting claims purportedly arising under the United States Constitution, the Administrative Procedure Act ("APA"), and a variety of other statutes. Compl. ¶¶ 150–234, ECF No. 1. On January 1, 2022, the Court granted Plaintiffs' motion for a preliminary injunction, enjoining Defendants from implementing the Rule in the Plaintiff States. *See* Jan. 1, 2022 Mem. Order ("PI Order") at 31, ECF No. 15. The Court granted Defendants' motion to extend the deadline to respond to the Complaint to March 24, 2022. *See* Feb. 17, 2022 Order, ECF No. 44. Defendants file the certified administrative record concurrently with the filing of this Motion.

STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), a plaintiff bears the burden to establish a court's jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted).

Under both Rule 12(b)(1) and Rule 12(b)(6), to survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). While the Court accepts well-pleaded factual allegations as true, "mere conclusory statements"

[3] On February 28, 2022, OHS 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.

and "legal conclusion[s] couched as . . . factual allegation[s]" are "disentitle[d] . . . to th[is] presumption of truth." *Id.* at 678, 681 (citation omitted).

While courts apply the plausibility standard under both rules, "in examining a Rule 12(b)(1) motion, a district court is empowered to find facts as necessary to determine whether it has jurisdiction." *Machete Prods., LLC v. Page*, 809 F.3d 281, 287 (5th Cir. 2015). Accordingly, "the district court may consider evidence outside the pleadings and resolve factual disputes." *In re Compl. of RLB Contracting, Inc. v. Butler*, 773 F.3d 596, 601 (5th Cir. 2014). In considering a Rule 12(b)(6) motion, courts may also consider "documents attached to the complaint," *Gomez v. Galman*, 18 F.4th 769, 775 (5th Cir. 2021) (quoting *Walker v. Beaumont Indep. Sch. Dist.*, 938 F.3d 724, 735 (5th Cir. 2019)), as well as "documents incorporated into the complaint by reference," *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007)).

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. "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. Plaintiff States Lack Standing to Pursue Their Claims.

To establish standing, Plaintiffs must show that they have suffered an injury that is "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). Where, as here, the case involves deciding "whether an action taken by one of the other two branches of the Federal Government was unconstitutional," the "standing inquiry [is] especially rigorous." *Raines v. Byrd*, 521 U.S. 811, 819–20 (1997).

Here, the Plaintiff States fail to meet "[t]he first and foremost of standing's three elements," injury in fact, *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338 (2016) (cleaned up), because they are not recipients of Head Start Program grants under the Head Start Act. The challenged Rule adds new provisions to the Head Start Program Performance Standards for entities receiving Head Start Program grants under 42 U.S.C. §§ 9836, 9840a. To be eligible for a Head Start grant, an entity must be a "*local* public or private nonprofit agency, including community-based and faith-based organization, or for-profit agency, within a community." 42 U.S.C. § 9836(a)(1) (emphasis added). Plaintiffs have not alleged that they are recipients of traditional Early Head Start grants under 42 U.S.C. § 9840a.

Plaintiffs try to avoid this jurisdictional flaw by asserting that two Plaintiffs—Georgia and Utah—"directly participate as grantees." Compl. ¶ 42. The facts, however, do not support this allegation. As Plaintiffs' own exhibits verify, the recipient of the cited Utah grant is Southern Utah University, not the State of Utah. *See* Decl. of Stephen Lisonbee ¶¶ 4, 9, Pls.' Ex. O, ECF No. 2-16. As a public university, Southern Utah University does receive funding from the State of Utah, but Utah fails to show how it has suffered a concrete injury from the Rule because it has appropriated funds to an entity that also receives Head Start funds.

Plaintiffs' reliance on the Early Head Start–Childcare Partnership grant received by the Georgia Department of Early Care and Learning ("DECAL") is likewise misplaced. *See* Decl. of Commissioner Amy Jacobs, Pls.' Ex. B, ECF No. 2-3. That grant was made under the authority of multiple appropriations acts, not the Head Start Act, and thus is not subject to the challenged requirements of the Rule. *See, e.g.*, Consolidated Appropriations Act, Pub. L. No. 116-260, 134 Stat. 1182, 1583 (2020). Unlike the grants provided to local entities to operate Head Start Programs under 42 U.S.C. § 9833, the grant received by Georgia is more administrative in nature. *See* Office of Head Start, *Early Head Start Child Care Partnership State Grantee Profile, Georgia* (Aug. 2016), https://www.acf.hhs.gov/sites/default/files/documents/ecd/ga_ehsccp_grantee_profile_final.pdf; HHS, *Policy and Program Guidance for the Early Head Start–Partnerships (EHS–CCP) ACF-IM-HS-15-03*, https://eclkc.ohs.acf.hhs.gov/policy/im/acf-im-hs-15-03-attachment. Thus, while some DECAL

staff may on occasion visit a partnership classroom, it is not part of their day-to-day duties, and they do not provide direct Head Start services.

Even if Georgia and Utah had standing, the other 22 states do not. Plaintiffs' attempt to establish "injury" by relying on the collaborative grants that states may receive under 42 U.S.C. § 9837b, *see* Compl. ¶ 55, has no merit. Such grants assist states in facilitating collaboration among Head Start agencies and other entities providing early childhood education and development. *See* 42 U.S.C. § 9837b(2), (4). Plaintiffs assert that the new obligations imposed on Head Start agencies will make it more difficult for states to promote collaboration and coordination because many entities with which Head Start programs interact do not impose vaccine and masking requirements. Compl. ¶¶ 144–46. This vague claim is purely speculative—"'[a]llegations of *possible* future injury' are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Such collaboration does not necessarily mean that non-Head Start personnel would directly interact with Head Start children in their classrooms such that they would be subject to the Rule.[4]

Plaintiffs' attempt to invoke *parens patriae* (Compl. ¶ 57) also has no merit. As the Supreme Court has recognized, "a state does not have standing as *parens patriae* to bring an action against the federal government to vindicate the rights of its citizens." *Chiles v. Thornburgh*, 865 F.2d 1197, 1209 (11th Cir. 1989) (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982)). While *Snapp* discussed a state's ability to assert a "quasi-sovereign" interest to support *parens patriae* standing, *see* 458 U.S. at 607, it expressly limited that analysis to suits against private defendants, not the federal government, *id.* at 610 n.16 (noting that a state "does not have standing as *parens patriae* to bring an action against the Federal Government" but "[h]ere, however, the Commonwealth is seeking to secure the federally created interests of its residents against private defendants"). The Court explained that "it is no part of [a state's] duty or power to enforce their rights in respect of their relations with the Federal Government" because "[i]n that field it is the United States, and not the

[4] Because Plaintiffs do not have grants that are directly impacted by the Rule, the facts here are clearly distinguishable from the circumstances in *Louisiana v. Biden,* No. 21-3867 (W.D. La. Dec. 16, 2021), where the states had grants directly impacted by the challenged rule.

