IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

R.K., et al., *Plaintiffs*, v. GOVERNOR BILL LEE, in his official capacity as GOVERNOR OF TENNESSEE, *et al.*, *Defendants*.	Case No. 3:21-cv-00725

BRIEF OF *AMICI CURIAE* TENNESSEE CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS AND AMERICAN ACADEMY OF PEDIATRICS IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

INTEREST OF *AMICI CURIAE*[1]

The Tennessee Chapter of the American Academy of Pediatrics ("TNAAP") is a non-profit educational organization and professional society comprising more than 1,000 members including pediatricians, residents, and medical students from Tennessee's hospitals, community clinics, and school-based health centers. TNAAP promotes the optimal health and development of children and adolescents of Tennessee, in partnership with their families and communities, and supports the pediatricians who care for them.

The American Academy of Pediatrics ("AAP") was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. The AAP's membership includes over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past year and a half, the AAP has devoted substantial resources to researching the scientific literature regarding how to treat COVID-19 and reduce its spread so that the AAP can provide up-to-date, evidence-based guidance for pediatricians and public health officials. This includes, among other things, interim guidance on the use of face masks as an infection control measure and on operating safe schools during the COVID-19 pandemic.

INTRODUCTION

The public interest is a paramount consideration in adjudicating Plaintiffs' motion for a preliminary injunction. As the U.S. Supreme Court has explained, "courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Here, there is no

[1] *Amici* certify that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money intended to fund this brief, and no person other than *Amici*, their members, and their counsel contributed money intended to fund this brief.

question about where the public interest points: the balance of the equities and the public interest weigh in favor of an injunction. The challenged Executive Order blocks universal mask policies that substantially reduce the risk of death and serious illness among Florida's school-age population and their families, and in particular among children with disabilities such as Plaintiffs. It puts Plaintiffs and all other parents to an untenable choice: either send children to schools where they have a high risk of contracting COVID-19, or keep them home from school with the attendant harm to their social, emotional, and educational development.

Over the past 18 months, *Amici* have worked ceaselessly to evaluate the dangers of and potential public health measures for reducing the deadly spread of COVID-19. COVID-19 poses grave risks to children, risks that are escalating rapidly with the rise of the Delta variant. The AAP has conducted a comprehensive review of the medical literature to determine what public health measures can effectively reduce the risk that COVID-19 poses to America's children. This comprehensive review and the experiences of the front-line pediatric practitioners who make up the TNAAP and AAP's membership prove two relevant facts beyond any doubt: universal mask policies in schools significantly reduce the spread of COVID-19 and protect all children, particularly the medically vulnerable; and remote or virtual learning negatively impacts children compared to in-person learning, particularly for children with disabilities. Despite the efforts of Defendants' declarant to muddy the waters, neither of these conclusions is the subject of any serious debate. This brief provides an overview of the literature the AAP has reviewed, explains why universal mask policies are so crucial in fighting COVID-19, and details the harms that children suffer from being unnecessarily forced into remote or virtual schooling.

ARGUMENT

I. Overview of the AAP's Research into, and the Evidence-Based Expert Consensus on, School Safety During the Pandemic

One of the AAP's chief functions is to provide evidence-based guidance to America's pediatric professionals and public health officials, thereby helping its members and policymakers improve the health of all children. To do so, the AAP issues Policy Statements that report the most up-to-date, evidence-based expert consensus on key issues of pediatric practice and public health. These Policy Statements are written by recognized pediatrician experts who undertake a comprehensive review of the medical literature and available data on the topic at hand. They are then peer-reviewed by additional experts across the AAP and approved by the AAP's executive staff and board of directors.

Since the spring of 2020, as the COVID-19 pandemic began to sweep across the country, the AAP's top focus has been supporting practicing pediatricians and public health policymakers in treating COVID-19 and reducing its spread, particularly among children. The AAP has issued Interim Guidance Statements on several topics related to COVID-19, including guidance on when and how pediatricians should test patients for COVID-19;[2] on providing clinical care to patients with COVID-19;[3] on treating post-COVID conditions;[4] on how to safely provide routine medical care such as check-ups, screenings, laboratory exams, treatment, and immunizations

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[2] *COVID-19 Testing Guidance*, AAP (last updated July 8, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-testing-guidance/.

[3] *COVID-19 Interim Guidance*, AAP (last updated Aug. 2, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/.

[4] *Post-COVID-19 Conditions in Children and Adolescents*, AAP (last updated July 28, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/post-covid-19-conditions-in-children-and-adolescents/.

during the COVID-19 pandemic;[5] on caring for youth with special health needs during the COVID-19 pandemic;[6] on supporting the emotional and behavioral health needs of children, adolescents, and families during the COVID-19 pandemic;[7] and—most relevant to this case—on the use of face masks as an infection control measure[8] and on operating safe schools during the COVID-19 pandemic that foster the overall health of children, adolescents, educators, staff, and communities.[9] The AAP has repeatedly reviewed and updated these Interim Guidance Statements to ensure that they reflect the best medical understanding and current scientific evidence of COVID-19, including its transmission and health effects.

II. The Importance of Universal Mask Policies in Schools as an Infection Control Measure

Beginning early in the pandemic, members of the AAP began receiving questions from families and school boards about how in-person education could be conducted safely during the

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[5] *Guidance on Providing Pediatric Well-Care During COVID-19*, AAP (last updated Aug. 30, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/guidance-on-providing-pediatric-well-care-during-covid-19/.

