IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS, *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. 5:21-CV-00300-H

DEFENDANTS' UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF IN EXCESS OF PAGE LIMITS

Defendants, various federal officials and agencies, respectfully request the Court's leave to file a brief in support of their motion to dismiss or, in the alternative, motion for summary judgment, in excess of the 50-page limit set by the local rules. Plaintiffs commenced this action by filing a 254-paragraph complaint challenging an interim final rule regarding COVID-19 mitigation strategies in Head Start programs. ECF No. 1.

Under local civil rule 56.5(b), briefs in support of a motion for summary judgment are normally limited to 50 pages. The government seeks the Court's leave to exceed that page limit for its brief in support of the motion to dismiss or, in the alternative, motion for summary judgment, so that the government may file a single consolidated brief of no more than 55 pages. The government respectfully submits that a response of this length is appropriate under the circumstances given the length of Plaintiffs' complaint and the important 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 the issues in 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 brief in support of its motion to dismiss or, in the alternative, motion for summary judgment of no more than 55 pages. Defendants conferred with Plaintiffs, who stated that they do not oppose this motion.

Dated: March 16, 2022

Respectfully submitted,

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Certificate of Conference

I have conferred with counsel for Plaintiffs about this Motion and it is unopposed.

/s/ *Madeline M. McMahon*

Certificate of Service

On March 16, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ *Madeline M. McMahon*

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

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SUMMARY

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, the State of Texas and Lubbock Independent School District ("LISD"), challenge the Rule on statutory and constitutional grounds. As a state that does not receive any Head Start funding, Texas lacks standing to pursue these claims, and the Court should dismiss Texas as a plaintiff. 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 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*, 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]

[1] *See id.* at 68,056 & nn.47–48 (citing Tracy Lam-Hine, Stephen A. McCurdy, Lisa Santora, et

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 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,

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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).

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

[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.

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 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) ("Grant Policy Statement"), https://perma.cc/PME5-9724. No one is entitled to receive 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 estimated 24.8 million children ages five and under in the United States, *see* Forum on Child and Family Statistics, https://www.childstats.gov/americaschildren/tables/pop1.asp [https://perma.cc/8EU9-V2HA], 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, 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://www.washingtonpost.com/local/education/head-start-expands-in-md-county-where-

scandal-flared-two-years-ago/2018/09/11/45f1e13a-b2c4-11e8-9a6a-565d92a3585d_story.html [https://perma.cc/RB7C-YP5B].

IV. Developments Before the Rule's Issuance 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

[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.

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. ¶¶ 224–52, ECF No. 1. Pursuant to the Court's order, Defendants filed the certified administrative record on December 27, 2021. *See* Dec. 21, 2021 Order, ECF No. 23; Administrative Record, ECF Nos. 27–35. On December 31, 2021, the Court granted Plaintiffs' motion for a preliminary injunction, enjoining Defendants from implementing or enforcing the Rule in the State of Texas. *See* Dec. 31, 2021 Mem. Opinion & Order ("PI Order") at 56, ECF No. 42. The Court granted Defendants' motion to extend the deadline to respond to the Complaint to March 16, 2022. *See* Feb. 10, 2021 Order, ECF No. 44.

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" 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. The State of Texas Lacks Standing to Pursue Its 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). "[S]tanding is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek (for example, injunctive relief and damages)." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021). "[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen v. Wright*, 468 U.S. 737, 752 (1984); *see also Fednav, Ltd. v. Chester*, 547 F.3d 607, 616-18 (6th Cir. 2008) (dismissing claims brought by three plaintiffs who lacked

standing). 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).

Texas fails to meet injury in fact—"[t]he first and foremost of standing's three elements," *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338 (2016) (cleaned up)—because they do not receive any Head Start funding. *Cf.* 86 Fed. Reg. 68,053 (describing the vaccination requirement as applying, with some exceptions to "all Head Start program staff, . . . , certain contractors, and volunteers in classrooms or working directly with children"). To be eligible for classic Head Start grants, 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), so Texas is not eligible for these grants. Texas has also not alleged that it is a recipient of Early Head Start grants under 42 U.S.C. § 9840a. Texas Tech University's Early Head Start program, Compl. Ex. 4 ("Eric Bentley Decl.") ¶ 2, ECF No. 1-4, does not change this. The recipient of the cited grant is Texas Tech—who is not a Plaintiff in this action—and not the State of Texas. As a public university, Texas Tech does receive funding from the State of Texas, but Texas 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. *See* Texas Tech Univ., Summary Operating Budget, Fiscal Year 2021, https://perma.cc/H3CB-B96R.

Texas has also not established any sovereign injury just because its law is preempted as applied to Head Start programs. The Rule is not broadly preemptive of the Governor's Executive Order GA-40 prohibiting mandatory vaccination; rather, it applies to a small subset of Head Start personnel in the state. "[I]t is black-letter law that the federal government does not 'invade[ ]' areas of state sovereignty 'simply because it exercises its authority' in a way that preempts conflicting state laws.'" *Florida v. Dep't of Health & Hum. Servs.*, 19 F.4th 1271, 1291 (11th Cir. 2021) (quoting *Hodel v. Va. Surface Mining and Reclamation Ass'n, Inc.*, 452 U.S. 264, 291 (1981)). Indeed, courts have recognized a cognizable Article III harm when a state's *own* enforcement efforts have been hampered, not when a

federal enactment merely raises the abstract question of whether state law is preempted. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011) ("To permit a state to litigate whenever it enacts a statute declaring its opposition to federal law . . . would convert the federal judiciary into a 'forum' for the vindication of a state's 'generalized grievances about the conduct of government.'" (quoting *Flast v. Cohen*, 392 U.S. 83, 106 (1968))). Plaintiffs rely on *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015), but in that case, the court referred to a state forced to choose between incurring costs and changing its legal regime. *Id.* at 752. Here, Texas does not identify a similar pressure on it to change its legal regime or face costs; it simply notes that federal law has preempted state law as to programs funded by certain federal grants.