State, which represents them as *parens patriae*." *Id.* (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 485–86 (1923)). And although a state may have "special solicitude" to vindicate injuries that directly harm it, such as shoreline erosion harming the State of Massachusetts as a coastal property owner, *see Massachusetts v. EPA*, 549 U.S. 497, 519, 520 n.17 (2007), the states have no similar sovereign interest. Whatever injuries Head Start grantees, personnel and students may claim, the states are not in a position to bring suit on their behalf. *See Brackeen v. Haaland*, 994 F.3d 249, 292 n.13 (5th Cir. 2021) (en banc) (States do not "have standing as the parent of its citizens . . . against the Federal Government, the ultimate parens patriae of every American citizen." (alterations in original) (quoting *South Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966))), *cert. granted*, No. 21-380, 2022 WL 585885 (U.S. Feb. 28, 2022) (mem.); *see also Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 182-83 (D.C. Cir. 2019) (holding that *Massachusetts v. EPA* does not "alter[] . . . longstanding precedent that a State in general lacks *parens patriae* standing to sue the federal government").

II. Plaintiffs Have Failed to State a Claim.

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. 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, PI Order at 15–22, 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, another court has interpreted the Head Start Act as authorizing HHS to implement the Rule. *See Livingston*, 2022 WL 660793, at *4–8.

1. The Plain Statutory Text Authorizes the Rule.

Like any other question of statutory interpretation, 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); *see, e.g.*, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020). Here, the Secretary's authority to adopt the Rule flows directly from the unambiguous text of the statute.

Congress charged the Secretary with adopting "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) (quotation marks omitted). 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) ("statutory language—'appropriate' and 'necessary and proper'—is a hallmark of vast discretion" (footnote omitted)).

The vaccination and masking Rule fits comfortably within the Secretary's statutory authority under this standard. *See Livingston*, 2022 WL 660793, at *4 ("[T]he Rule plainly falls within the

Secretary's authority."). 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 it was also a standard "relating to the condition . . . of facilities" to ensure they do not become places of viral contagion, *id.* § 9836a(a)(1)(D). At a bare minimum, he was imposing a "standard[]" he found to be "appropriate" for the Head Start program. *Id.* § 9836a(a)(1)(E). As noted above, Congress created the Head Start program as a means to provide a healthy and safe learning environment for low-income children across the country. This measure was "appropriate" to protect student health. The agency began by noting a CDC report that showed that over 51 million COVID 19 cases and 800,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, https://perma.cc/4CNT-7SKN (cited at 86 Fed. Reg. at 68,052 n.6). It then explained that "vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission and in avoiding severe illness, hospitalization, and death." 86 Fed. Reg. at 68,052 (footnote omitted). HHS went on to reason that "[g]iven that children under age 5 years are too young to be vaccinated at this time, requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19." *Id.* 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). In short, the agency spelled out in great detail the connection between the Rule and the purposes of the Head Start Act.

Plaintiffs make much of the supposed limits of the phrase "modifying" 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." 42 U.S.C. § 9836a. Plaintiffs argue that the phrase cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. But even under the Plaintiffs' own first definition of this term as "[t]o make somewhat different; to make small changes

to (something) by way of improvement, suitability, or effectiveness," Compl. ¶ 161 (quoting *Modify*, Black's Law Dictionary (10th ed. 2014)), the Secretary's rule is authorized. Requiring masking of children over age two and staff vaccinations against a deadly and highly contagious disease are two moderate improvements 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, the Secretary is charged with issuing deficiencies when programs fail to follow "program performance standards," 42 U.S.C. § 9836a(e)(1). The act defines a "deficiency" as "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 childhood development and health services . . . ." *Id.* § 9832(2)(A). By its 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").

2. The Agency's Construction of the Statute Is Reasonable.

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. In order to determine whether an interpretation is permissible, courts consider the statute's text, whether the agency's interpretation matches the purpose of the statute (discussed above), and the history of

past regulation in the area. *See Bankers Life & Cas. Co. v. United States*, 142 F.3d 973, 983 (7th Cir. 1998).

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

For decades, HHS has issued regulations under the Head Start Act that concern the health and safety of Head Start children and personnel, similar to the Rule at issue here. In upholding a COVID-19 vaccine requirement for health care workers who treat Medicare and Medicaid patients, the Supreme Court emphasized a similar "longstanding practice of [HHS] in implementing the relevant statutory authorities." *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 health care, not simply sound accounting." *Id.*; *see also Livingston*, 2022 WL 660793, at *7.

Here, numerous provisions in the Head Start Act similarly charge the Secretary with the responsibility to issue regulations, as he deems necessary, to protect the health and safety of program participants and personnel. *See Missouri*, 142 S. Ct. at 653 (explaining numerous health and safety regulations fall within agency's grant of authority with respect to CMS). Those precise statutory provisions show that the health of children is a relevant consideration in the broader context of the statute. The Head Start Act directs that funding be used by Head Start agencies to provide "intensive training and technical assistance" for "[a]ctivities . . . to support . . . health services, and other services necessary to address the needs of children enrolled in Head Start programs." 42 U.S.C. § 9843(d)(1)(G). Other provisions are similarly in accord. *See id.* § 9832(21)(G)(i) (defining the "professional development" of "Head Start teachers and staff" that the act is intended to promote to include "activities that . . . assist teachers with . . . the acquisition of the content knowledge and teaching strategies needed to provide effective instruction and other school readiness services regarding . . . physical health and development"); *id.* § 9843(a)(3)(B)(xii)(VI), (b)(2)(D) (instructing the Secretary "to the maximum extent practicable" to "assist Head Start agencies and programs to address the unique needs of programs located in rural communities, including . . . removing barriers to

obtaining health screenings for Head Start participants in rural communities" and also to "support training for personnel . . . to recognize common health . . . problems in children for appropriate referral"); *see also id.* § 9835(m)(2) (directing the Secretary to establish rules requiring Head Start agencies "to allow families of homeless children to apply to, enroll in, and attend Head Start programs while required documents, such as . . . immunization and other medical records . . . are obtained within a reasonable time frame"); *id.* § 9836a(a)(2)(C)(ii) (requiring the Secretary to consider the effects of any revisions in Head Start standards on the "quality, scope, or types of health . . . services required to be provided under such standards as in effect on December 12, 2007").