[6] *Caring for Children and Youth with Special Health Needs During the COVID-19 Pandemic*, AAP (last updated June 28, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/caring-for-children-and-youth-with-special-health-care-needs-during-the-covid-19-pandemic/.

[7] *Interim Guidance on Supporting the Emotional and Behavioral Health Needs of Children, Adolescents, and Families During the COVID-19 Pandemic*, AAP (last updated July 28, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-on-supporting-the-emotional-and-behavioral-health-needs-of-children-adolescents-and-families-during-the-covid-19-pandemic/.

[8] *Face Masks*, AAP (last updated Aug. 8, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/cloth-face-coverings/.

[9] *COVID-19 Guidance for Safe Schools*, AAP (last updated July 18, 2021), https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-planning-considerations-return-to-in-person-education-in-schools/.

pandemic. Because of the importance of in-person learning, the AAP researched and drafted its Interim Guidances on Face Masks[10] and Safe Schools[11] to facilitate in-person education and protect children during the pandemic. The initial AAP Interim Guidances, developed in the spring of 2020, were drafted and reviewed by a number of pediatricians with expertise in a wide variety of disciplines. The drafters reviewed dozens of articles and available data to determine whether and how children could safely attend school during the pandemic. These statements were first issued in the spring of 2020 and have been continually reviewed and updated since that time. By this point, the AAP's experts have reviewed hundreds of articles related to the efficacy and safety of masks, as well as their effects (or lack thereof) on the cognitive, social, and psychological development of children. The following discussion is based principally on the current (summer 2021) iterations of these interim guidance documents.

Based on this review of the medical literature, the AAP has determined that "at this point in the pandemic, given what we know now about low rates of in-school transmission *when proper prevention measures are used*, together with the availability of effective vaccines for those age 12 years and up, that the benefits of in-person school outweigh the risks in almost all circumstances." *COVID-19 Guidance for Safe Schools*, *supra* n. 9 (emphasis added). Among the recommended prevention measures (such as immunization of all eligible individuals and adequate and timely COVID-19 testing), one of the most important is that "**[a]ll students older than 2 years and all school staff should wear face masks at school (unless medical or developmental conditions prohibit use)**." *Id.* (emphasis in original).

[10] *Face Masks*, *supra* n. 8.

[11] *COVID-19 Guidance for Safe Schools*, *supra* n. 9.

Although AAP has modified other recommendations when indicated by new research or the changing nature of the pandemic, the AAP's strong recommendation of universal masking for students, teachers, and support staff in school has remained consistent from the beginning—because masks are a safe, effective, and critical infection control measure. This conclusion has been consistently reinforced by all relevant data and credible research regarding the transmission and health risks of COVID-19 and the effect of wearing masks on children's education, health, and development.

After significant analysis, including analysis of the emerging Delta variant, the AAP reaffirmed its recommendation of universal masking in school settings on July 19, 2021. Eight days later, on July 27, 2021, the Centers for Disease Control ("CDC") followed suit, recommending "universal indoor masking for all teachers, staff, students, and visitors to schools, regardless of vaccination status."[12]

There are several reasons for AAP's (and the CDC's) recommendation of universal masking in school. These include:

a. a significant portion of the student population is not eligible for vaccination;

b. the need to protect unvaccinated students from COVID-19 and to reduce transmission;

c. the lack of systems to monitor vaccine status among students, teachers and staff;

d. the potential difficulty in monitoring or enforcing mask policies for those who are not vaccinated;

e. in the absence of schools being able to conduct this monitoring, universal masking is the best and most effective strategy to create consistent messages,

[12] *Interim Public Health Recommendations for Fully Vaccinated People—Summary of Recent Changes*, CDC (July 28, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

expectations, enforcement, and compliance without the added burden of needing to monitor vaccination status;

f. the possibility of low vaccination uptake within the surrounding school community; and

g. the continued concerns for variants that are more easily spread among children, adolescents, and adults.

COVID-19 Guidance for Safe Schools, *supra* n. 9.

Most importantly, the research literature has confirmed that masks are both effective and safe. As the CDC has explained, masks "reduce the emission of virus-laden droplets . . . , which is especially relevant for asymptomatic or presymptomatic infected wearers who feel well and may be unaware of their infectiousness to others, and who are estimated to account for more than 50% of transmissions." [13] Cloth masks "not only effectively block most large droplets (i.e., 20-30 microns and larger) but they can also block the exhalation of fine droplets."[14] As a result, "[m]ulti-layer cloth masks can both block up to 50-70% of these fine droplets and particles," with "[u]pwards of 80% blockage" recorded in some studies.[15] To a slightly lesser extent, masks also "help reduce inhalation of these droplets by the wearer"; multi-layer cloth masks can filter out "nearly 50% of fine particles less than 1 micron."[16]

[13] *Science Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2*, CDC (May 7, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html (citations omitted).

