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Director Bernadine Futrell, Ph.D.
Office of Head Start
330 C. Street SW, 4th Floor
Washington, DC 20201

Submitted Electronically via Regulations.gov

Re: Comments by the Commonwealth of Kentucky, and the States of Louisiana, Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Kansas, Mississippi, Missouri, Montana, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Texas, and Utah, on *Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs* (Docket No. ACF-2021-0003)

Dear Director Futrell:

The undersigned States submit the following comments on the Interim Final Rule with Comment, 86 Fed. Reg. 68,052 (November 30, 2021), entitled "*Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs*" ("Head Start Rule" or "Rule"). Several of the States have already filed actions¹ challenging the Head Start Rule that requires all staff and volunteers working with children be vaccinated against COVID-19 by January 31, 2022, and that all adults and children over two-years old wear masks effective immediately.

Federally funded Head Start programs provide school readiness and other vital services to vulnerable children and their families in each of the States. Nationally, Head Start provides billions

¹ See *Louisiana, et. al. v. Becerra, et. al.*, Case No. 3:21-cv-04370 (W.D. La.); *Texas v. Becerra, et. al.*, Civil Action No. 5:21-cv-300 (N.D. Texas).

of dollars to fund services for about one million children. These services are facilitated by approximately 273,000 staff and over one million volunteers.²

The States also place high priority on pre-school education and fund the education of additional pre-school programs. If the Rule stands, the States and their citizens will suffer irreparable harm as many Head Start programs will have to reduce services and enrollment because staff, volunteers, and partners will refuse to comply with vaccination requirements. We submit these comments to reiterate that the Secretary of Health and Human Services lacks statutory authority under 42 U.S.C. § 9836a to impose such a harmful, sweeping, and unnecessary rule. In submitting these comments, we do not waive our right to continue the pending legal challenges or institute any new ones; rather, we request that the Secretary vacate the Rule voluntarily.

I. The Secretary exceeded the scope of his authority granted by 42 U.S.C. § 9836a when he issued the Head Start Rule.

In issuing the Rule, the Secretary purports to exercise his authority under 42 U.S.C. § 9836a(a)(1) of the Head Start Act (“Act”) to “modify, as necessary, program performance standards by regulation applicable to Head Start agency and programs.” *See* 86 Fed. Reg. at 68,052. The Secretary specifically cites 42 U.S.C. § 9836a(a)(1)(C), (D), and (E) without explaining how the Rule falls within the reach of any those specific provisions. Nor could the Rule do so because none of these provisions permit the Secretary to commandeer Head Start agencies—and in some cases, state officials—to institute and enforce President Biden’s public health initiatives against COVID-19, including forced vaccination of all Head Start staff and volunteers.

First, the Secretary lacks authority to impose the Rule under 42 U.S.C. § 9836a(a)(1)(C), which relates to the modification of program “administrative and financial standards.” The Rule does not fit that mold. The Secretary did not even codify the Rule in existing subsections of the Code of Federal Regulations addressing administrative or financial standards. *See* 45 C.F.R. Part 1303. Those regulations relate to financial responsibility, insurance, facilities acquisition and management, transportation, and other topics completely unrelated to virus mitigation strategies or vaccination of staff.

Second, 42 U.S.C. § 9836a(a)(1)(D), which addresses “standard[s] relating to the condition and location of facilities (including indoor air quality assessment standards),” also does not apply. The Rule has no reasonable relation to the condition and location of facilities or the requirement that they “meet or exceed State and local requirements concerning licensing for such facilities.” *Id.* The Rule instead imposes conditions on people’s eligibility to participate in, be employed by, or volunteer with Head Start programs.

Last, the general language of “such other standards as the Secretary finds to be appropriate” as set forth in 42 U.S.C. § 9836a(a)(1)(E) is devoid of the requisite specificity to support the broad sweeping mandates of the Rule. This Rule impacts millions of people and

² *See* Head Start Program Facts: Fiscal year 2019, available at <https://perma.cc/84KE-QNT4>.

implicates billions of dollars of federal funding. If imposed, many Head Start programs are at risk of having to terminate staff and reduce the services currently offered to vulnerable children. Such policy decisions reflected by the Rule address issues of vast economic, social, and political significance. Accordingly, the Rule implicates the major questions doctrine and the mandates imposed thereby must be supported through a more specific grant of Congressional authority than what is set forth in 42 U.S.C. § 9836a(a)(1)(E). *See Ala. Ass’n of Realtors v. Dep’t of Health & Human Servs*, 141 S. Ct. 2485, 2489 (2021); *In re MCP No. 165, Occupational Safety and Health Admin., Interim Final Rule: COVID-19 Vaccination and Testing*, --- F.4th ---, 2021 WL 5914024, at *1 (Dec. 15, 2021) (Sutton, C.J., dissenting from denial of initial hearing *en banc*).