HHS also has a long history of rulemaking related to Head Start health standards, including measures similar to the vaccine requirement at issue here, to which Plaintiffs have never objected. 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 child care 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 requirements 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). Current standards also include staff training on prevention and control of infectious diseases and establishing administrative procedures regarding protection from contagious diseases. *Id.* § 1302.47(b)(4)(i)(A) & (b)(7)(iii). Commonsense measures like demonstrably safe vaccines are logically included in Head Start Programs' preexisting obligations to prevent the spread of communicable diseases.

Further, HHS has long implemented regulations pertaining to program participants. The first

Head Start Program Performance Standards were issued in 1975, and they included comprehensive health screening that "should be carried out for all of the Head Start children," including tests for anemia and tuberculosis as well as urinalyses. 45 C.F.R. § 1304.3-3(b)(4)–(6) (1975). Head Start staff were also required to verify immunizations records, *id.* § 1304.3-3(b)(8) (1975), and participants were required to complete all recommended immunizations, including for diphtheria/pertussis/tetanus, polio, rubeola, rubella, and mumps. 45 C.F.R. § 1304.3-4(2) (1975).[5]

Over the years, Head Start requirements pertaining to both staff and students have evolved in response to the most pressing health and medical threats of the times. For example, in the 1990s, guidance as an appendix to the performance standards included the appropriate treatment of children with HIV. 45 C.F.R. § 1308 App'x (2015). In 1996, HHS added health examinations for staff and tuberculosis screening for staff and regular volunteers to the Head Start Program Performance Standards. 61 Fed. Reg. at 57,210, 57,223. And in response to suggestions in comments that it no longer made sense to single out tuberculosis, HHS revised the staff health standard in 2016 to include more general language about staff health and communicable diseases. Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,357, 61,433 (Sept. 6, 2016). Up through 2015, HHS even specifically mandated vaccinations for pets of families with children enrolled in home-based Head Start programs. 45 C.F.R. § 1306.35(b)(2)(ix) (2015).

Current and past standards have also included regulations similar to the Rule to avoid the spread of contagious diseases. In the past, standards have included spacing cribs three feet apart to avoid the spread of contagious diseases, *id.* § 1304.22(e)(7) (2015), and temporarily excluding children with acute or short-term contagious illnesses, *id.* § 1304.22(b). Current regulations also require Head Start Programs to "[o]btain determinations from health care and . . . oral health care professionals as

[5] These Standards are entitled to "peculiar weight" given that they were promulgated just a year after Congress made Head Start a permanent program and thus represent "a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion; of making the parts work efficiently and smoothly while they are yet untried and new." *Norwegian Nitrogen Prods. Co. v. United States*, 288 U.S. 294, 315 (1933); *see also Kisor v. Wilkie*, 139 S. Ct. 2400, 2426 (2019) (Gorsuch, J., concurring in the judgment) ("The government's early, longstanding, and consistent interpretation of a statute, regulation, or other legal instrument could count as powerful evidence of its original public meaning." (emphasis omitted)).

to whether or not the child is up-to-date on a schedule of age appropriate preventative and oral health care," including following "immunizations recommendations issued by the Centers for Disease Control and Prevention," *id.* § 1302.42(b)(1)(i), which currently include the COVID-19 vaccine for most Americans over age five, *see* CDC ACIP Recommendations. If a child is not up-to-date on vaccines, Head Start programs are directed to "[a]ssist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent." 45 C.F.R. § 1302.42(b)(1)(ii). In order to accomplish this, Head Start programs are even permitted to "use program funds for professional medical and oral health services when no other source of funding is available." *Id.* § 1302.42(e)(2). 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.

All of the aforementioned health regulations, including those regarding vaccinations and communicable disease precautions, have been considered "modifications" to the existing Head Start regulatory structure ever since 1975. 42 U.S.C. § 9836a(a)(1). Indeed, prior to this lawsuit, none of the Head Start Performance Standards had ever been challenged. Entities in the Plaintiff states, some of which received their first Head Start grant as early as 1974, have abided by all of the Head Start Program Performance Standards, including the health standards such as health screening for staff and vaccination rules for participants, for decades. Those entities have never suggested that those standards should be limited to exclude health, nor have the states. Many of these entities applied and entered into the Head Start program with the knowledge that those standards already existed, and they accepted them. Yet now, as Head Start regulations continue to evolve to meet the challenges of the greatest public health threat of the present day—the global COVID-19 pandemic—Plaintiff States oppose the same sorts of health measures with which grantees have always complied. This history of compliance without complaint further undermines Plaintiffs' argument that the Secretary somehow lacks statutory authority for the similar measures required in the Rule.

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. Further, *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 has 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 has previously exercised its rulemaking authority to respond to novel challenges with nationally significant implications, and the exercise of that authority has never before been challenged.

ii. Nothing in the Statute Forecloses the Secretary's Reading of the Statute.

The agency's interpretation of the statute as including the authority to require masks and vaccinations should also be given deference as reasonable because the statute does not clearly express otherwise. *See generally Gonzales v. Oregon*, 546 U.S. 243, 255–56 (2006) (*Chevron* deference is warranted "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority" (citation omitted)); *see also Florida v. Dep't of Health & Hum. Servs.*, No. 21-14098 (11th Cir. Dec. 1, 2021), Order at 15–16 ("The imposition of a vaccine mandate as a condition on the receipt of federal funds to ensure patient safety within those facilities is not expressly foreclosed by this statute. There appears little likelihood of success on the APA claim.").

In discussing the Secretary's authority, Plaintiffs note the Supreme Court's statement that regulations of vast economic significance "must be authorized by a clear statement of unambiguous congressional intent." Compl. ¶ 154 (quoting *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*,

141 S. Ct. 2485, 2489 (2021) (per curiam)). Plaintiffs are likely to draw comparisons to the Occupational Safety and Health Administration ("OSHA") vaccination-or-testing requirement that the Supreme Court struck down in *National Federation of Independent Businesses v. Department of Labor*, 142 S. Ct. 661 (2022) ("*NFIB*") (per curiam). But *NFIB* is *particularly* distinguishable in that regard. The two rules are dramatically different in scope and operation. Whereas the OSHA requirement was considered inappropriate because it was overbroad in "imposing a vaccine mandate on 84 million Americans," *id.* at 665, this Rule's vaccination requirement would apply to only approximately 273,000 Head Start personnel, 86 Fed. Reg. at 68,077. 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," *NFIB*, 142 S. Ct. at 666, the threat exists with full force in a classroom environment with children who are too young to be vaccinated and where social distancing is often not possible. The Head Start context is 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*).