[14] *Id.*

[15] *Id.*

[16] *Id.*

Numerous studies have shown that increasing the rate of mask-wearing, including through universal mask policies in particular, significantly reduces the spread of COVID-19.[17] In particular, studies have shown that masking and similar mitigation measures can limit transmission in schools.[18] Just this past Friday, the CDC released three new studies conducted

[17] *See, e.g.*, Jeremy Howard, et al., *An Evidence Review of Face Masks Against COVID-19*, 118 Proc. of the Nat'l Acad. of Servs. e2014564118 (2021), https://www.pnas.org/content/118/4/e2014564118; John T. Brooks & Jay C. Butler, *Effectiveness of Mask Wearing to Control Community Spread of SARS-CoV-2*, 325 J. of Am. Med. Ass'n 998 (2021), https://jamanetwork.com/journals/jama/fullarticle/2776536; Heesoo Joo, et al., *Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates—10 States, March–October 2020*. 70 Morbidity & Mortality Weekly Rep. 212 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7006e2.htm; Derek K. Chu, et al., *Physical Distancing, Face Masks, and Eye Protection to Prevent Person-to-Person Transmission of SARS-CoV-2 and COVID-19: A Systematic Review and Meta-Analysis*, 395 Lancet 1973 (2020), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31142-9/fulltext; Christopher T. Leffler, et al., *Association of Country-wide Coronavirus Mortality with Demographics, Testing, Lockdowns, and Public Wearing of Masks*, 103 Am. J. Tropical Med. Hygiene 2400 (2020), https://pubmed.ncbi.nlm.nih.gov/33124541/; Miriam E. Van Dyke, et al., *Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate—Kansas, June 1-August 23, 2020*. 69 Morbidity & Mortality Weekly Rep. 1777 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e2.htm; Wei Lyu & George L. Wehby, *Community Use of Face Masks and COVID-19: Evidence from a Natural Experiment of State Mandates in the US*, 39 Health Aff. 1419 (2020), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00818.

[18] *See, e.g.*, Patrick Dawson, et al., *Pilot Investigation of SARS-CoV-2 Secondary Transmission in Kindergarten Through Grade 12 Schools Implementing Mitigation Strategies—St. Louis County and City of Springield, Missouri, December 2020*, 70 Morbidity & Mortality Weekly Rep. 449 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7012e4.htm?s_cid=mm7012e4_w; Darria L. Gillespie, et al., *The Experience of 2 Independent Schools With In-Person Learning During the COVID-19 Pandemic*, 91 J. Sch. Health 347 (2021), https://onlinelibrary.wiley.com/doi/10.1111/josh.13008; Rebecca B. Hershow, et al., *Low SARS-CoV-2 Transmission in Elementary Schools - Salt Lake County, Utah, December 3, 2020-January 31, 2021*, 70 Morbidity & Mortality Weekly Rep. 442 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7012e3.htm; Amy Falk, et al., *COVID-19 Cases and Transmission in 17 K-12 Schools - Wood County, Wisconsin, August 31-November 29, 2020*, 70 Morbidity & Mortality Weekly Rep. 136 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e3.htm; Fiona Russell et al., *COVID-19 in Victorian Schools: An Analysis of Child-Care and School Outbreak Data and Evidence-Based Recommendations for Opening Schools and Keeping Them Open*, Murdoch Children's Rsch.

during this school year, all of which found that "school districts without a universal masking policy in place were more likely to have COVID-19 outbreaks."[19] Notably, studies suggest that there is no substitute for universal masking requirements: while studies have found *universal masking requirements* effective at reducing transmission, as discussed above, mask *recommendations* have proven far less effective (if effective at all).[20] As the ABC Science Collaborative, a 13-state initiative coordinated by the Duke Clinical Research Institute at the Duke University School of Medicine, summed it up, "[p]roper masking is the most effective mitigation strategy to prevent COVID-19 transmission in schools when vaccination is unavailable or there are insufficient levels of vaccination among students and staff."[21]

Inst. & The Univ. of Melb. (Nov. 9, 2020), *available at* https://www.mcri.edu.au/sites/default/files/media/documents/covid-19_in_victorian_schools_report.pdf.

[19] *Studies Show More COVID-19 Cases in Areas Without School Masking Policies*, CDC (Sept. 24, 2021), https://www.cdc.gov/media/releases/2021/p0924-school-masking.html; *see* Megan Jehn, et al., *Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks—Maricopa and Pima Counties, Arizona, July–August 2021*, 70 Morbidity & Mortality Weekly Rep. (Early Release) (Sept. 24, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039e1-H.pdf; Samantha E. Budzyn, et al., *Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1–September 4, 2021*, 70 Morbidity & Mortality Weekly Rep. (Early Release) (Sept. 24, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039e3-H.pdf; Sharyn E. Parks, et al., *COVID-19–Related School Closures and Learning Modality Changes—United States, August 1–September 17, 2021*, 70 Morbidity & Mortality Weekly Rep. (Early Release) (Sept. 24, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039e2-H.pdf.

[20] *See* Henning Bundgaard, et al., *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers*, Annals of Internal Med. (2020), https://www.acpjournals.org/doi/pdf/10.7326/M20-6817.

[21] ABC Science Collaborative, *The ABCs of North Carolina's Plan*, https://abcsciencecollaborative.org/the-abcs-of-north-carolinas-plan-a/ (last visited Sept. 1, 2021); *see also* ABC Science Collaborative, *Final Report for NC School Districts and Charters in Plan A*, at 3 (June 30, 2021) , *available at* https://abcsciencecollaborative.org/wp-content/uploads/2021/06/ABCs-Final-Report-June-2021.06-esig-DB-KZ-6-29-21.pdf.