Plaintiffs' attempt to invoke *parens patriae* standing (Compl. ¶ 25) 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*, 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 State, which represents them as *parens patriae*." *Id.* (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 485–486 (1923)). And although a state may have standing 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), Texas has 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) ("[A] State [does 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*, ---S. Ct.---, No. 21-380, 2022 WL 585885 (U.S. Feb. 28, 2022) (mem.).

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 9–24, 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 "program performance standards" in 42 U.S.C. § 9836a(1), arguing that it cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. Compl. ¶¶ 102-06. But

even under the Plaintiffs' own definition of this term as "standards to measure a program's quality and conditions in terms of administration, facilities, and education," Compl. ¶ 104, the Secretary's rule is authorized. Standards designed to keep students and personnel healthy and classrooms open clearly measure "a program's quality and conditions in terms of administration, facilities, and education." *See* 86 Fed. Reg. at 68,056–57 (describing how school closures harm Head Start participants).

In any event, Plaintiffs fundamentally misunderstand the nature of the Head Start program, which was not intended to be limited to setting academic performance standards, but also geared toward improving the health and safety of impoverished children and their families and addressing all facets of students' readiness to succeed in an academic setting. *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.").

Plaintiffs turn to dictionaries and case law related to other statutes to support their argument, *see* Compl. ¶¶ 103–07 & n.41, but they ignore the Head Start Act itself. In fact, although Plaintiffs are correct that the act does not explicitly define "performance standards," Compl. ¶ 102, 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). Texas's Minimum Standards for Child-Care Centers require child care programs to develop a policy requiring staff to be vaccinated against "vaccine-preventable diseases" and for exempted employees to follow additional protective procedures "such as the use of protective medical equipment, including gloves and masks." Tit. 26 Tex. Admin. Code § 746.3611. A "vaccine-preventable disease" is defined by Texas as "a disease that is included in the most current recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention." *Id.* § 746.3609. One of these diseases is COVID-19. CDC, COVID-19 ACIP Vaccine Recommendations (Nov. 5, 2021), https://perma.cc/B2U6-GFYR (hereinafter "CDC ACIP Recommendations"). All Head Start personnel in Texas are therefore likely already required to be vaccinated for COVID-19, irrespective of the Rule.[4]

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." 45 C.F.R. § 1302.93(a). Current standards also include staff training on prevention and control of

[4] To the extent Plaintiffs may argue that there is a conflict between the Texas Standards and the executive orders issued by Governor Abbott related to COVID-19 vaccines referenced in their Complaint, *see* Compl. ¶ 79, those arguments carry no weight. The Texas Standards were updated on November 10, 2021, *see* Minimum Standards for Child-Care Centers, Texas Health and Human Services Commission (Nov. 10, 2021), https://www.hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/protective-services/ccl/min-standards/chapter-746-centers.pdf, which was after Governor Abbott issued his executive orders related to vaccines between July 29, 2021 and October 22, 2021, and the Standards did not address any potential conflict.

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

[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 Prod. 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)).

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 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). In fact, Plaintiff Lubbock Independent School District, which received its first Head Start grant in 1974, has 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 forty-seven years. LISD has never challenged the idea that those standards should be limited to exclude health. Similarly, although not named as a plaintiff in this action, Plaintiffs reference the anticipated burdens of compliance with the Rule on a Head Start program operated by Texas Tech University and submitted a declaration of Eric Bentley, the Vice Chancellor and General Counsel of the Texas Tech University System, in support of their motion for a preliminary injunction. *See* Compl. ¶ 213; Eric Bentley Decl., ECF No. 1-4. The Court should not consider these references to alleged harm to a non-party like Texas Tech, but in any event, like LISD, Texas Tech has complied with all of the health and medical regulations discussed above since it received its first Early Head Start grant in 2004. Indeed, Texas Tech applied and entered into the Head Start program with the knowledge that those standards already existed. 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—Plaintiffs oppose the same sorts of health measures with which they have always complied. Plaintiffs' 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 Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" Compl. ¶ 123 (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) (per curiam) ("*NFIB*"). 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," *NFIB*, 142 S. Ct. 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*, 19 F.4th at 1287; *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, 2007 WL 3375993 (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).

iii. The Nondelegation Doctrine Does Not Apply.

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. ¶ 113. 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.

B. 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." *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).

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. 68,052. Plaintiffs lodge a litany of conclusory claims that the Rule is arbitrary and capricious. Compl. ¶¶ 146–70. Although this Court previously found that Plaintiffs had established a likelihood of success on at least one of these claims, PI Order at 33–39, that opinion was issued before the Supreme Court rejected similar arbitrary-and-capricious claims against the CMS vaccine requirement, *see Missouri*, 142 S. Ct. at 653–54, and before another court found that the Rule was not arbitrary and capricious, *see Livingston*, 2022 WL 660793, at *8. None of Plaintiffs' claims has merit.