II. The Rule was promulgated in violation of 42 U.S.C. § 9836a(a)(2).

The Head Start Mandate not only lacks clear Congressional authorization—it also clearly violates several provisions of the Act. The Rule acknowledges in its economic analysis that a significant number of unvaccinated staff will quit or be terminated.³ The predictable result of this personnel reduction is that Head Start programs will either close or be unable to serve the same number of children or provide the same level of services that they did before the Rule. Because of this, the Rule violates the Act in at least five ways.

First, the Rule violates the Act’s text and structure. The Head Start program’s purpose is “to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development.” 42 U.S.C. § 9831. And the program has been reauthorized several times for the purpose of expanding eligibility and enrollment. *See, e.g.*, Improving Head Start for School Readiness Act of 2007 (P.L. 110-134). The Rule undermines the program’s existence because it will decrease enrollment in at least two ways. First, programs can expect to see a decrease in enrollment because parents disagree with the Rule as applied to their children. Second, as the Secretary himself admits, staff and volunteer levels are expected to plummet. The Rule cuts against, instead of advancing, Head Start’s core mission: improving the school readiness of low-income children. The Act forbids the Secretary from issuing such a regulation or standard. *See* 42 U.S.C. §§ 9836a(a)(2)(C)(ii) (no reduction in quality of education/care), (b)(3)(B) (no reduction in enrollment).

Second, the Rule violates 42 U.S.C. § 9836a(a)(2)(B)(x), which requires the Secretary to “take into consideration . . . the unique challenges faced by individual programs, including those programs that are seasonal or short term and those programs that serve rural populations.” The Rule is devoid of *any* analysis on its impact on rural or geographically distinct areas. In Kentucky, for example, vaccination rates in rural areas are lower than in urban areas.⁴ In some areas, Head Start programs along with school systems have been open all year but will lose the staff need to keep the Head Start program open. It therefore is more likely that Head Start programs in these

³ *See* 86 Fed. Reg. at 68,090 -91 (stating that 11,517 to 23,035 staff will not submit to the vaccine requirement).

⁴ *See* Kentucky Covid-19 Vaccination Dashboard, available at <https://perma.cc/V9RL-9GY5> (click on “View Dashboard”)

areas will be disproportionately impacted when forced to terminate staff and banish volunteers who not to comply with the Rule’s vaccination requirement.

Third, the Rule violates 42 U.S.C. § 9836a(2)(A), which requires the Secretary to “consult with experts in the fields of child development, early childhood education, child health care, family services (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.” The Rule does not disclose that any of these types of experts were consulted. In fact, Head Start directors in Kentucky were certainly not consulted about the Rule prior to its issuance, have received insufficient guidance from the Office of Head Start on how to comply with it, and now predict having to shutter programs if the Rule stands.⁵ And the Secretary’s consultation with “experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA,” 86 Fed. Reg. at 68054, fails to meet §9836a(2)(A)’s specific requirements. In fact, the Secretary did not even disclose who was specifically consulted, if anyone.

Fourth, the Rule violates the mandate in 42 U.S.C. § 9836a(a)(2)(C)(ii) that the Secretary “ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” By excluding children whose parents refuse to have their children wear masks and reducing eligible staff, contractors, and volunteers, the Rule will predictably reduce the quality, scope, and types of health, education, parental involvement, nutrition, social, and other services provided to students. The National Head Start Association survey confirmed that more than 50% of all Head Start programs could close.⁶

Last, the Rule violates the fundamental command in 42 U.S.C. § 9836a(b)(3)(B) that measures promulgated under the Act “shall not be used to exclude children from Head Start programs.” That is precisely the purpose of part of the Rule—excluding the children of parents who refuse to have their children comply with the masking requirement. And children are already being excluded from Head Start programs due to the Rule.⁷

⁵ John Mountjoy, *Op-Ed: Kentucky’s Head Start programs need flexibility, not mandates*, Lane Report (Dec. 20, 2021), available at <https://perma.cc/3AAS-C67Q>. Mr. Mountjoy is the Executive Director and CEO of the Kentucky Head Start Association.