In the face of this overwhelming evidence, the State suggests that "there is little evidence to support the efficacy of masks, and the best evidence suggests no correlation between mandating that children wear masks and disease outcomes." Gov.'s Opp'n to Pls.' Mot. for Prelim. Inj. at 13, ECF No. 39 ("Opp'n"). This assertion is based on a declaration from Dr. Jay Bhattacharya, who has advocated since the beginning of the pandemic for *accelerating* the transmission of COVID-19 among people without known vulnerabilities, by removing all restrictions and "resum[ing] life as normal."[22] This is because he believes that people "who are at minimal risk of death [should] live their lives normally to build up immunity to the virus through natural infection,"[23] a view that is grossly inconsistent with the consensus of the medical and public health community.

Given Dr. Bhattacharya's precommitment to eliminating measures that would reduce the spread of COVID-19 among populations at relatively lower risk of death from the illness, it is unsurprising that he disputes the efficacy of masking as an infection control measure. His attempt to do so, however, is deeply flawed. First, he cites outdated studies from early in the pandemic for the proposition that children pose a "negligible" or "small" risk for transmitting COVID-19. Decl. of Jay Bhattcharya in Supp. of Opp'n to Pls.' Mot. for Prelim. Inj. ¶¶ 44-56, ECF No. 42 ("Bhattacharya Decl."). Those studies all took place prior to the rise of the Delta variant, which is more than twice as contagious as previous variants, and at a time when children were frequently not tested due to testing shortages and the perception that asymptomatic or

[22] Jay Bhattacharya, et al., *Great Barrington Declaration* (Oct. 4, 2020), https://gbdeclaration.org/.

[23] *Id.*

minimally symptomatic individuals were at low risk for transmission or serious consequences.[24] Dr. Bhattacharya provides no reason to believe that the findings he cites remain accurate given the far higher viral load of the Delta variant.

Second, his criticism of the paucity of randomized controlled trials regarding the efficacy of masks against COVID-19, and particularly in schools, is misleading and omits key information. *See id.* ¶¶ 57-59. While randomized controlled trials can provide useful evidence on the efficacy of a treatment or preventive measure, they are by no means the only kind of meaningful scientific evidence.[25] Tellingly, Dr. Bhattacharya does not cite *any* scientific or medical authority suggesting that the absence of randomized controlled trials undermines the value of evidence such as that cited above—nor does he acknowledge the serious ethical issues with subjecting children to a randomized trial involving the withholding of a vital preventive measure in the middle of a pandemic.

Where Dr. Bhattacharya does cite randomized trials, he misrepresents them. *See* ¶¶ 58-59. The only published study he cites dealt not with mask *requirements* but mask *recommendations*.[26] A finding that simply encouraging people to wear a mask, without more, does not significantly reduce transmission *supports* the need for a non-optional requirement, rather than undercuts it. He also cites a forthcoming study (also dealing with recommendations,

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[24] *See Delta Variant: What We Know About the Science*, CDC (Aug. 26, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.

[25] *See generally* Seán M. Muller, *Masks, Mechanisms and Covid-19: The Limitations of Randomized Trials in Pandemic Policymaking*, 43 Hist. & Phil. Life Sci. 43 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7992121/ (arguing that it is "misguided both as an epistemological matter and from a policy perspective" not to endorse mask usage due to the lack of randomized trials, given the strong mechanistic evidence for their efficacy).

[26] *See Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers*, *supra* n. 20.

not requirements) while omitting that the study found that increasing mask wearing by 30% among adults led to a 9% or higher reduction in COVID-19, and that the authors concluded that "[i]f everyone wore masks, the reductions in Covid-19 cases would most likely have been substantially larger."[27] Similarly, Dr. Bhattacharya relies on three reviews that primarily analyzed studies of non-epidemic-level influenza exposures, *id.* ¶¶ 62-67, ignoring explicit warnings *against* "generalising the findings to the current COVID-19 pandemic."[28] At the same time, he summarily dismisses the one review that actually included studies regarding COVID-19. *See id.* ¶ 67.

His handling of observational evidence is just as unreliable. Rather than address the legion of peer-reviewed evidence noted above, *see supra* pp. 7-9, he highlights two non-peer-reviewed analyses that support his preexisting hypothesis. *Id.* ¶¶ 69, 71.[29] He rejects the CDC's

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[27] Jason Abaluck, et al., *We Did the Research: Masks Work, and You Should Choose a High Quality Mask If Possible*, N.Y. Times (Sept. 26, 2021), https://www.nytimes.com/2021/09/26/opinion/do-masks-work-for-covid-prevention.html; *see also* Jason Abaluck, et al., *The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh* (preprint) (Aug. 31, 2021), https://www.poverty-action.org/sites/default/files/publications/Mask_RCT____Symptomatic_Seropositivity_083121.pdf.

[28] Tom Jefferson, et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses*, 11 Cochrane Database of Systematic Revs. (2020), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub5/epdf/full.

[29] Damian D. Guerra & Daniel J. Guerra, *Mask Mandate and Use Efficacy for COVID-19 Containment in US States*, 5 Int'l Rsch. J. Pub. Health 55 (2021), https://escipub.com/Articles/IRJPH/IRJPH-2021-08-1005.pdf; Emily Oster, et al., *COVID-19 Mitigation Practices & COVID-19 Rates in Schools: Report on Data from Florida, New York, and Massachusetts*, medRxiv (preprint) (May 21, 2021), https://www.medrxiv.org/content/10.1101/2021.05.19.21257467v1.full-text. While Dr. Bhattacharya claims that the Guerra & Guerra article was peer-reviewed, *see* Bhattacharya Decl. ¶ 69, this is false; the journal specifically noted that it was "accepted for publication without peer-review," *see* Guerra & Guerra, *supra* (Notes from Editorial Office).

analyses[30]—which were based on dozens of studies if not more—because *one* of the studies the CDC cited lacked a control group. *Id.* ¶ 70. In short, his analysis appears designed to fit his conclusion, rather than the other way around, and is inconsistent with the recommendations of both the AAP and TNAAP and the CDC.