1. Plaintiffs first say that the agency's decision to require masks for Head Start personnel while no requirement exists for staff in K through 12 schools "makes no sense." Compl. ¶ 148. However, ACF does not have authority to require masks for K through 12 staff. Head Start is a federally funded program for pre-K children only, so ACF can only implement standards for those personnel. These standards are binding on Head Start programs, regardless of state law. *See, e.g.*, *City of New York v. FCC*, 486 U.S. 57, 63 (1988) (noting that federal regulations, like federal statutes, preempt state laws under the Supremacy Clause). To the extent that there are incongruities in the requirements at Plaintiffs' schools, they are the result of the state and local school districts' decisions not to implement mask requirements for K through 12 staff that align with the federal standards for Head Start.

2. Plaintiffs next argue that the agency acted arbitrarily and capriciously by "enforcing a vaccine mandate against Head Start staff" while "the federal government does not enforce the vaccine mandate against federal employees." Compl. ¶ 149. Plaintiffs allege, without evidentiary support, that after the deadline for federal employees to be vaccinated had passed, the government "allowed federal employees an unspecified additional amount of time to 'demonstrate progress towards becoming vaccinated'" rather than immediately terminate unvaccinated employees. Compl. ¶ 21. As an initial matter, there is no basis for holding a regulation of one agency arbitrary and capricious merely because another part of the federal government chooses to enforce a similar rule or regulation in a different

way as applied to a different group of people, much less a rule that applies to the entire federal government workforce writ large. To the contrary, it is a "well known" principle of administrative law that regulations "are not arbitrary just because they fail to regulate everything that could be thought to pose any sort of problem." *Pers. Watercraft Indus. Ass'n v. Dep't of Com.*, 48 F.3d 540, 544 (D.C. Cir. 1995). ACF's regulation should be upheld because the agency acted within the "zone of reasonableness," *Prometheus Radio Project*, 141 S. Ct. at 1158, irrespective of what other parts of the government are doing as to vaccination requirements in different contexts and for different populations. Federal employees who have not satisfied their obligation to be fully vaccinated are subject to discipline, including counseling, suspension, and, where noncompliance continues, removal or termination. *See* Safer Federal Workforce Task Force Guidance, Vaccinations, https://perma.cc/LN5M-RQCA (choose "Enforcement of Vaccination Requirement for Employees").[6] Here, Plaintiffs have not indicated that HHS has taken any enforcement action yet. Indeed, the Rule similarly provides some leeway akin to that granted to federal employees, stating that "for purposes of this regulation, staff, certain contract[or]s and volunteers will meet the requirement even if they have not yet completed the 14-day waiting period required for full vaccination." 86 Fed. Reg. at 68,052.

3. Plaintiffs argue that the agency failed to consider "the adverse effects resulting from resignations of unvaccinated Head Start workers who do not want to be vaccinated" and "the withdrawal of children from families who do not want to wear masks." Compl. ¶ 150. To the contrary, the Rule takes these factors into account. It states 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

[6] The vaccine requirement for federal employees is currently enjoined nationwide. *See Feds for Med. Freedom v. Biden*, No. 3:21-cv-356, 2022 WL 188329, at *8 (S.D. Tex. Jan. 21., 2022).

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. 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).

4. Plaintiffs relatedly argue that the Rule ignores "the interests of Head Start workers" who choose to remain unvaccinated "for any number of varying personal reasons." Compl. ¶ 151. As stated above, ACF did, in fact, consider that some Head Start personnel would refuse vaccination and may even resign from the program, and nevertheless found that the benefits of the vaccine requirement outweighed those costs. 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.

5. Plaintiffs next argue that the agency should have provided a "testing option" for personnel who refuse to comply with the vaccine requirement,[7] noting in particular that the rule adopted by OSHA for private companies with over 100 employees allowed for this alternative. Compl. ¶ 152; *see Missouri*, 142 S. Ct. at 653–54 (rejecting a similar argument). In promulgating the Rule, ACF considered "screening and diagnostic testing" as one alternative approach. 86 Fed. Reg. at 68,066. ACF ultimately decided to require vaccinations and mask use instead because those are two of the most effective mitigation strategies, as supported by numerous studies cited by the agency, and

[7] The Rule does require weekly testing for personnel who are exempt from the vaccine requirement. *See* 86 Fed. Reg. at 68,053.

because those requirements align with the program performance standards already in place for the Head Start program. *Id.*; *see, e.g.*, CDC, "Science Brief: COVID-19 Vaccines and Vaccination," updated Sept. 15, 2021, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html (cited at 86 Fed. Reg. at 68,053 n.20); Fowlkes, et al., *supra* (cited at 86 Fed. Reg. at 68,055 n.33); Delahoy, et al., *supra* (cited at 86 Fed. Reg. at 68,054 n.26). The fact that OSHA's rule requires different standards is beside the point. As noted above, there is no rule that one agency acts arbitrarily and capriciously merely because a different agency has adopted a different approach to address a common health risk in a different context. As the Rule explains, the OSHA rule, which covered over 80 million employees nationwide, was promulgated pursuant to a different statutory authority from the Rule and covered a far broader array of workplace contexts. 86 Fed. Reg. at 68,061, 68,069. It is thus not surprising that the two agencies determined that different standards were appropriate for different situations.