⁶ See attached NHSA Letter of Dec. 15, 2021, to Xavier Becerra & Summary of Survey results.

⁷ Andrea Johnson, *Head Start must close classrooms, fire staff due to federal COVID-19 vaccine mandate*, Minot Daily News (Dec. 10, 2021), <https://bit.ly/3ykUvBT>.

III. The Rule violates the notice and comment provision of the APA.

The Administrative Procedure Act requires agencies to publish notice of all “proposed rule making” in the Federal Register, 5 U.S.C. § 553(b), and to “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments,” *id.* § 553(c). The Secretary acknowledges that the Head Start Rule is a major rule that normally is subject to the APA’s notice-and-comment procedures, and the Secretary admits that the Rule did not receive the benefit of notice and comment. 86 Fed. Reg. at 68058. He attempts to justify this failure by invoking the incredibly narrow “good cause” exception to the APA’s notice-and-comment requirement.

But this narrow exception does not apply for at least two reasons. *First*, the Secretary states that although “COVID-19 cases, hospitalizations and deaths have begun to trend downward at a national level,” notice and comment must be avoided because of a vague “threat to the country’s progress on the COVID-19 pandemic” posed by the unvaccinated (presumably those in Head Start programs). 86 Fed. Reg. at 68058-59. But this justification amounts to no more than a claim of administrative inconvenience—precisely the justification courts have repeatedly rejected. *See, e.g., United States v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011) (“[T]he good cause exception should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them.”); *Ass’n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 498 (D. Md. 2020) (“[A]n agency may not dispense with notice and comment procedures merely because it wishes to implement what it sees as a beneficial regulation immediately.”).

And *second*, the Secretary’s concerns about the onset of winter and flu season represent a crisis of its own making, which is not sufficient to establish good cause. *See, e.g., United States Steel Corp. v. EPA*, 595 F.2d 207, 213-14 & n. 15 (5th Cir. 1979); *see also NRDC v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) (“We cannot agree . . . that an emergency of [an agency’s] own making can constitute good cause.”). The Secretary waited months after the President’s September announcement to issue this supposedly emergency measure. Moreover, this purported reason is irrational given the absence of any similar measures (ever) regarding *flu* shots. This delay does not constitute good cause “because ‘[o]therwise, an agency unwilling to provide notice or an opportunity to comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then raise up the good cause banner and promulgate rules without following APA procedures.’” *NRDC v. NHTSA*, 894 F.3d 95, 114-15 (2d Cir. 2018) (alteration in original).

IV. The Rule was promulgated in violation of the Congressional Review Act.

The Rule was also promulgated in violation of the Congressional Review Act (“CRA”), 5 U.S.C. §§ 801–808. The CRA requires a delayed effective date for major rules so that Congress has an opportunity to review the rule and, potentially, disapprove it.⁸ *See generally* 5 U.S.C. § 801.

⁸ Federal law defines a “major rule” in relevant part as follows:

Even though the Head Start Rule is a major rule, the Secretary has purported to invoke the “good cause” exception to make the Rule effective immediately upon publication in the Federal Register. *See* 5 U.S.C. §808 (providing that an agency may determine the effective date of a rule “which an agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest”). The CRA’s good-cause standard is effectively the same good-cause standard found in the APA’s exception to the notice and public comment requirement. And for the reasons already discussed in the context of the APA, the Secretary cannot make the requisite good-cause showing to justify bypassing Congressional review prior to the Rule’s effective date. *See Sorenson Commc’ns v. F.C.C.*, 755 F.3d 702, 706 (D.C. Circ. 2014) (“Deference to an agency’s invocation of good cause—particularly when its reasoning is potentially capacious, as is the case here—would conflict with this court’s deliberate and careful treatment of the exception in the past.”); *see also* OMB, Memorandum No. M-19-14, *Guidance on Compliance with the Congressional Review Act* (Apr. 11, 2019) (noting APA good-cause standard applies in CRA context).

V. The Rule violates the Treasury and General Government Appropriations Act of 1999.

The Rule also violates Section 654 of the Treasury and General Government Appropriations Act of 1999, which requires that agencies “shall” prepare an impact assessment “[b]efore implementing policies and regulations that may affect family well-being.” Public Law 105-277, 5 U.S.C. § 601 note. The impact analysis must meet several specific requirements including, among others, an assessment of whether the regulatory action “strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children,” whether “the action may be carried out by State or local government or by the family,” and whether “the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.” 5 U.S.C. § 601 note.