The State also suggests that enjoining the Executive Order would not redress Plaintiffs' injuries because the school districts here allowed medical and religious exceptions. Opp'n at 4. This misunderstands the purpose and function of a universal mask policy. It is entirely appropriate to make exceptions to mask requirements where "medical or developmental conditions prohibit use," as the AAP's Interim Guidance explains. *Face Masks*, *supra* n. 8. Because disabilities that truly prevent masking are rare, exceptions to accommodate an individual child's legitimate medical needs are unlikely to seriously impair a mask policy's power to inhibit transmission, particularly when accompanied by other measures to mitigate the risk.[31] Such isolated, targeted exceptions bear no resemblance to the blanket, justification-free exemptions allowed by the Executive Order.

III. Masks Do Not Harm Children

The State also asserts that "some studies show developmental harms to children from masking." Opp'n at 15. The AAP's comprehensive review of the medical research has shown that this is false: masking does not harm children. The State and its proffered expert suggest that

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[30] *See Science Brief Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs—Update*, CDC (July 9, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html#in-person; *Science Brief: Community Use of Cloth Masks*, *supra* n. 13.

[31] With respect to other school-related health requirements, Tennessee law requires certification from a qualified physician for medical exemptions. See Tenn. Code. Ann. § 49-6-5001. Schools could use a similar process for assessing appropriate exemptions from masking requirements.

masks can cause both developmental harms and physical harms. *Id.*; Bhattacharya Decl. ¶¶ 73-77. Neither assertion has any basis in scientific research.

Developmental harms: While concerns about the impact of masks on children's development are understandable, there is currently "no known evidence that use of face masks interferes with speech or language development . . . ."[32] Not being able to see part of a person's face is not a significant impediment to social and speech development—as the experience of children who are blind from birth confirms. "[V]isually impaired children develop speech and language skills at the same rate as their peers."[33] Indeed, being unable to see speakers' mouths for a portion of the day may help children use other clues to understand and learn language and non-verbal communication, such as gestures, changes in tone of voice, and the like.[34] Crucially, the AAP does not recommend (and Plaintiffs do not insist) that children wear masks 24 hours a day, or that their parents do so. In the home, children's experiences will presumably be largely or entirely maskless, providing ample opportunity for interacting with people without masks.

The main piece of evidence that the State and Dr. Bhattacharya proffer is an advisory document by the World Health Organization ("WHO")—but the State and its expert misrepresent that document. According to the State and its expert, the WHO "indicates that masking young children may harm developmental milestones." Opp'n at 15; *see also* Bhattacharya Decl. ¶ 74. What the WHO actually said was that it was not recommending that children five years old or younger should wear masks for source control because they may not

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[32] *Do Masks Delay Speech and Language Development?*, AAP (last updated Aug. 26, 2021), https://healthychildren.org/English/health-issues/conditions/COVID-19/Pages/Do-face-masks-interfere-with-language-development.aspx.

[33] *Id.*

[34] *Id.*

have "achieve[d] significant developmental milestones, including the manual dexterity and fine motor coordination movements needed to appropriately use a mask with minimal assistance."[35]

Beyond this misreading, Dr. Bhattacharya cites a survey of self-reported discomfort with masks. Bhattacharya Decl. ¶ 75. This survey merely asked pediatricians and parents whether certain types of discomfort were ever reported; it did not purport to attribute frequency, severity, or causation to masks.[36] Notably, this study had no control group—the exact flaw that Dr. Bhattacharya suggested discredits the CDC's entire findings on the efficacy of masks in schools. *See supra* pp. 12-13. It is telling that Dr. Bhattacharya views this fact as fatal when it applies to one of scores of studies cited in support of mask-wearing, but does not even acknowledge it when it applies to one of just two studies he can cite to suggest developmental harms from masks. He also cites a study that dealt with recognition of emotions in still photographs, rather than in interpersonal interactions where other cues (verbal, contextual, body language, etc.) that may aid in recognition. Bhattacharya Decl. ¶ 76.[37] Even the opinion piece he blockquotes notes that "emotions can also be decoded from the body posture, a process quite similar to the decoding from faces, as well as from prosody (the 'melody of speech') and gesture"—and,

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[35] *Advice on the Use of Masks for Children in the Community in the Context of COVID-19* at 3, WHO (Aug. 21, 2020), https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_Masks-Children-2020.1. The WHO also noted that decisions regarding masking of children between six and 11 should consider among other factors the "potential impact of mask wearing on learning and psychosocial development," *id.*, but it did not suggest that any such hypothetical impacts were supported by research or should outweigh other considerations.

[36] *See* Rémy Assathiany, et al., *Face Masks in Young Children During the COVID-19 Pandemic: Parents' and Pediatricians' Point of View*, 9 Frontiers in Pediatrics 676718 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8260829/#:~:text=Many%20pediatricians%20agreed%20with%20mandatory,become%20accustomed%20to%20wearing%20it.