6. Plaintiffs claim that the Rule is arbitrary and capricious because it does not "provide an exemption to persons with natural immunity to COVID-19." Compl. ¶ 153; *see Missouri*, 142 S. Ct. at 653–54 (rejecting a similar argument). Plaintiffs state, without any support, that "natural immunity is at least as effective as vaccination in preventing re-infection, transmission, and severe health outcomes." Compl. ¶ 153. The agency disagreed with Plaintiffs' assertion, finding 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. *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. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983). ACF reasonably concluded that, based on the evidence, vaccinations are a superior mitigation strategy, regardless of a recipient's supposed "natural

immunity."

7. Plaintiffs next argue that the Rule is pretextual and therefore arbitrary and capricious. Compl. ¶ 154. They correctly cited many of the reasons that the Rule was adopted, as follows:

> The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA. The Secretary considered the Office of Head Start's past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. 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. The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.

Compl. ¶ 154 (quoting 86 Fed. Reg. at 68,054). Plaintiffs then state that these reasons are pretextual, despite the ample support for these justifications throughout the Rule, and that the real reason the agency implemented the Rule is "because President Biden ordered it." *Id.* Even if Plaintiffs are correct that the agency was prompted by the President, 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. The rationale provided in the Rule justifies the decision made, and Plaintiffs do not provide any explanation otherwise.

8. Plaintiffs argue that the fact that ACF adopted the Rule in November 2021, when vaccines had been authorized for nearly a year, suggests that the agency acted arbitrarily and capriciously. Compl. ¶ 155. But the Rule explains the reasons for its change in approach. It notes that "ACF initially chose, among other actions, to allow Head Start programs to decide whether or not to require staff vaccination rather than require vaccination, to provide information on the

COVID-19 vaccine . . . , and to emphasize that grant recipients can use" certain federal funds "to support staff in getting the COVID-19 vaccine." 86 Fed. Reg. at 68,054. However, as the agency eventually determined after study over a period of time, "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.* In particular, "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. *Id.* The Rule cites CDC data regarding the Delta variant, which led to an increase in the total number of COVID-19 cases in the latter half of 2021 and has "resulted in greater rates of cases and hospitalizations among children." *Id.* at 68,053. It also notes that, 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.* at 68,054. The changed circumstances, including the emergence of the Delta variant and the updated CDC recommendations shortly before ACF issued the Rule, justified the change of 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). The delay between the authorization of vaccines and ACF's implementation of the vaccine requirement is therefore reasonable.

9. Plaintiffs argue that the Rule is arbitrary and capricious because it treats all communities alike, without regard to the specific rate of COVID-19 transmission in each. Compl. ¶ 156. The Rule explains the agency's decision, stating that "ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rates. For example, the requirement could make masking voluntary once community transmission drops below a certain level, consistent with CDC guidance." 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,

"[t]ransmission rates could be significantly different across service areas." *Id.* "It would be burdensome for" a grant recipient covering an entire state "to change its mask guidance for different centers through the state as transmission rates change." *Id.* As such, "in the case of mask use, ACF is prioritizing a clear and transparent policy that is easy for grantees to follow across their service areas." *Id.*[8]

Plaintiffs also take issue with the fact that "[t]here is no end date or criteria for ending the universal mask mandate." Compl. ¶ 156. Again, the Rule provides a reasoned explanation: "[C]hildren benefit from routine and predictability. ACF determined that the best course of action was not to provide an end date on the" masking requirement and testing requirement for vaccine-exempt adults at this time. 86 Fed. Reg. at 68,066; *see Prometheus Radio Project*, 141 S. Ct. at 1158 (stating that the agency only needs to have "reasonably considered the relevant issues and reasonably explained the decision"). Additionally, ACF invited comments on this decision regarding an end date, indicating a willingness to adjust course if needed when it finalizes the Rule.[9]

10. Plaintiffs contend that the Rule is arbitrary and capricious because "Defendants do not know how many staff and volunteers are already vaccinated." Compl. ¶ 157. The Rule estimated the current vaccination rate of Head Start staff based on a survey of 21,663 child care providers, including 1,456 individuals providing services through Head Start or Early Head Start. 86 Fed. Reg. at 68,069. The survey, conducted between May and June 2021, found that 73.0% of respondents had "received at least one dose" of the COVID-19 vaccine, compared to 65% of the U.S. general adult

[8] The four counties (McMullen, Kenedy, Sterling, and Borden) cited by Plaintiffs as having no recently reported COVID-19 cases, Compl. ¶ 156, are sparsely populated and thus do not have a Head Start program, *see* Compl. Ex. 2, ECF No. 1-2 (providing a list of Head Start programs in Texas). If a child in those counties wanted to attend a Head Start program, that child would need to travel to a different county, which would have a different COVID-19 transmission level.

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

population at that time. *Id.* From this, ACF determined that Head Start staff are "about 12% more likely to be vaccinated than the general adult population." *Id.* Extrapolating from CDC data on the vaccination rates for the total U.S. population, ACF modeled that Head Start staff were vaccinated at a rate of 77.1% on November 10, 2021. *Id.* at 68,070. The model also predicts the vaccination rate at future dates without a vaccine requirement based on the CDC data, estimating that 79.8% of Head Start staff would be vaccinated on March 1, 2022. *Id.* Because the goal of the Rule is to ensure that as many Head Start personnel are vaccinated as possible, *see id.* at 68,077 (predicting that, in the long run, 5% of personnel will be granted an exemption and 95% of personnel will be vaccinated), ACF reasonably relied on this estimate to conclude that the current vaccination rate "has been insufficient to create a safe environment for children and families," *id.* at 68,054. Additionally, part of the Rule implements a system for reporting vaccination status, so that the agency will have more accurate data on vaccination rates in the future. *See id.* at 68,061.