In any event, Congress did speak 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*, 140 S. Ct. at 2380. And courts may not "impos[e] limits on an agency's discretion that are not supported by the text." *Id.* at 2381. Plaintiffs can point to no statutory text that would indicate that Congress intended the broad powers it granted the Secretary over "administrative . . . standards," "standards relating to the condition . . . of facilities," and "such other standards as the

Secretary finds to be appropriate" to mean anything other than their natural implication, which includes the protection of Head Start students and employees at federally-funded Head Start facilities from a virus that has killed more than 960,000 Americans. 42 U.S.C. § 9836a(a)(1)(C), (D), (E). 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.

For this reason, Plaintiffs' reliance on *Alabama Ass'n of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. There, the Supreme Court held that an eviction moratorium imposed by the CDC exceeded the agency's authority to "prevent the [interstate] introduction, transmission, or spread of communicable diseases[.]" 42 U.S.C. § 264(a). Reading that language in context, the Court held that its scope was informed by the next sentence "illustrating the kinds of measures that could be necessary," such as "fumigation" or "pest extermination." *Ala. Ass'n of Realtors*, 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 who move "from one State to another." *Id.*

Here, the connection between the vaccine and masking requirements and student and employee health and safety is clear and direct: By requiring program personnel and participants to take the measures that most effectively reduce the risk that they contract and spread the virus that causes COVID-19, the Secretary sought to reduce the risk that students and workers would contract the virus. *Cf. Florida v. Dep't of Health & Hum. Servs.*, 19 F.4th 1271, 1287 (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, should Head Start personnel and students become infected with COVID-19, all students' ability to learn is hampered.

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 specific 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 regarding Medicare and Medicaid facilities). At a bare 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).

B. The Rule is Not Contrary to Law.

Plaintiffs next argue that the Rule violates four specific statutory provisions, but there is no substance to these arguments. *First*, the Rule complies with 42 U.S.C. § 9836a(a)(2)(B)(x), which requires the Secretary to "take into consideration . . . the unique challenges faced by individual programs, including those programs that are seasonal or short term and those programs that serve rural populations." *See* Compl. ¶ 170. Plaintiffs provide no explanation regarding the basis for this claim, but in any event, HHS plainly complied with this provision, as the Rule's preamble confirms. *See, e.g.*, 86 Fed. Reg. at 68,054 ("The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due

to SARS-CoV-2 exposures."); *id.* at 68,066 ("ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rate" in individual communities but found "[i]t would be burdensome for this program to issue separate guidance across its service area to account for changing transmission levels across those counties").

Second, the Rule complies with 42 U.S.C. § 9836a(2)(A), which requires the Secretary to "consult with experts in the fields of child development, early childhood education, child health care, family services . . . , administration, and financial management, and with persons with experience in the operation of Head Start programs." *See* Compl. ¶ 171. 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. Plaintiffs state that this "comes nowhere close to meeting § 9836a(2)(A)'s specific requirements" but never actually explain why that is except to assert that HHS "failed to disclose who specifically it actually consulted." Compl. ¶ 170. Notably 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 Plaintiffs do not point to any authority requiring such specificity. *Cf.* 5 U.S.C. § 553(c) (requiring only "a concise general statement of [a final's rule] basis and purpose").

Third, the Rule complies with 42 U.S.C. § 9836a(a)(2)(C)(ii), which requires the Secretary to "ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007." *See* Compl. ¶ 172. Plaintiffs' entire argument on this point is that, in their opinion, the rule will "exclud[e] children" and "reduc[e] eligible staff and volunteers." *Id.* Plaintiffs' assertions are speculative; as evidenced by vaccine requirements in other contexts, most people choose to comply with such requirements rather than leave their jobs. *See* 86 Fed. Reg. at 68,055 & nn.52–54. In fact, one of the Secretary's primary reasons for adopting the Rule was to ensure the continuity of Head Start services, including the "health, educational, parental involvement, nutritional, social, or other services" such facilities provide. 42 U.S.C. § 9836a(a)(2)(C)(ii). The Secretary explained that he

> considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

86 Fed. Reg. at 68,054. The Secretary noted that in the absence of reasonable measures like the Rule to prevent the spread of COVID-19, there would likely be intermittent closures of Head Start programs or even a switch to providing services virtually, *id.* at 68,055, which could reduce the quality, scope, or types of services offered to something below pre-2007 levels.[6] To the extent parents choose to exclude their own children from Head Start because they do not want them to wear face masks, that is no different from parents choosing to exclude their children because they do not want them to receive immunizations or to receive all medical treatments on their state's Early and Pediatric Screening, Diagnosis, and Treatment schedule, all of which are already required for participation in Head Start and which none of the twenty-four plaintiff states have ever challenged. *See* 45 C.F.R. § 1302.42(b)(1)(i). The same goes for Head Start personnel, who are already required to undergo a number of health assessments and screenings and take precautions to avoid transmitting infectious diseases. *See supra* Section II.A.2.i.

Fourth, the Rule complies with 42 U.S.C. § 9836a(b)(3)(B), which requires that any rule promulgated under Section 641A "shall not be used to exclude children from Head Start programs." *See* Compl. ¶ 173. As already explained immediately above, requiring masking does not reasonably exclude children any more than requiring vaccines and other standard health treatments, which Head Start has required for decades. In fact, HHS promulgated the Rule in large part to make Head Start programs available to more students during the COVID-19 pandemic. *See supra* Background Section I (explaining how COVID-19 results in program closures, depriving Head Start children across the country from accessing the invaluable resources it provides). HHS plainly followed all the statutory

[6] The vaccine requirement does not eliminate or reduce services from pre-2007 levels when tuberculosis screening, crib spacing, and temporary exclusion were required for contagious disease control. *See supra* Section II.A.2.i. Rather, it updates the performance standards so they address the realities of the current environment, and therefore, support the continuation of the quality, scope, and types of services at the same or higher level as pre-2007.

criteria laid out in these four statutory provisions. Plaintiffs' real qualm amounts to a policy disagreement, but that is not a basis for invalidating a rule under the APA.