[37] *See* Claus-Christian Carbon & Martin Serrano, *The Impact of Face Masks on the Emotional Reading Abilities of Children—A Lesson from a Joint School–University Project*, 12 Iperception (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383324/;

crucially, that "wearing face masks is one of the most effective preventive measures people can take to protect themselves and others from becoming infected with the virus."[38]

Perhaps most importantly, neither the State nor Dr. Bhattacharya provides *any* evidentiary support for their most serious claims: that "masking children causes psychological stress in children" or "exacerbates the chances that a child will experience anxiety and depression." *Id.* ¶¶ 75-76. Dr. Bhattacharya asserts this without citation. Based on the AAP's review of the literature, no supportive studies exist. Mask-wearing is not linked to emotional or psychological harm, particularly when caregivers promote positive associations around mask-wearing.[39] While children can develop secondary anxieties about wearing a mask, this is no different from the possibility of developing secondary anxieties about eating, attending school, or any other activity. The risk of developing secondary anxiety or disordered behavior related to masking may be especially high when parents or community members perpetuate false claims that masks are harmful. But there is nothing intrinsic about mask-wearing that makes it particularly harmful, whether physically, socially, or emotionally.

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[38] Manfred Spitzer, *Masked Education? The Benefits and Burdens of Wearing Face Masks in Schools During the Current Corona Pandemic*, 20 Trends in Neurosci. Educ. 100138 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7417296/ (citation omitted).

[39] *Interim Guidance on Supporting the Emotional and Behavioral Health Needs of Children, Adolescents, and Families During the COVID-19 Pandemic,* supra n. 7; *Face Masks*, *supra* n. 8 (providing recommendations for "help[ing] my child get used to wearing a mask"); *Supporting your child's mental health during COVID-19 school returns*, UNICEF (Aug. 28, 2020), https://www.unicef.org/coronavirus/supporting-yourchilds-mental-health-during-covid-19-school-return ("Approach this conversation with empathy, saying that you know she is feeling anxious about coronavirus, but that it's healthy to talk about our worries and emotions. Children may also get upset or frustrated if they are finding it hard to wear masks, especially when running or playing. You can reassure your children that lots of adults are working hard to help keep your family safe, but emphasize that it's important we all follow the recommended measures to take care of more vulnerable members of our community.").

Physical harms: Dr. Bhattacharya also suggests that masking may impair breathing sufficiently to cause hypoxia, a shortage of available oxygen in blood tissues. *Id.* ¶ 77. However, masking has no significant effect on respiratory function in the vast majority of cases. Cloth and surgical masks are gas-permeable, which means that carbon dioxide can flow out of the mask and oxygen flow in, without obstruction. Masks do not present a risk of hypercapnia (excess CO_2) or hypoxemia (inadequate oxygen saturation in the blood), even among people with lung disease, as proven by studies using pulse oximetry to test changes in end-tidal CO_2 and oxygen saturation.[40] Even among infants and young children, the use of facial masks is not associated with significant changes in respiratory function.[41]

Dr. Bhattacharya's claim is also belied by the decades-long history of mask usage in surgical settings, for immunocompromised individuals (including children) such as chemotherapy patients, and in countries where masks have long been used to prevent spread of illness. For example, surgeons and other medical professionals may wear surgical masks for 6 to 8 hours at a time while performing involved surgery. If masks posed a risk of hypercapnia, hypoxemia, or any other harm, it would have been discovered long ago due to surgeons and attendants fainting or hospitals in other countries receiving adult or pediatric patients who were

[40] *See*, *e.g.*, Rajesh Samannan, et al., *Effect of Face Masks on Gas Exchange in Healthy Persons and Patients with Chronic Obstructive Pulmonary Disease*, 18 Annals of Am. Thoracic Soc'y 539 (2021), https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.202007-812RL; Steven L. Shein, et al., *The effects of wearing facemasks on oxygenation and ventilation at rest and during physical activity*, PLoS One (Feb. 24, 2021), https://pubmed.ncbi.nlm.nih.gov/33626065/ ("The risk of pathologic gas exchange impairment with cloth masks and surgical masks is near-zero in the general adult population.").

[41] *See, e.g.*, Ricardo Lubrano, et al., *Assessment of Respiratory Function in Infants and Young Children Wearing Face Masks During the COVID-19 Pandemic*, J. Am. Med. Ass'n Network Open (Mar. 2, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776928.

harmed by mask wearing. The complete lack of such reports is strong evidence, if more were needed, that this concern is entirely unfounded.

IV. The Importance of In-Person Learning and the Harm of Remote Education

One of the reasons AAP and TNAAP have devoted such significant resources into determining how to make in-person schooling safe is that, as pediatrician organizations, we recognize and are seriously concerned about the impact on children of not being able to attend school in person. Extensive literature has shown that this can negatively affect children's cognitive, educational, and social development, as well as children's short- and long-term mood, behavior, and mental health.[42] Children with special needs suffer the additional loss of access to educational support structures, school-based therapies, school meals, and school-based professionals who are often the front-line identifiers of special needs.[43]

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[42] *See, e.g.*, Jorge V. Verlenden, et al., *Association of Children's Mode of School Instruction with Child and Parent Experiences and Well-Being During the COVID-19 Pandemic—COVID Experiences Survey, United States, October 8–November 13, 2020*, 70 Morbidity & Mortality Weekly Rep. 369 (2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7011a1.htm?s_cid=mm7011a1_w; Dimitri A. Christakis, et al., *Estimation of U.S. Children's Educational Attainment and Years of Life Lost Associated with Primary School Closures During the Coronavirus Disease 2019 Pandemic*, 3 J. Am. Med. Ass'n Network Open e2028786 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772834; Meira Levinson, et al., *Reopening Primary Schools During the Pandemic*, 383 New Eng. J. Med. 981 (2020), https://www.nejm.org/doi/full/10.1056/NEJMms2024920; Megan Kuhfeld, et al., *Projecting the Potential Impact of COVID-19 School Closures on Academic Achievement*, 49 Educ. Researcher 549 (2020), https://journals.sagepub.com/doi/full/10.3102/0013189X20965918; Emma Dorn, et al., *COVID-19 and Education: The Lingering Effects of Unfinished Learning*, McKinsey & Co. (July 27, 2021), https://www.mckinsey.com/industries/public-and-social-sector/our-insights/covid-19-and-education-the-lingering-effects-of-unfinished-learning.