The Secretary acknowledges that Section 654 applies to the Head Start Rule. *See* 86 Fed. Reg. at 68062. But he arbitrarily rejects the need for an impact assessment with the conclusory and audacious claim that the Rule “will not have *any* impact on the autonomy or integrity of the family as an institution.” *Id.* (emphasis added). This is an absurd claim that is flatly contradicted by many of the agency’s own statements regarding the *importance* of Head Start to Head Start families and the children in attendance. The Rule also intrudes into fundamental decisions about whether a toddler must wear a mask at school, be exposed to additional discipline if he or she fails to or is

The term “major rule” means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—

- (A) an annual effect on the economy of \$100,000,000 or more;
- (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

unable to comply with directives, imposes obligations on parents picking children up from school, and goes straight to the heart of the allocation of power between the state and family. The Rule is therefore contrary to Section 654 of the Act.

VI. The Rule violates the Constitution.

The Secretary is also interpreting his authority in a manner contrary to the United States Constitution.

First, the Rule violates the Nondelegation Doctrine. The Constitution vests Congress with legislative power. U.S. Const. art. 1, §1. “Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is vested.” *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529-30 (1935). The Act’s amorphous phrase “such other standards as the Secretary finds to be appropriate” lacks a sufficient intelligible principle that would authorize the Secretary to force Head Start programs to mandate vaccines and masks. Accordingly, the Rule reflects an unconstitutional delegation of legislative power to the Executive and is void. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019).

Second, the Rule violates the Tenth Amendment by intruding into two core areas of State police power, education and public health. *See, e.g., BST Holdings, LLC*, 17 F.4th 604, 617 (5th Cir. 2021) (“[T]o mandate that a person receive a vaccine or undergo testing falls squarely within the States’ police power.”); *see also Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (“[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.”); *Missouri v. Jenkins*, 515 U.S. 70, 131-32 (1995) (Thomas, J., concurring) (“We have long recognized that education is primarily a concern of local authorities.”). The Rule expressly conflicts with State laws, rules, and policies issued under their long-established police powers over education and public health and purports to preempt them.⁹ Fed. Reg. at 68,063. By encroaching upon these inherent State powers, particularly without clear authorization from Congress, the Secretary has exceeded his authority and violated the Tenth Amendment.

Third, the Mandate violates the Anti-Commandeering Doctrine by requiring State entities to enforce it. The Tenth Amendment and structure of the Constitution deprive Congress of “the power to issue direct orders to the governments of the States,” *Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018), or to commandeer State entities “into administering federal law,” *Printz v. United States*, 521 U.S. 898, 928 (1997). The Rule violates this doctrine by requiring State entities to enforce the Rule against students, employees, and volunteers. *NFIB v. Sebelius*, 567 U.S. 519, 585 (2012) (noting that the federal government is prevented from “conscript[ing] state [agencies] into the national bureaucratic army”).

Last, the Rule violates the Spending Clause by conditioning the receipt of federal funds on enforcement of the Rule. “[I]f Congress intends to impose a condition on the grant of federal

⁹ *See e.g.*, 2021 (Extra. Sess.) Ky. Acts Ch. 5, Sec. 11 (abolishing state-wide mask mandate for schools in Kentucky); Texas EO GA-40 (Oct. 11, 2021) (executive order prohibiting mandatory vaccination requirements by employers in Texas); Fla. Stat. § 381.00317 (prohibiting mandatory vaccination requirements in Florida).

moneys, it must do so unambiguously.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). The Head Start Act does not clearly authorize or unambiguously impose the Head Start Rule. And there is no nexus between Head Start grants and vaccine or toddler mask requirements. *Cf. South Dakota v. Dole*, 483 U.S. 203 (1987). Accordingly, the Head Start Rule is an unconstitutional condition on the receipt of federal funds.

VII. The Rule is pre-textual, arbitrary, and capricious.

Any justification of the Rule is patent pretext for the true motive for it—the Biden Administration’s public health initiative to force people to get vaccinated against COVID-19. And even if the purported justifications were not pretext, they are based on flawed reasoning, invalid assumptions, and insufficient data. For these reasons, the Rule is arbitrary and capricious and is likely to be set aside.