C. The Rule is Not Arbitrary and Capricious.

Plaintiffs' arbitrary-and-capricious claims 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 Plaintiffs' APA claims should be confined to the record before the agency. "[T]he focal point for judicial review should be the administrative record already in existence [on the basis of which the administrator'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)). "[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.* To the extent Plaintiffs seek to introduce expert opinions going to the merits, for example, addressing the wisdom of vaccine and masking requirements, Pls.' Exs. S, T, ECF No. 2-20, 2-21, those opinions are not a proper subject of APA review because they were not before the Secretary and are irrelevant to his decision.

Here, the agency adopted a reasonable Rule after considering the relevant issues. The fifty-page Rule reasonably explains the agency'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. Plaintiffs lodge a litany of conclusory claims that the Rule is arbitrary and capricious. Compl. ¶¶ 187–208. None of Plaintiffs' claims has merit. Although this Court previously stated that some of these 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 another court has found that the Rule is not arbitrary and capricious, *see Livingston*, 2022 WL 660793, at *8. Adopting Plaintiffs' numbering:

First, Plaintiffs argue that the Rule overlooked that staff or students might leave the program due to the Rule, or overlooked the effects on specific groups, like children with special needs or underserved communities. *See* Compl. ¶¶ 193–200. But the agency considered these factors. The agency explicitly considered that the Rule might result in staff vacancies, and stated that "[t]o value the countervailing risk of staff vacancies, [ACF] 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 Rule also finds 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 is to reduce instances in which a positive case of COVID-19 in the classroom results in program closures and service interruptions. *See id.* at 68,054. Thus, the agency considered that some personnel and students may 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. 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).

While Plaintiffs argue that the agency failed to consider children with special needs, the agency did consider them, and provided exceptions to the masking requirements for "persons who cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with

Disabilities Act (ADA), consistent with CDC guidance on disability exemptions; and for children with special health care needs, for whom programs should work together with parents and follow the advice of the child's health care provider for the best type of face covering." 86 Fed. Reg. at 68,060. The Rule relies on November 10, 2021 guidance from the CDC, which recommended "universal indoor masking for ECE [early childhood education and child care] programs for everyone aged 2 years and older" and found that "ECE program staff can model consistent and correct use for children aged 2 years or older in their care." *Id.* at 68,054. It is reasonable for ACF to rely on the recommendation of CDC, an agency with scientific expertise in protection from infectious diseases, over competing information from non-governmental agencies. *See Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (recognizing that courts must be at their "most deferential" when reviewing an agency's "scientific determination"); *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."). 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).

The Rule also explicitly considers its impact on underserved children and communities in particular, concluding that the Rule would "promote[] public and community health and health equity for children and staff in Head Start programs" "[g]iven the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups." 86 Fed. Reg. at 68,055–56 (footnotes omitted); *see also id.* at 68,058 ("Program closures [from positive COVID-19 cases] impede Head Start families from participating in the workplace, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.").

Second, contrary to Plaintiffs' argument, *see* Compl. ¶¶ 201–03, HHS did consider alternatives to the Rule. Indeed, the Rule has an entire section outlining a number of options considered but rejected by the Secretary. 86 Fed. Reg. at 68,066. Plaintiffs specifically refer to natural immunity and the potential for vaccine efficacy to decrease over time, claiming that the Rule is arbitrary because it

did not offer natural immunity as an alternative to vaccination or mask wearing, and because it insufficiently considered changes in vaccine efficacy over time. *See* Compl. ¶¶ 202–03. The agency considered scientific literature on the efficacy of vaccines, and concluded that "[t]he COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus." 86 Fed. Reg. at 68,054–55. The Rule supports this finding with numerous scientific studies.[7] *Id.* at 68,055 & nn.31–36. "When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co.*, 462 U.S. at 103. ACF reasonably concluded that, based on the evidence, vaccinations are a superior mitigation strategy, regardless of a recipient's supposed "natural immunity."

The agency's decision was based on the most reliable scientific evidence available, especially given the contrast between the inexorable and, at times, surging pace of the pandemic and the necessarily measured pace of scientific research. It is common for an agency "not [to] have perfect empirical or statistical data"—particularly on complex issues like the interplay between protection provided by prior infection and vaccines, or the efficacy of vaccination over time—the APA does not require such evidence before an agency may act. *Prometheus Radio Project*, 141 S. Ct. at 1160; *see also San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) ("[Even] if the only available data is 'weak, and thus not dispositive,' an agency's reliance on such data 'does not render the agency's determination arbitrary and capricious.'" (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1336 (9th Cir. 1992))). Indeed many, if not most, statistical analyses have some limitations

[7] Indeed, the agency considered scientific literature that acknowledged and took into account the possibility that vaccine efficacy decreases as time from vaccination increases, but still concluded that COVID-19 vaccines are highly protective. *See* Fowles, A., Gaglani, M., Groover, K., 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, Morbidity and Mortality Weekly Report, August 27, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w, https://perma.cc/5YKH-QYR4 (finding that the evidence "further affirm[ed] the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves" despite some apparent decrease in vaccine effectiveness, and noting that "[vaccine effectiveness] might also be declining as time since vaccination increases") (cited at 86 Fed. Reg. 68,055 n.33).

regarding sample size, etc., but that does not mean that they do not also provide valuable information upon which an agency may rely. Here, ACF "made a reasonable predictive judgment based on the evidence it had," *Prometheus Radio Project*, 141 S. Ct. at 1160, which is all the APA requires.

Third, the Rule's rationale—to mitigate the spread of COVID-19 in Head Start programs—is not pretextual. *Contra* Compl. ¶ 204. Plaintiffs try to cast the Rule as a sinister attempt "aimed at increasing vaccination rates throughout American society, writ large." *Id.* But there was no need for the agency to "pigeonhole the Mandate into the Head Start Act's statutory factors," *id.*—the Act's statutory factors have long permitted the Secretary to include health related standards. *See supra* Section II.A.1-2. Nor, given the copious evidence about the effectiveness of vaccines in reducing the spread of COVID-19, *e.g.*, 86 Fed. Reg. at 68,059, is it 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 participate in their programs or that are regulated by them. The thorough explication in the fifty-page Rule of the Secretary's justifications and reasons likewise rebuts any accusation that his reasons are pretextual. And, of course, to the extent that the Rule is 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 is not a "significant mismatch between the decision the Secretary made and the rationale he provided." *Id.* at 2575.

Fourth, Plaintiffs' allusion to "reliance interests," Compl. ¶ 205, is unavailing. Plaintiffs refer to their interest "in public and private Head Start programs continuing to operate under existing rules," *id.*, but the Rule analyzed its costs and benefits and concluded that the benefits outweighed the costs. Likewise, Plaintiffs refer to Head Start providers' interests "in staffing their facilities under the existing rules without facing this new Mandate that threatens their workforce," *id.*, which appears to reduce to their same argument that the Rule will cause employees to leave or endanger Head Start services, and Head Start workers' interests "in selecting a job and building a career under the existing rules," *id.*, which appears to reduce to Plaintiffs' same argument that the Rule will harm Head Start employees.