[43] Ramkumar Aishworiya & Ying Qi Kang, *Including Children with Developmental Disabilities in the Equation During this COVID-19 Pandemic*, 51 J. Autism & Dev. Disorders 2155 (2021), https://link.springer.com/article/10.1007%2Fs10803-020-04670-6; Amy Houtrow, et al., *Children with disabilities in the United States and the COVID-19 pandemic*, 13 J. of Pediatric Rehabilitation Med., 415, 415-24 (2020), *available at* https://content.iospress.com/articles/journal-of-pediatric-rehabilitation-medicine/prm200769.

Based on the AAP's expert review of this scientific literature and the guidance outlined by the WHO, CDC, United Nations Children's Fund ("UNICEF"), along with AAP's members' collective expertise as pediatricians and researchers, the AAP has concluded that "[e]verything possible must be done to keep students in schools in-person." *COVID-19 Guidance for Safe Schools*, *supra* n. 9. This is because "[s]chools and school-supported programs are fundamental to child and adolescent development and well-being and provide our children and adolescents with academic instruction; social and emotional skills, safety, reliable nutrition, physical/occupational/speech therapy, mental health services, health services, and opportunities for physical activity, among other benefits." *Id.* By contrast, "[r]emote learning highlighted inequities in education, was detrimental to the educational attainment of students of all ages, and exacerbated the mental health crisis among children and adolescents." *Id.* This is especially true for students with disabilities: "[t]he impact of loss of instructional time and related services, including mental health services, as well as occupational, physical, and speech/language therapy during the period of school closures and remote learning is significant for students with disabilities." *Id.*

The State previously suggested that the availability of remote education as an alternative to in-person learning obviates the need to take reasonable steps to make in-person learning safe. *See* Gov.'s Resp. to Pls.' Mot. for TRO & Prelim. Inj., at 8-9, ECF No. 16 ("TRO & PI Opp."). To be sure, remote education may have been an imperfect, but necessary, solution in the early stages of the pandemic, when vaccines were unavailable even for adults and our ability to reduce the transmission of the COVID-19 virus were more limited. But that is a far cry from saying that remote learning is equal to in-person learning. The Americans with Disabilities Act and the Rehabilitation Act are intended to "enabl[e] each covered person (sometimes by means of

reasonable accommodations) to participate *equally* to all others in public facilities." *Fry v. Napoleon Comm'y Schs.*, 137 S. Ct. 743, 756 (2017) (emphasis added). Shunting persons with disabilities to an inferior form of services, when equal services would be available if reasonable accommodations were made, does not satisfy a state's obligations to people with disabilities.

To support its argument to the contrary, the State cited a U.S. Department of Education advisory from the earliest days of the pandemic explaining that schools should not be "reluctant to provide any distance instruction because they believe that federal disability law presents insurmountable barriers to remote education." TRO & PI Opp. at 8 (quoting *Addressing the Risk of COVID-19 in Preschool, Elementary, and Secondary Schools While Serving Children with Disabilities*, U.S. Dep't of Educ. (Mar. 21, 2020), https://bit.ly/3hx1iRJ. This misrepresents the current state of the Department of Education's guidance. The Department has come to the same conclusion as the AAP and TNAAP:

> [W]e must provide every student—from every community and background—the opportunity to safely learn in-person full-time. Abrupt shifts to remote learning over the past two school years have affected students, negatively impacting their social, emotional, and mental well-being and academic achievement. They have also exacerbated racial, socioeconomic, and other educational inequities.
>
> Data collected before and during the COVID-19 pandemic have shown that in-person learning, on the whole, leads to better academic outcomes, greater levels of student engagement, higher rates of attendance, and better social and emotional well-being, and ensures access to critical school services and extracurricular activities when compared to remote learning.[44]

Because of the superiority of in-person education over remote learning, *see supra* n. 42, the Department explicitly advises schools to employ "universal and correct indoor masking

[44] *Supporting Students During the COVID-19 Pandemic: Maximizing In-Person Learning and Implementing Effective Practices for Students in Quarantine and Isolation*, U.S. Dep't of Educ. (last visited Sept. 27, 2021), https://www.ed.gov/coronavirus/supporting-students-during-covid-19-pandemic.

regardless of vaccination status."[45] Thus, even the State's own authorities do not support its argument.