Plaintiffs confusingly manipulate a variety of numbers to undermine ACF's straightforward statistical modeling. They note, from a different part of the Rule that models future coverage with a vaccine requirement, that the May to June survey found that 5.0% of unvaccinated respondents were "absolutely certain" to get the vaccine in the future and 6.9% were "very likely" to get the vaccine. Compl. ¶ 158; *see* 86 Fed. Reg. at 68,077. Plaintiffs then appear to add 5.0%, 6.9%, and 73.0% to conclude that "the final vaccine uptake among child care providers may settle around 90%" without a vaccine requirement. Compl. ¶ 158. This is wrong for three reasons. First, 5.0 + 6.9 + 73 is 84.9, not 90. Second, Plaintiffs ignore that the 5.0% and 6.9% figures are only of those respondents *who reported being unvaccinated*, *i.e.* 5.0% of 27% (or 1.35%) and 6.9% of 27% (or 1.863%). Adding these values to the 73% who were already vaccinated yields 76.213%, which is not far from the 77.1% figure

modeled by ACF.[10] Third, Plaintiffs' approach does not take into account that adults, including child care providers, may have changed their preferences between June and November for a variety of reasons, including the increased prominence of the Delta variant during that time period. Plaintiffs then go back to relaying data based on ACF's extrapolation of CDC data (which are constantly updated, thus accounting for slight variations in numbers calculated at the time the Rule was written and present) to conclude that 80.2% of Head Start personnel were fully vaccinated when the Rule was published on November 30, 2021. Compl. ¶ 159.

Plaintiffs say that the agency "abruptly switch[ed] the modeling criteria" and conclude that the agency "do[es] not actually know" the vaccination rate among Head Start staff. *Id.* ¶¶ 159–60. The Rule uses a single model, described above, to estimate the vaccination rate as of November 2021. 86 Fed. Reg. at 68,069. The agency reasonably relied on this estimate in determining that the vaccine requirement was necessary.

11. Plaintiffs state that the mask requirement is arbitrary and capricious because the agency did not consider conflicting evidence from the World Health Organization ("WHO") and the United Nations Children's Fund ("UNICEF"). Compl. ¶ 161. According to Plaintiffs, these organizations report that children ages five and under should not be required to wear masks based on the safety and interests of the child and "the capacity to appropriately use a mask with minimal assistance." *Id.* The Rule instead relies on November 10, 2021 guidance from the CDC, which recommended "universal indoor masking for ECE 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." 86 Fed. Reg. at 68,054. It is reasonable for ACF to rely on the recommendation of CDC over competing information from non-governmental agencies. *See Balt. Gas & Elec. Co.*, 462

[10] An additional 28.2% of unvaccinated respondents said they were "somewhat likely" to get vaccinated in the future, which accounts for slightly higher estimates. *See* 86 Fed. Reg. at 68,078.

U.S. at 103 (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.").

12. Plaintiffs argue that ACF acted arbitrarily and capriciously by not providing support for the decision to require children to wear a mask outdoors. Compl. ¶ 162. The Rule cites and relies upon the November 10, 2021 updated CDC guidance. *See* CDC, "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs" (Nov. 10, 2021), https://perma.cc/6VRE-FRTR (cited at 86 Fed. Reg. at 68,054 & n.54). That guidance states that "CDC recommends that people age 2 and older who are not fully vaccinated wear a mask in crowded outdoor settings or during activities that involve sustained close contact with other people." *Id.* This recommendation matches precisely the outdoor mask requirement adopted by the Rule. *See* 86 Fed. Reg. at 68,053. The agency acted reasonably in relying on CDC recommendations over competing information from other organizations. Plaintiffs also state that the Rule "is arbitrary and capricious because it failed to consider evidence that doesn't support masking children between the ages of two and five." Compl. ¶ 164. But Plaintiffs do not cite to any evidence that was before the agency. Further, Plaintiffs claim that the Rule only considered evidence concerning the effect masks have on adults and older children. Compl. ¶ 163. On the contrary, the CDC recommendation that the agency relied upon in adopting the Rule explains that children ages two and older should wear masks in certain settings. 86 Fed. Reg. at 68,054.

13. Plaintiffs argue that the CDC guidelines on which the Rule relies are "merely nonbinding recommendations and have never otherwise been imposed on Head Start programs." Compl. ¶ 165. This argument is meritless. Nowhere does the Rule suggest that ACF is *required* to implement a vaccine and mask requirement in accordance with CDC guidelines. Instead, ACF chose to rely on the scientific expertise of CDC in determining performance standards for Head Start.