None of these interests implicates reliance in the traditional sense, *i.e.*, Plaintiffs do not allege that they undertook actions to their detriment because of representations that the agency had made to them about the future. Indeed, it would be difficult for Plaintiffs to argue that they relied on the prior rules to their detriment, given that they do not directly receive Head Start grants to operate classrooms, and that they elsewhere question why the agency "did not require toddlers to wear masks in the Head Start program before now, including when case numbers were higher . . . ." *Id.* ¶ 93. Furthermore, the Plaintiffs were well aware that the Performance Standards were subject to modification, as the Head Start Act explicitly instructs the Secretary to "modify" them "as necessary." 42 U.S.C. § 9836a. And, as discussed, the agency has long imposed vaccine requirements. In any event, as has previously been discussed, the agency considered that the Rule might result in some Head Start employees choosing to leave their jobs, but determined that the benefits of the Rule outweighed that risk. That Plaintiffs would have reached a different conclusion had they been weighing the potential benefits does not mean that the Rule is arbitrary or capricious.

Fifth, Plaintiffs misapprehend the issue when they argue that the agency failed to consider conflicting state laws. Compl. ¶ 206. The agency recognized that some states have differing requirements (and indeed, if all states had uniform requirements that matched the Rule, the Rule would be unnecessary). As the Rule noted, pursuant to the Supremacy Clause, the Rule preempts any conflicting state laws, relieving any issues of uncertainty regarding which requirements Head Start providers should implement. *See, e.g.*, 86 Fed. Reg. at 68,061 ("[T]his IFC preempts the applicability of any state or local law providing for exemptions to the extent such law provides broader exemptions than provided for by federal law and are inconsistent with this IFC."); *id.* at 68,063 ("In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule."). The agency did not take this step lightly, and as part of its preemption analysis noted that it had "considered other alternatives [to preempting state law] (for example, relying entirely on measures such as voluntary vaccination, source control alone, and physical distancing) and has concluded that the mandate

established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute." *Id.*

Sixth, the Rule is not arbitrary and capricious for failure to "'account for differences in' community measures, levels of transmission, levels of hospitalization, [or] levels of infection across communities." Compl. ¶ 207.[8] The agency considered these issues, including 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" a 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 predicability" and to "prioritiz[e] 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)).

Seventh, Plaintiffs speculate that some harm may occur because Head Start students attend school with non-Head Start students—without citing anything to substantiate this theoretical harm—and that HHS overlooked this potential harm. Compl. ¶ 208. ACF, of course, only has authority to implement standards for Head Start programs, not other programs, and it is not arbitrary or capricious for it to cabin itself to that limitation. To the extent that there are discrepancies among policies applying to students at the same school, they result from state and local school districts' decisions not to implement mask requirements that align with the federal standards for Head Start.

Finally, the Rule *did* engage with the "fundamental questions" that Plaintiffs argue it omitted. Compl. ¶ 93. As to why the Secretary did not implement a mask requirement "before now, including

[8] Plaintiffs liken the supposed overbreadth of this rule to the OSHA rule that the Fifth Circuit found to be "staggeringly overbroad." Compl. ¶ 207 (quoting *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 615 (5th Cir. 2021)). There is no comparison. That Rule applied to "2 out of 3 private-sector employees in America." *BST Holdings*, 17 F.4th at 615.

when case numbers were higher and everybody was unvaccinated," *id.*, 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 approach, particularly given that "uptake of vaccination among Head Start staff has not been as robust as hoped for and has 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 ACF 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). 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). And while Plaintiffs criticize the Rule for including a masking requirement where President Biden's COVID-19 action plan did not, Compl. ¶ 93, the agency did consider an alternative that did not include a masking requirement, but concluded, in weighing the available evidence, that adding the masking requirement "will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public." 86 Fed. Reg. at 68,100. That Plaintiffs would have reached a different conclusion does not mean that the agency acted arbitrarily or capriciously.

D. The Secretary Had Good Cause to Issue the Interim Rule Without Advance Notice and Comment.

Notice-and-comment rulemaking is not required "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C.

§ 553(b)(B). The exception excuses notice and comment where delay could result in serious harm. *See Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). The Supreme Court in *Missouri* recently upheld the good cause exception for a COVID-19 vaccination requirement in a substantially similar context, where the Secretary found that "accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID–19 infections, hospitalizations, and deaths." 142 S. Ct. at 654.

Based on this clear precedent, the Secretary properly invoked the good cause exception in promulgating the Rule. *Livingston*, 2022 WL 660793, at *8 (upholding Secretary's application of good cause exception in promulgating the Rule). He noted nearly identical concerns as in *Missouri*. *See* 86 Fed. Reg. at 68,058. He identified the "potential for the rapid and unexpected development and spread of additional new and more transmissible variants." *Id.* at 68,053. He addressed the proven efficacy of both masking and vaccines in mitigating the spread of COVID-19, noting that "[i]t is critical that all Head Start staff get fully vaccinated for COVID-19 and consistently wear masks to protect children, staff, and families from exposure." *Id.* Further, the emergence of the highly transmissible Delta variant, which "has resulted in greater rates of cases and hospitalizations among children," 86 Fed. Reg. at 68,053, 68,055, amply justified taking urgent measures. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (although good cause is rarely invoked, "we have approved an agency's decision to bypass notice and comment where delay would imminently threaten life"). Given the Rule's "life-saving importance," *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981), the Secretary found that any delay in issuing the Rule would "endanger the health and safety of staff, children and families, and be contrary to the public interest," 86 Fed. Reg. at 68,059. These factors are more than the "something specific . . . required to forgo notice and comment." *Missouri*, 142 S. Ct. at 654 (citation omitted); *see also Livingston*, 2022 WL 660793, at *8 (holding that the Secretary's good cause finding amounted to "something specific" permitting HHS to bypass notice and comment).