When announcing his plans for five vaccine mandates on September 9, 2021, President Biden made clear that he intended to increase vaccination rates to address a public health concern.¹⁰ After stating “his patience was wearing thin” with the unvaccinated, he stated that his administration would require “all the nearly 300,000 educators in the federal paid program, Head Start,” to get vaccinated.¹¹ Even the Rule cited to the President’s speech and his overall federal public health plan as its impetus. 86 Fed. Reg. at 68,069. Having been ordered by the President to create a vaccine rule for Head Start staff, the Secretary had no other choice but to pre-textually couch the Rule in terms of promoting some purpose of the Act even though he had no statutory authority to mandate its issuance in the first place. It is therefore not surprising that the Rule’s analysis of its costs and benefits is faulty in numerous ways.

First, the Secretary completely ignores the negative impact of the Rule caused by the admitted reduction of staff and the concomitant reduction in the number of children receiving in-person services at Head Start programs. The Rule estimates that Head Start programs will have to fire at least 11,519 staff. The National Head Start Association survey of Head Start programs also found that over one-fourth of Head Start programs anticipate losing more than 30% of their staff and expect closing of as many as 1,300 Head Start classrooms. The Rule does not determine how many volunteers will refuse to comply, although a higher percentage is a reasonable assumption as they are unpaid volunteers to begin with.

To state the obvious, a Head Start program cannot operate without staff and volunteers. Ironically, the primary justification for the Rule is “to 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.” 86 Fed. Reg. at 68,053. Perhaps also ironically, the only way for

¹⁰ Joseph Biden, Remarks at the White House (Sep. 9, 2021), *available at* <https://perma.cc/GQG5-YBXX>. These included a vaccine mandate for federal employees, a vaccine mandate for private employers with greater than 100 employees, a vaccine mandate for federal contractors, a vaccine mandate for staff at Head Start programs, and a vaccine mandate for health care facilities receiving Medicaid and Medicare reimbursement.

¹¹ *Id.*

Head Start programs to sustain a loss of 30% of their staff is to have a corresponding drop in enrolled students, a result the Rule all but ensures. That's because the Rule allows Head Start programs to exclude qualified students if the parents of those children refuse to abide by the masking component of the Rule. In sum, the Rule will have the exact opposite effect of its purported justification, as personnel shortages and parents' unwillingness to comply with toddler mask mandates will drop the overall enrollment of children at Head Start programs and diminish the quality of services provided.¹²

This fundamental flaw also skews the Rule's cost benefit-analysis. Although the Rule acknowledges significant costs in hiring replacement staff, it fails to account that there are already staffing shortages that make hiring qualified Head Start educators nearly impossible.¹³ Without sufficient staff, there will be a reduction in program services. And a reduction in program services will have a drastic economic impact on parents whose children attend services provided by Head Start programs while the parents work. At the very least, the Rule should have balanced these costs against the purported economic benefits to working parents gained by minimizing temporary closures due to potential COVID outbreaks that the Secretary believes will be realized under the Rule.

Second, the Secretary failed to consider or arbitrarily rejected obvious alternatives to vaccine and toddler masking requirements. Emerging studies show that natural immunity affords benefits comparable to or better than vaccination.¹⁴ The Rule is even more arbitrary than the other COVID-19 mandates because it fails to consider or mention natural immunity as an alternative to vaccination or mask wearing. It also rejected a testing alternative to vaccination, even though

¹² *Day care says parents are removing kids due to state masking mandate*, ABC/WHAM (Sept. 16, 2021), <https://bit.ly/3y8ltMU>; Kailey Schuyler, *Parents pulling students out of school systems due to mask mandates*, WAFF/NBC (Aug. 15, 2021); Chad Frey, *Vaccine mandate affecting Newton Head Start staff*, The Kansan (Nov. 9, 2021), <https://bit.ly/3oB1dQL>; Adam Kurtz, *Mayville State University's Head Start program could be impacted by vaccine mandate*, Grand Forks Herald (Dec. 9, 2021), <https://bit.ly/3oFENOA> (“Van Horn said he was concerned about being able to maintain services for all of those children if the mandate remains in place.”)

¹³ *See* State Survey Data: Child Care at a Time of Progress and Peril, Sept. 2021, available at <https://perma.cc/27WC-XJ36>; *Child Care Industry Increasingly Fragile as Programs Face Staffing Challenges*, Foundations for Families, Dec. 7, 2021, available at <https://perma.cc/BKL2-7B8E>; SURVEY: Four in five childcare centers in the U.S. are understaffed, NAEYC, July 27, 2021, available at <https://perma.cc/XC8Q-BTX3>; Stephanie Ebbert, *Child-care providers are facing a staffing crisis, forcing some to close with little notice to parents*, Bost Globe, Aug. 17, 2021, available at <https://perma.cc/K32U-3NKJ>.