14. Plaintiffs next argue that ACF failed to consider whether the mask requirement may stigmatize Head Start students, who are disproportionately from low-income and minority families, due to the fact that non-Head Start students may not be required to wear masks. Compl. ¶ 166. Plaintiffs cite no evidence to support the assertion that mask wearing will lead to stigmatization, or that educators would allow the hypothesized behavior to occur. Moreover, the Rule explicitly considers its impact on underserved children and communities in particular:

> Studies have shown that COVID-19 has disproportionately affected some racial and ethnic minority groups such as Hispanic or Latino, Black or African American, American Indian or Alaskan Native (AIAN), and Native Hawaiian and other Pacific Islander people. It is also estimated that these disparities may have long term implications for these populations: for example, it is estimated that COVID-19 morbidity and mortality impacts can reverse over 10 years of progress in reducing the gaps in life expectancy between Black and White populations. Many families of Head Start children and staff are members of minority communities; 71 percent of families, and 69 percent of staff, self-identify as Hispanic/Latino, Black/African American, American Indian, or Alaska Native, who have been shown to be at increased risk of exposure to SARS-CoV-2. Given the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups, requiring vaccination among Head Start staff is not only an issue of personal health, but also promotes public and community health and health equity for children and staff in Head Start programs.

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.").

15 Plaintiffs also argue that the Rule is arbitrary and capricious because the agency did not consider "the effectiveness of masking in preventing the spread of COVID-19 when mixing masked and unmasked children." Compl. ¶ 167. The Rule concludes that mask use is one of "the most effective mitigation strategies available to reduce transmission of SARS-CoV-2," 86 Fed. Reg. at 68,053, and cites multiple studies demonstrating the effectiveness of mask use, *see id.* at 68,054. Thus,

the Rule requires "universal" masking for all Head Start participants. *Id.* To the extent that Head Start students and non-Head Start students come into contact with one another, there is no study that suggest that masks lose all effectiveness at slowing the spread of SARS-CoV-2 merely because some unmasked individuals are present with masked individuals; to the contrary, evidence shows that a mask provides at least some protection to the wearer even when others around them are unmasked. *See, e.g.*, CDC, "Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, Feb. 19, 2021 https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm. Finally, as noted at the beginning of this section, ACF's authority to implement a mask requirement does not extend beyond the Head Start program; if Plaintiffs are concerned about the incongruity present between classes at their schools, they can choose to implement mask requirements for K through 12 programs to align with the federal Head Start standards—or not—but they cannot dictate the federal standards.

16. Plaintiffs argue that the Rule is arbitrary and capricious because a study cited in the Rule does not justify the mask requirement. Compl. ¶ 168. But Plaintiffs are mistaken about the purpose of the cited study; the study is not meant to justify the mask requirement specifically, but rather to provide background information that a variety of mitigation methods, including masks, have some degree of effectiveness at reducing the transmission of SARS-CoV-2. The Rule states that "during the period from September to October 2020, ACF collaborated with CDC to conduct a mixed-methods study in Head Start programs." 86 Fed. Reg. at 68,056. "The study found that implementing and monitoring adherence to recommended mitigation strategies, *such as* mask use, can reduce risk for SARS-CoV-2 transmission in Head Start settings." *Id.* (emphasis added). As Plaintiffs note, "[m]ask policies for children varied" in the programs studied. Compl. ¶ 168 (alteration in original). That fact does not undermine the more general conclusion that various mitigation strategies, including masks (where used), demonstrated some effectiveness in the study. Elsewhere in the Rule,

the agency cites a CDC brief in determining that masks are one of "the most effective mitigation strategies." 86 Fed. Reg. at 68,066 & n.86. There is therefore no inconsistency between the cited studies and the propositions for which the Rule cites them.

17. Lastly, Plaintiffs claim that the Rule is arbitrary and capricious because a particular study that ACF considered does not justify the mask requirement in Plaintiffs' opinion. Compl. ¶ 169. The Rule finds that "counties without school mask requirements experienced larger increases in pediatric COVID-19 case rates after the start of school compared to counties that had school mask requirements," 86 Fed. Reg. at 68,056, and cites a study from July to September 2021, *id.* at 68,056 n.49. The problem with the study, Plaintiffs argue, is that it states that the findings contained therein "are subject to at least four limitations" in the statistical analysis conducted. Compl. ¶ 169. There is no requirement under the APA that an agency only rely on perfect scientific studies, much less disregard studies that particular individuals or entities find unreliable. *See Prometheus Radio Project*, 141 S. Ct. at 1160 (noting that it is "not unusual" for an agency "not [to] have perfect empirical or statistical data"). Indeed many, if not most, statistical analyses have some limitations regarding sample size, etc., but that does not mean that they do not also provide valuable information upon which an agency may rely. *See generally* Richard Royall & Tsung-Shan Tsou, *Interpreting Statistical Evidence by Using Imperfect Models: Robust Adjusted Likelihood Functions*, Journal of the Royal Statistical Society, Apr. 25 2003, https://www.jstor.org/stable/3647511. In any event, this study is not the only source relied upon by ACF in adopting the mask requirement. As discussed above, ACF also relied on the CDC's updated guidance. ACF "made a reasonable predictive judgment based on the evidence it had." *Prometheus Radio Project*, 141 S. Ct. at 1160.