Plaintiffs contend that the Secretary should have issued the Rule earlier, Compl. ¶ 175, but *Missouri* rejected a nearly identical claim. *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."). Similarly, crafting a fifty-page rule with 144 cited sources in under two months is eminently reasonable. The agency's care in taking the time to make a reasoned and careful policy determination hardly means that the circumstances were not urgent enough to justify expediting the rulemaking by dispensing with a notice-and-comment period for the time being. As experience has shown, any delay in fighting the worst pandemic in a century can quite literally be fatal. Instead, the Secretary acted consistently with the reasons he gave for finding good cause. As noted, *see supra* Section II.C., the Secretary initially chose a policy of "allow[ing] Head Start programs to decide whether or not to require staff vaccination." 86 Fed. Reg. at 68,054. But because of the Delta variant and the potential for new variants, the prospect of returning to fully in-person programs in January 2022, and a vaccination uptake among Head Start personnel that "has not been as robust as hoped for," *id.*,[9] the Secretary properly concluded that further delay would be intolerable and invoked the good cause exception.

Because the Secretary had good cause to dispense with notice and comment rulemaking, Plaintiffs' claim that the Rule violates the Congressional Review Act ("CRA"), Compl. ¶¶ 187–94, is also unavailing. *See Livingston*, 2022 WL 660793, at *8 (rejecting Plaintiffs' argument that the Rule violated the CRA). 5 U.S.C. § 808 simply grafts the APA's good cause standard onto the Congressional Review Act. Moreover, 5 U.S.C. § 805 "denies courts the power to void rules on the basis of agency noncompliance with the [CRA]." *Montanans for Multiple Use v. Barbouletos*, 568 F.3d 225, 229 (D.C. Cir. 2009) (Kavanaugh, J.).

E. The Rule Complies with the Treasury and General Government Appropriations Act of 1999.

Plaintiffs' contention that the agency violated the Treasury and General Government Appropriations Act here by not conducting a family impact assessment, Compl. ¶¶ 230–34, is a red herring. As an initial matter, that statute is not judicially enforceable. *See* Pub. L. No. 105-277, 112

[9] Comparing whether Head Start staff are more likely to be vaccinated than the general population has no bearing on the Secretary's conclusion that he had hoped for more robust vaccine uptake among Head Start personnel.

Stat. 2681 (1998), 5 U.S.C. § 601 note (f) ("This section is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person."). And in any event, the agency explained that it had followed the requirements of that statute. Section 654 of that act requires agencies to first determine whether a policy or regulation "may affect family well-being" and then, only if the policy or regulation may do so, to "assess such actions with respect to" seven different criteria. The agency explained that it followed the statutory requirement, stating, "ACF believes it is not necessary to prepare a family policymaking assessment . . . because the action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an institution." 86 Fed. Reg. at 68,062. The agency also "invite[d] public comment on whether the actions set forth in this interim final rule would have a negative effect on family well-being," *id.*, thereby leaving the door open to a future family impact assessment if and when it might become necessary.

Plaintiffs fault ACF for failing to conduct this assessment, but tellingly, they do not argue how the Rule "may affect family well-being," 5 U.S.C. § 601 note (f), or assert that it was arbitrary or capricious for the agency to make the determination that the Rules does *not* affect family well-being. Rather, they include a single conclusory sentence that the Rule "intrudes into fundamental decisions about whether a toddler must wear a mask at school," "imposes obligations on parents picking children up from school," and "goes straight to the heart of the allocation of power between State and family." Compl. ¶ 233. Plaintiffs do not provide any support whatsoever for this statement. Without arguing that ACF was wrong to determine that the Rule would not impact family well-being, Plaintiffs cannot argue that the assessment was required.

It makes sense that Plaintiffs do not argue, beyond their single unadorned sentence, that the Rule may affect family well-being given that the Rule simply requires two commonsense measures that slow the spread of a highly contagious virus while children are with their peers and personnel at Head Start facilities. When children are with their families at home or anywhere else, they are not covered by the Rule, so they are free to wear masks or not, as they and their families so choose. The seven factors included in the family impact assessment plainly do not apply to the requirements of the Rule.

For example, there is no reason to believe Congress intended ACF to assess whether vaccine and mask requirements "strengthen[] or erode[] the stability or safety of the family and, particularly, the marital commitment" or "increase[] or decrease[] disposable income or poverty of families and children." 5 U.S.C. § 601 note. Because Congress plainly did not intend that agencies apply these factors to a rule like this one, and Plaintiffs do not so much as argue how any of these specific factors would apply to this Rule, Plaintiffs' claim should be dismissed.

F. The Rule Does Not Violate the Nondelegation Doctrine.

Plaintiffs also invoke the nondelegation doctrine to contend that Congress could not delegate to the Secretary the authority to protect the health and safety of participants and employees at schools that receive Head Start funding. Compl. ¶¶ 214–16. But "[d]elegations are constitutional so long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (cleaned up), *cert. denied*, 141 S. Ct. 2746 (2021). The Secretary's statutory authority to protect the health and safety of Head Start students and personnel easily meets this minimal standard. *Cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2001) (upholding "public health" standard). The Secretary has been delegated authority in the Head Start Act merely to set standards for the performance of the Head Start program. Any performance standards that he implements under this statute, in addition to being "appropriate," must of course further the purpose of the Head Start program. He is not regulating broad swaths of the economy. He is setting the terms on which grantees may accept federal funds. There is no nondelegation issue here.

G. The Rule Complies with the Spending Clause.

Plaintiffs further contend that the Rule violates the Spending Clause, s*ee* Compl. ¶¶ 209–11, 244–46, which gives Congress the power to "lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and the general Welfare of the United States." U.S. Const., art. I, § 8, cl. 1. As interpreted by courts, under that clause, if Congress "intends to impose a condition on the grant of federal moneys, it must do so unambiguously" so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981); *see also South*

Dakota v. Dole, 483 U.S. 203, 206–07 (1987). Just as the court found in *Livingston*, 2022 WL 660793, at *9, Plaintiffs' Spending Clause claim fails for several reasons.

Congress permits HHS to impose certain health and safety requirements upon those Head Start grants. *See supra* Section II.A. "Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579 (2012) ("*NFIB*"). And any "consequences of imprecision" in spending legislation "are not constitutionally severe" when the Federal Government "is acting as patron rather than as sovereign." *See Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998); *see also Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002) ("[T]he Supreme Court has held that conditions may be 'largely indeterminate,'" and yet constitutionally permissible, as long as the States have clear notice that accepting funds "obligate[s them] to comply with [the conditions].") (quoting *Pennhurst*, 451 U.S. at 24–25). "Grant recipients are aware when they apply to the program that they must abide by the Head Start Performance Standards and that they are free to leave the program and operate outside the Secretary's standards if they choose to do so." *Livingston*, 2022 WL 660793, at *9 (citing Grant Policy Statement; 42 U.S.C. §§ 9836(d)(2)(F), 9836a(a)(1)).