¹⁴ *See, e.g.*, Melissa Healy, *Study shows dramatic decline in effectiveness of all three COVID-19 vaccines over time*, L.A. Times (Nov. 4, 2021), <https://lat.ms/30hQIbj> (“As the Delta variant became the dominant strain of coronavirus across the United States, all three COVID-19 vaccines available to Americans lost some of their protective power, with vaccine efficacy among a large group of veterans dropping between 35% and 85%, according to a new study”); Sivan Gazit et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, Medrxiv (Aug. 25, 2021), <https://bit.ly/3DnKzIZ>; R. R. Goel et al., *mRNA vaccines include durable immunity to SARS-CoV-2 and variants of concern*, Science (Oct. 14, 2021), <https://bit.ly/3DXLS1K>; Gazit, Roei Shlezinger, et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, MEDRXIV (Aug. 30, 2021), <https://bit.ly/3GM82pb>.

OSHA determined weekly testing was sufficient for workplace safety.¹⁵ And the Secretary did not attempt to reconcile the Rule with studies showing the wilting effects of the vaccines over time, at least as it relates to preventing infection, or how the vaccines may not be as effective at preventing infection with the Omicron variant.¹⁶

Third, the Secretary has not determined the current voluntary vaccination rates among Head Start staff or volunteers with rational scientific methods. The Secretary admits to *not knowing* current vaccination rates among Head Start staff or volunteers. The Rule purports to rely on a survey of only 1,456 Head Start staff conducted between *May and June* of 2021 to determine the percentage of staff who are already vaccinated (73%).¹⁷ This study was of “a multi-state cross-sectional survey of the childcare workforce,” with a 37.8% response rate to an email link. According to the study, 13 states did not participate, and some respondents may not have even been currently employed as childcare workers. The study did not specify whether the respondents were fully or partially vaccinated, and concluded, “Overall vaccine uptake among U.S. child care providers []was significantly higher than that of the US general population (65%) at the time of the survey . . . Of those reporting having not yet received the COVID vaccine, another 11.9% stated that they were ‘absolutely certain’ (5.0%) or ‘very likely’ (6.9%) to get vaccinated in the future, suggesting that the final vaccine uptake among childcare providers may settle around 90%.” The Secretary chose to ignore this conclusion and assume that all the Head Start respondents in the study were only partially, and not fully, vaccinated. 86 Fed. Reg. 68,069. If one extrapolates the data from this survey showing that Head Start staff were 12% more likely to get vaccinated, then approximately 80.2% of Head Start staff were fully vaccinated when the Rule was published. But the Secretary claims that vaccination is lower than that (74.6%). *Id.* To the extent the study provides any useful information at all, the Secretary appear to have ignored data that should have caused concern. For example, the vaccine uptake data “limited by small sample sizes,” showed dramatically different ranges by geography and demography. Vaccine uptake was lower in the South and Mountain West compared to Eastern States, and vaccination uptake rates “was lower among black or African American providers.” Annual income was associated with higher vaccine uptake as well, with those earning less than \$75,000 lower rates. Ultimately, the Rule lacks any analysis as to why either the actual or extrapolated vaccination percentage insufficiently maintains

¹⁵ To be clear, the undersigned believe that OSHA overstepped its authority in requiring weekly testing or vaccination of workers and have filed legal challenges to the emergency temporary standard that purports to institute such measures. *See In re: Occupational Safety and Health Administration rule on COVID-19 Vaccination and Testing*, 86 Fed. Reg. 61402, Case No. 21-7000 (lead), MCP No. 165 (Consolidated), (Sixth Circ.)