C. The Rule Does Not Improperly Rely on Existing Regulations.

Related to Plaintiffs' arbitrary-and-capricious claims, Plaintiffs take issue with the portion of the Rule that discusses existing regulations for Head Start. Compl. ¶¶ 132–45. But Plaintiffs

misunderstand the purpose of this discussion. The existing regulations are cited in the section of the Rule entitled "Alternatives Considered," and explains why ACF adopted a vaccine and mask requirement over other mitigation strategies, including "staying home if sick; handwashing; improving ventilation; screening and diagnostic testing; cleaning and disinfecting; keeping physical distance; and cohorting." 86 Fed. Reg. at 68,066. This portion of the Rule was discussed in the previous section of this brief. *See supra* Section II.B.5. (explaining the lack of a "testing" option). The Rule explains that the vaccine and mask requirements were chosen for two reasons. 86 Fed. Reg. at 68,066. One is that these are "two of the most effective mitigation strategies available to reduce transmission of COVID-19." *Id.* The other is that those requirements align with the program performance standards already in place for the Head Start program. *Id.* The Rule states:

> Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of § 1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which OHS sees as a strategy for a program's infection control practices). In addition, § 1302.47(b)(1)(iii) states that facilities need to be "free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety," though it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

Id.

The point of this discussion is not, as Plaintiffs suggest, to say that the already existing requirements "themselves justify the Vaccine Mandate and the Mask Mandate." Compl. ¶ 133. Instead, this paragraph merely states that ACF already has a variety of program performance standards on health-related requirements, and a vaccine and mask requirement is not unusual given these existing standards. Plaintiffs go on to contend that the agencies' description of the regulations cited in this paragraph are not the best interpretation of the text of those regulations. Compl. ¶¶ 135–38. These arguments are beside the point. As Plaintiffs recognize, this is not a case involving an "interpretive rule, or an informal interpretation of Defendants' own regulations." Compl. ¶ 133. In other words,

ACF is not requesting that the Court give deference to these interpretations of 45 C.F.R. § 1302.47 under *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). The precise contours of 45 C.F.R. § 1302.47 are not at issue in this case.

Plaintiffs also point to a statement in the background section of the Rule, which states that the "Head Start Program Performance Standards require children to be up to date on immunizations and their state's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a schedule to catch up." 86 Fed. Reg. at 68,059. Plaintiffs state that this is an incorrect interpretation of 45 C.F.R. § 1302.42. But that regulation, discussed *supra* Section II.A.2, clearly states that a Head Start program must "[o]btain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventative and primary medical and oral health care," including "immunization recommendations issued by the Centers for Disease Control and Prevention," and must "[a]ssist parents with making arrangements to bring the child up-to-date as quickly as possible." 45 C.F.R. § 1302.42(b)(1)(i), (ii);[11] *see also Kisor*, 139 S. Ct. at 2414 (affirming that an agency's interpretation of its own regulation is accorded deference). Again, though, the interpretation of § 1302.42 is beside the point because the Rule does not rely on this provision for the proposition that Plaintiffs claim it does. Plaintiffs assert that the regulation "does not justify requiring children to wear masks without parental consent."[12] Compl. ¶ 141. But in the context of the Rule, the immunization requirements are

[11] The regulation also provides that "if necessary," the Head Start program should "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). Contrary to Plaintiffs' assertion, Compl. ¶ 141, the "parent consent" phrase only applies to the direct provision of health services by a Head Start program. It does not provide parents an opt-out of the immunization requirement. *See* 81 Fed. Reg. at 61,336.

[12] As noted in the preceding footnote, "parental consent" in this context does not provide an opt-out of Head Start requirements. Indeed, by voluntarily enrolling their child in a Head Start program, parents are consenting to the performance standards laid out for the program, including those in the Rule.

discussed merely as background information in the economic analysis section. They are not themselves used to justify the mask requirement.

Plaintiffs repeat the same arguments with respect to the Rule's background statement that "[i]t is equally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a))." Compl. ¶ 143 (quoting 86 Fed. Reg. at 68,059) (alteration omitted). Plaintiffs assert that 45 C.F.R. § 1302.93(a) applies only to staff members who "already have a communicable disease" and not to those who might become "infected by an airborne virus" in the future. *Id.* The text of 45 C.F.R. § 1302.93(a) states that the Head Start program "must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program." Plaintiffs' reading of the regulation narrows its scope and contradicts the plain text, which applies to both pre-existing diseases and diseases Head Start personnel might contract. However, the interpretation of 45 C.F.R. § 1302.93(a) is not at issue, and contrary to Plaintiffs' assertion, the Rule does not rely on this regulation to justify the vaccine requirement; it is cited for background purposes.

Finally, Plaintiffs note that the Rule relies on 42 U.S.C. § 9842 to justify the requirements for staff to document their vaccination status. *See* Compl. ¶ 144; 86 Fed. Reg. at 68,061. Under this statute, "[e]ach recipient of financial assistance under this subchapter shall keep such records as the Secretary shall prescribe, *including*" various financial records. 42 U.S.C. § 9842(a) (emphasis added). Plaintiffs assert that this statute only authorizes recordkeeping of financial documents. However, the statute is broadly phrased to cover "such records as the Secretary shall prescribe." *Id.* Notably, Head Start is a federal grant program, so every Head Start grantee is a "recipient of financial assistance under this subchapter," *id.*, and the record-keeping provision should not be read narrowly so as to exclude non-financial records, *see In re Huckfeldt*, 39 F.3d 829, 831 (8th Cir. 1994) ("Use of the introductory

word 'including' means . . . nonexclusive."). ACF thus reasonably relied on this statute in determining that it could require documentation of vaccination status.[13]

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.

[13] Plaintiffs do not appear to separately challenge the documentation requirement, only the vaccine requirement and the mask requirement. *See generally* Compl. As such, the arguments concerning 42 U.S.C. § 9842 are not reasonably related to the relief Plaintiffs seek.