The Rule also unambiguously puts states on notice that they are obligated to comply with the mask and vaccine requirements when they receive Head Start funding. The Rule ensures that "the existence of the condition itself" will be "explicitly obvious" to grant recipients by clearly laying out the Rule's three requirements: (1) universal masking for those two years or older; (2) vaccination for all Head Start personnel; and (3) weekly testing for those exempted from vaccination. *See Benning v. Georgia*, 391 F.3d 1299, 1307 (11th Cir. 2004) (citation omitted). A grant recipient will be capable of making "an informed," voluntary decision whether to accept the attendant obligations of contracting with the Federal Government. *See Pennhurst*, 451 U.S. at 25; *see also Livingston*, 2022 WL 660793, at *9. The challenged condition thus satisfies the Spending Clause.

H. The Rule Does Not Violate the Tenth Amendment or the Anti-Commandeering Doctrine.

Plaintiffs cannot succeed on their Tenth Amendment claim, Compl. ¶¶ 217–21, by simply

invoking general maxims of federalism. The Tenth Amendment provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X. The powers specifically delegated to the federal government by the Constitution "are not powers that the Constitution 'reserved to the States.'" *United States v. Comstock*, 560 U.S. 126, 144 (2010) (citation omitted); *accord New York v. United States*, 505 U.S. 144, 156 (1992) ("If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States[.]"). As long as federal action rests on a constitutionally delegated power, "there can be no violation of the Tenth Amendment." *United States v. Mikhel,* 889 F.3d 1003, 1024 (9th Cir. 2018) (citation omitted), *cert. denied*, 140 S. Ct. 157 (2019); *accord United States v. Hatch*, 722 F.3d 1193, 1202 (10th Cir. 2013).

As mentioned, § 9836a(a)(1) was enacted pursuant to the Spending Clause, an evident exercise of Congress's legislative power under the Constitution. *See Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 480 (1982). And where (as here) a federal statute is validly enacted under one of Congress's enumerated powers, and the Executive Branch exercises authority lawfully delegated under that statute, the Tenth Amendment is no bar to federal action. *See Livingston*, 2022 WL 660793, at *9 (finding that the Rule did not violate the Tenth Amendment because it "rests on a constitutionally delegated power"). Congress has charged the Secretary with the responsibility to ensure that federal funds are used in the way that Congress directed, and this includes the responsibility to protect the health and safety of those in the Head Start program. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, . . . [and] to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates "in an area historically of state concern." *Id.* at 608 n.*; *see also Livingston*, 2022 WL 660793, at *9. "The Secretary did not intrude on state police powers when he issued the Rule any more than he did when he issued the long-standing rules conditioning federal funds on requiring that Head Start personnel do not 'pose a significant risk' 'of communicable disease.'" *Id.* at *10 (quoting 45 C.F.R. § 1302.93(a)).

Moreover, there is no general "doctrine implied in the Federal Constitution that the two governments, national and state, are each to exercise its power[s] so as not to interfere with the free and full exercise of the powers of the other." *Case v. Bowles*, 327 U.S. 92, 101 (1946). Indeed, it is axiomatic that 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); *accord Okla. ex rel. Okla. Dep't of Pub. Safety v. United States*, 161 F.3d 1266, 1272 (10th Cir. 1998). Thus, "the Federal Government, when acting within a delegated power, may override countervailing state interests, whether those interests are labeled traditional, fundamental, or otherwise." *Brackeen*, 994 F.3d at 310 (citation omitted).

Plaintiffs also cannot establish a Tenth Amendment violation by asserting that states are "commandeer[ed]" into enforcing the Rule. *See* Compl. ¶¶ 222–25. As the Supreme Court has explained, the Tenth Amendment's anti-commandeering principle acknowledges a constitutional limitation of "the circumstances under which Congress may use the States as implements of [federal] regulation." *New York*, 505 U.S. at 161. For example, the federal statute at issue in *New York* unconstitutionally "'commandeer[ed]' state governments" by forcing state legislatures or executive officials to enact state regulation according to Congress's instructions. *Id.* at 175. In *Printz v. United States*, 521 U.S. 898 (1997), the federal statute "conscript[ed]" local law enforcement officials by requiring them to perform background checks in connection with firearms sales. *Id.* at 935. And in *Murphy v. National Collegiate Athletic Ass'n*, 138 S. Ct. 1461 (2018), the federal statute "commandeered the state legislative process" by "command[ing] state legislatures to . . . refrain from enacting [new] state law[s]." *Id.* at 1478–79.

The Rule does none of these things. For starters, whether a state chooses to participate in the Head Start program is entirely voluntary. Moreover, the statute authorizing the Office of Head Start to implement performance standards, 42 U.S.C. § 9836a(a)(1), was enacted under the Spending Clause. The Rule merely amends the conditions to which a Head Start participant must agree in order to receive grant funding. "[W]here Congress places conditions on a State's receipt of federal funds—

whether directly, or by delegation of clarifying authority to an executive agency—there is no commandeering of reserved State power so long as the State has 'a legitimate choice whether to accept the federal conditions in exchange for federal funds.'" *New York v. Dep't of Just.*, 951 F.3d 84, 115 (2d Cir. 2020) (quoting *NFIB*, 567 U.S. at 578), *cert dismissed*, 141 S. Ct. 1291 (2021).

Missouri confirms that Plaintiffs' constitutional claims are meritless. In their briefing before the Supreme Court, the Missouri plaintiffs argued that the vaccination rule challenged there unconstitutionally intruded on the states' police powers, *see* Response to Application for a Stay Pending Appeal, *Becerra v. Louisiana*, Nos. 21A240, 21A241, at 23–24, 27 (U.S. Dec. 30, 2021); violated the Spending Clause, *id.* at 26–27; violated the Tenth Amendment, *id.* at 1; and violated the non-delegation doctrine, *id.* at 27. The Supreme Court effectively rejected these claims, explaining that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered below." *Missouri*, 142 S. Ct. at 653. Accordingly, these claims should be dismissed.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint, or in the alternative, enter summary judgment in favor of Defendants.

Dated: March 24, 2022

Respectfully submitted,

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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

[DRAFT] PROPOSED ORDER

On this day came to be considered Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b). It is hereby **ORDERED** that Defendants' motion is **GRANTED**. Plaintiffs' Complaint, ECF No. 1, is hereby dismissed.

IT IS SO ORDERED.

March ___, 2022

THE HONORABLE TERRY A. DOUGHTY
UNITED STATES DISTRICT JUDGE