¹⁶ *See* Barbara A. Cohn, *SARS-Cov-2 vaccine protection and deaths among US veterans during 2021*, Science (2021) <https://bit.ly/307PLCP> (reporting that within six months, efficacy of vaccines against infection plummeted to 13% (Johnson & Johnson), 43% (Pfizer), and 58% (Moderna)); Michaelen Doucleff, *Studies suggest sharp drop in vaccine protection vs. omicron – yet cause for optimism*, NPR (Dec. 8, 2021), available at <https://perma.cc/4DS4-72NT>; Stephanie Nolan, *Most of the World’s Vaccines Likely Won’t Prevent Infection From Omicron*, N.Y. Times (Dec. 19, 2021), available at <https://perma.cc/26N5-HMXD>

¹⁷ *See* 86 Fed. Reg. at 68,078, citing to Kavin Patel, M.D., et. al., *COVID-19 Vaccine Uptake Among U.S. Child Care Providers*, Pediatrics, Nov. 1, 2021, available at <https://perma.cc/MF3G-RD9Y>.

safety at Head Start centers. And without employing an accurate method to determine Head Start staff vaccination rates from the get-go, the Secretary's conclusions about the Rule's impact on staff vaccination rates are arbitrary.

Fourth, the Rule fails to support with sufficient evidence its requirement that toddlers wear masks. The Secretary did not consider that the World Health Organization and the United Nations Children's Fund specifically advise that "Children aged 5 years and under should not be required to wear masks. This is based on the safety and overall interest of the child and the capacity to appropriately use a mask with minimal assistance."¹⁸ Not only that, but there is an additional study showing that COVID transmission rates are higher among masked children over six than unmasked children three to five years old.¹⁹ The Secretary also failed to consider that universal masking ignores the best interest of speech- or language-impaired children, autistic children, and deaf children in experiencing a complete preschool education.²⁰ While some of these children may obtain exemptions from the toddler mask mandate for themselves, the Rule does not examine who masking all their teachers and peers will also impede their development. The Rule is also arbitrary in requiring masks outdoors when children are playing or engaged in group activities. Outdoor transmission is exceedingly rare, and many experts believe that outdoor masking is misguided.²¹ Policing a toddler mask mandate during outdoor playtime would be virtually impossible, but would nevertheless expose these children to discipline for non-compliance. The Secretary failed to even consider this evidence and instead relied on CDC's non-binding recommendations, *one* study on mask effectiveness that was not specific to the ages of Head Start children,²² and another study that studied Head Start centers with differing masking policies and a plethora of other mitigation strategies such as increased cleaning and health screenings.²³ Given this dearth of evidentiary support and conflicting evidence, the Secretary's masking requirement is arbitrary and capricious.

¹⁸ *Coronavirus disease (COVID-19): Children and masks*, World Health Org. (Aug. 21, 2020), <https://bit.ly/3Gxzg2n>

¹⁹ Alonso, Sergio, PhD, et. al., *Age-dependency of the Propagation Rate of Corona Virus Disease 2019 Inside School Bubble Groups in Catalonia, Spain*, *The Pediatric Infectious Disease Journal*, Nov. 2021, available at https://journals.lww.com/pidj/fulltext/2021/11000/age_dependency_of_the_propagation_rate_of.2.aspx.

²⁰ See, e.g., Deepa Shivaram, *New normal of masks is an 'added barrier' for deaf and hard-of-hearing community*, NBC News (May 23, 2020), <https://nbcnews.to/3pHBply>.

²¹ Tim O'Donnell, *Is the CDC exaggerating the risk of outdoor COVID-19 transmission?*, Yahoo News, May 11, 2021 available at <https://perma.cc/57DU-MUHE>; Vinay Prasad, M.D., M.P.H., *The Downsides of Masking Young Students are Real*, *The Atlantic*, Sept. 2, 2021, available at <https://perma.cc/MT25-LYXG>.

²² Budzyn SE, Panaggio MJ, et al., *Pediatric COVID-19 Cases in Counties with and Without School Masking Requirements – United States, July 1- September 4, 2021*, *MMWR Morb. Mortal. Wkly Rep.*, Oct. 1, 2021, available at <https://perma.cc/4GQZ-RZPS> (studying cases in children and adolescents aged 18 or less).

²³ Coronado F., Blough S., Bergeron D., et. al, *Implementing Mitigation Strategies in Early Care and Education Settings for Prevention of SARS-CoV-2 Transmission – Eight States, September-October 2020*, *MMWR Morb. Mortal. Wkly. Rep.*, Dec. 11, 2020, available at <https://perma.cc/ZYE2-JRC6>.