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* at Section II.B.8., 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.*,[14] 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 42 U.S.C. § 9836a(a)(2).

Plaintiffs also argue that the Rule violates a different section of the statute—42 U.S.C. § 9836a(a)(2). That section imposes two requirements on the Secretary's development of any modifications to Head Start standards. First, it requires him to

> consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs.

42 U.S.C. § 9836a(a)(2)(A). Second, it requires him to "take into consideration" nine different factors including such things as "past experience with use of the standards in effect," "projected needs of an expanding Head Start program," and "the unique challenges faced by individual programs." *Id.* § 9836a(a)(2)(B). Plaintiffs argue that the Secretary violated both subparagraph A and subparagraph B because the Rule does not explicitly list each of the factors these subparagraphs require the Secretary to consider. *See* Compl. ¶¶ 195–99. But notably absent from 42 U.S.C. § 9836a(a)(2) is any

[14] 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.

requirement that the Secretary document his consideration of each and every statutory factor using the exact wording of the statute. And to the extent Congress actually intended the Secretary to certify that he considered the specifically delineated factors, the Rule makes clear that he did just that: "In developing these modifications, the Secretary included relevant considerations pursuant to . . . 42 U.S.C. 9836a(a)(2)." 86 Fed. Reg. at 68,053–54.

While the Rule does not explicitly reference every factor in identical wording to that found in the statute, it includes ample explanation of the types of consideration the Secretary made, which clearly encompass the full breadth of the factors Congress intended him to consider under 42 U.S.C. § 9836a(a)(2). For example, Plaintiffs fault the Secretary for not fully documenting his consideration of "guidelines and standards that promote child health services and physical development, including participation in outdoor activity that supports children's motor development and overall health and nutrition." Compl. ¶ 199 (quoting 42 U.S.C. § 9836a(a)(2)(B)(vi)). But in fact the Rule explains, "The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children." 86 Fed. Reg. at 68,060. So, actually, the Secretary did consider "child health services and physical development" including "outdoor activity." 42 U.S.C. § 9836a(a)(2)(B)(vi). Plaintiffs complain that the Secretary did not explicitly spell out what he found to be the costs and benefits in this regard such as how wearing a mask under outdoor circumstances involving close contact with others might affect children's physical development. Compl. ¶ 199. But Plaintiffs' complaint amounts to a disagreement with how the Secretary came out on this issue—not a valid claim that he did not consider the issue.

Similarly, Plaintiffs wrongly claim that the Secretary failed to "ensure that [the] revisions in the [program performance] 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." Compl. ¶ 200

(quoting 42 U.S.C. § 9836a(a)(2)(C)(ii)). Plaintiffs assert that "[n]o such analysis appears in the Interim Final Rule." Compl. ¶ 200. But in fact one of the Secretary's primary reason for adopting the Rule was to insure 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). ACF explained that the Secretary

> 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. In any case, 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. The vaccine requirement does not change 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. 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. Plaintiffs' argument that the Secretary did not consider how revising the standards would affect Head Start services is meritless.

Finally, although Plaintiffs do not explicitly identify any particular factor they believe the Secretary incorrectly considered, they state that "[n]one of these factors that Defendants say they considered are factors that they must consider." Compl. ¶ 198. To the extent Plaintiffs are arguing that the Secretary's consideration of factors not explicitly laid out in the statute is unlawful, that argument is also wrong. Nothing in 42 U.S.C. § 9836a(a)(2) indicates that Congress intended it to be an exhaustive list of all of the factors the Secretary may consider in promulgating new rules.

F. 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. ¶¶ 203–08, is a red herring. As an initial matter, that statute is plainly not judicially enforceable. *See* Omnibus Consolidated & Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277 (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."). But 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 had 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 went on to "invite[] 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 that they argue is "mandatory" under the law, Compl. ¶ 205, but tellingly, they do not argue that the Rule "may affect family well-being," 5 U.S.C. § 601 note (f), explain how it might conceivably do so, or assert that it was arbitrary or capricious for the agency to make the determination that the Rule does not affect family well-being. Without arguing that the 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 that the Rule may affect family well-being given

that the Rule simply requires two commonsense measures while children are with their peers and personnel at Head Start facilities that are proven to slow the spread of a highly contagious virus. When children are with their families at home or anywhere else, they are of course free to wear masks or not, as they 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 factors would apply to this Rule, Plaintiffs are not likely to succeed on the merits of this claim.[15]

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. 1, § 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.

[15] Plaintiffs also argue that "Defendants limit the meaning of 'family well-being'. . . . [to the] 'autonomy or integrity of the family as an institution.'" Compl. ¶ 207. That argument is irrelevant because Plaintiffs do not argue that this specific rule may affect *either* family well-being *or* the autonomy or integrity of the family as an institution. But at any rate, an agency is not required to mimic the text of a statute verbatim in a simple statement in a rulemaking that it complied with it. *Cf.* B*reniser v. Shinseki*, 25 Vet. App. 64, 73 (Vet. App. 2011) ("Because the primary function of any regulation is to interpret the statute it implements, not mimic it, a regulation need not, and should not, parrot the statute it implements.").

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 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*, 452 U.S. at 291 (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. ¶¶ 212-15. 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, this Court should dismiss the Complaint, or in the alternative, enter summary judgment in favor of the Defendants.

Dated: March 16, 2022 Respectfully submitted,

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