Fifth, the Rule's economic analysis fails to account for increased vaccination rates among older Head Start staff. COVID-19 does not pose the same risk to everyone. Approximately 80% of COVID-related deaths have occurred in people over the age of 65.²⁴ Moreover, certain other risk factors such as pre-existing medical conditions and obesity lead to higher mortality rates.²⁵ People seem to understand these risks as indicated by data showing that older people have much higher vaccination rates than the overall public.²⁶ The Rule acknowledges that older Head Start workers are at a higher risk of death, but arbitrarily does not account for the data showing that those older workers are also most likely vaccinated. Instead, the Rule uses an assumed vaccination rate applicable to all age groups when calculating the economic benefit of saved lives due to the Rule. This erroneous and arbitrary assumption predictably results in an overstated economic benefit of the Rule's vaccine mandate.

Sixth, the Rule fails to account for its impact on Head Start programs operating at public school facilities where vaccination and masking are not required. These school districts employ support staff, including cafeteria workers, bus drivers, and janitorial staff who encounter Head Start children and, in some instances, offer services to them in partnership with the Head Start program. These employees are not currently subject to vaccination requirements, and some will not voluntarily agree to get a vaccine. Head Start children at these schools will also come into contact with children who are not part of the program, some of whom will not be wearing masks. Grantees surveyed in Kentucky stated that around 50% of the school district partners will refuse to comply with the Head Start Mandate, and approximately 34% may withdraw from current contracts, agreements or MOUs with Head Start programs. Consequently, a significant number of Head Start programs at these school district locations cannot continue to offer Head Start services if forced to comply with the Rule. The Rule does not even consider these issues and is therefore arbitrary and capricious.²⁷

Seventh, the Secretary did not consider how the Rule may affect States that must backfill the loss of services caused by the Rule. Kentucky, like many other States, commits state funding to pre-school programs. Each year, school districts and Head Start programs enter into full utilization agreements to coordinate services to eligible children to avoid duplication of preschool services with the goal of serving as many children as possible. The Rule threatens to upset this

²⁴ *Percentage of Percentage of COVID-19 infections, symptomatic illness, and hospitalizations, and deaths, by age group—United States, February 2020-September 2021*, <https://perma.cc/Y5EM-2YR6>; Civilian labor force participation rate by age, sex, race and ethnicity, U.S. Bureau of Labor Statistics, *available* at <https://perma.cc/6BAE-USXX> (noting that participation rate in 2020 for people age 65-74 was only 26.6% and 7.4% for people 75 or older).

²⁵ *See People with Certain Medical Conditions*, <https://perma.cc/6FWM-J7TG>.

²⁶ *See CDC Vaccination Trends by Age and Sex*, *available* at <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends> (last visited Dec. 21, 2021).

²⁷ Some school systems may be subject to federal oversight through continuing supervision of older desegregation cases. The closure of Head Start programs could also upset the balance of teacher and student racial balance achieved through various means designed to increase minority enrollment in a school.

balance and place more burden on Kentucky to fund preschool programs with state funds. The Rule does not even consider this issue.

Last, the Rule fails to consider that breakthrough infections are probably more likely among vaccinated people now that the Omicron variant is the most predominant strain of COVID-19.²⁸ The Rule's economic analysis related to breakthrough infection was premised on Delta being the most predominate strain. Thus, a major assumption underlying the Rule's economic benefit analysis no longer applies. Although there is hope that existing vaccines are effective at preventing severe disease from an Omicron infection, such breakthrough infections will still require quarantine or convalescent leave and cause more frequent disruptions of in-person services even with an increase in vaccination among staff and volunteers.

* * *

We appreciate the opportunity to provide input on the Head Start Rule. But to be clear, the undersigned believe that Secretary Beccerra has overstepped his authority by issuing a Rule that coerces employees to undergo vaccination and requires two- to five-year-old children to wear masks through an unprecedented use of the Head Start Act's rule making authority. The Head Start Rule should be vacated, and we hope that the Biden Administration reconsiders its position and abandons its future efforts to force vaccination on the American public.

Respectfully submitted,



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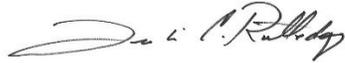
²⁸ Michaeleen Doucleff, *Studies suggest sharp drop in vaccine protection vs. omicron – yet cause for optimism*, NPR (Dec. 8, 2021), available at <https://perma.cc/4S4-72NT>; Stephanie Nolan, *Most of the World's Vaccines Likely Won't Prevent Infection From Omicron*, N.Y. Times (Dec. 19, 2021), available at <https://perma.cc/26N5-HMXD>.



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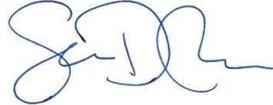
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