V. Enjoining the Executive Order Is in the Public Interest

Finally, the public interest weighs heavily in favor of an injunction. COVID-19 poses a profound and escalating threat to both children and adults. As Plaintiffs explain, Tennessee (and Williamson County specifically) have seen a rapid and dramatic spread of COVID-19 cases among both students and staff since the start of the school year. Plaintiffs' statistics are consistent with what the AAP and TNAAP are observing around the country and state. As of September 23, 2021, 5,725,680 total child COVID-19 cases have been reported in the United States to date, representing 16% of the total U.S. cases.[46] The prevalence of pediatric COVID-19 has skyrocketed since the school year began, with nearly 12% of all child cases since the beginning of the pandemic diagnosed between September 2 and September 23.[47] And the rate of serious cases has soared; just among the 24 states and 1 city that report child hospitalizations, 21,814 children have been hospitalized due to COVID-19, including nearly 2,000 in the three weeks from September 2 to September 23.[48] Since the beginning of August, more children have

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[45] *Id.*

[46] AAP, *Children and COVID-19: State-Level Data Report*, Summary of Findings (data available as of Sept. 23, 21), *available at* https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/.

[47] *Id*.

[48] *See Children and COVID-19: State Data Report* at Appx. Tab. 2B, Children's Hosp. Ass'n & Am. Acad. of Pediatrics (Sept. 23, 2021), https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%209.23%20FINAL.pdf.

died each week than in all but one previous week of the pandemic.[49] Tennessee has been especially hard hit: with at least 268,378 cumulative child cases diagnosed to date, Tennessee has the *highest rate* of cumulative cases per 100,000 children of any state in the nation (15,225.7 per 100,000 children).[50] More than 740 Tennessee children have been hospitalized from COVID-19, and 20 have died.[51]

Dr. Bhattacharya suggests that "COVID-19 is not a severe threat to schoolchildren, especially younger children—even if they contract the disease." Bhattacharya Decl. ¶ 30. Here again, his opinion is based on dubious statistics and an unconscionable discounting of the risk to children. Dr. Bhattacharya's view throughout the pandemic has been that all but the most vulnerable should "live their lives normally to build up immunity to the virus through natural infection."[52] Even accepting the infection fatality rate he claims in his declaration, this would mean the deaths of dozens of children in Tennessee—mostly those with preexisting conditions like Plaintiffs'. But that almost certainly understates the consequences of Dr. Bhattacharya's prescriptions. The seroprevalence studies he cites—and particularly the Santa Clara County study he authored—have been criticized and undermined by later analysis.[53] Tellingly, he omits

[49] *Id.* at Appx. Tab. 2C. The week ending December 3, 2020 is the only previous week in which as many child deaths were reported as even the *lowest* week since the beginning of August. *Id.* Notably, this was the week after Thanksgiving. This drives home the importance of promptly enjoining the Executive Order, to reduce the rate of COVID-19 in advance of the surge that will likely accompany the upcoming holidays.

[50] *Id.* at Tab. 3B.

[51] *Id.* at Tabs. 5B, 6B.

[52] *Great Barrington Declaration*. *supra* n. 22.

[53] *See, e.g.*, Andrew Gelman & Bob Carpenter, *Bayesian Analysis of Tests with Unknown Specificity and Sensitivity*, J. Royal Stat. Soc'y: Series C (Applied Stat.) (July 2, 2020), https://www.medrxiv.org/content/10.1101/2020.05.22.20108944v3 (explaining that the data in

to mention subsequent studies that found dramatically higher infection fatality rates.[54] Dr. Bhattacharya has severely understated the pandemic's mortality rate from the beginning, [55] and there is ample reason to doubt his predictions now.

Dr. Bhattacharya's opinion on the severity of COVID-19 symptoms is similarly flawed. *See* Bhattacharya Decl. ¶¶ 40-42. For example, in dismissing the risk of persistent symptoms (often called "long COVID"), he first relies on a study that actually found that 4.4% of children had symptoms for at least four weeks, with 1.8% lasting at least eight weeks.[56] He then cites another study's finding that reporting of *any* symptoms was relatively similar between people

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the Santa Clara study "do not provide strong evidence about the number of people infected or the infection fatality ratio" because of limitations in the specificity of the serological test). For summaries of the studies' shortcomings in laymen's terms, see, e.g., Catherine Offord, *How (Not) to Do an Antibody Survey for SARS-CoV-2*, The Scientist (Apr. 28, 2020), https://www.the-scientist.com/news-opinion/how-not-to-do-an-antibody-survey-for-sars-cov-2-67488; Lisa M. Krieger, *Stanford Coronavirus Research: Did Politically-Motivated Scientists Hype Their Speedy Study?*, San Jose Mercury News (May 24, 2020), https://www.mercurynews.com/2020/05/24/coronavirus-research-stanford-scientists-accused-of-hyping-covid-19-antibody-study/; Andrew Gelman, *Concerns with the Stanford Study of Coronavirus Prevalence*, Stat. Modeling, Causal Inference & Social Science (Apr. 19, 2020), https://statmodeling.stat.columbia.edu/2020/04/19/fatal-flaws-in-stanford-study-of-coronavirus-prevalence/.

[54] *See, e.g.*, Gideon Meyerowitz-Katz, Lea Merone, *A Systematic Review and Meta-Analysis of Published Research Data on COVID-19 Infection Fatality Rates*, 101 Int'l J. Infectious Diseases 138 (2020), https://www.ijidonline.com/article/S1201-9712(20)32180-9/fulltext.

[55] Eran Bendavid & Jay Bhattacharya, *Is the Coronavirus as Deadly as They Say?*, Wall St. J. (Mar. 24, 2020), https://www.wsj.com/articles/is-the-coronavirus-as-deadly-as-they-say-11585088464 (explaining, based on his view of seroprevalence, his "surmise of . . . a mortality rate of 0.1%," translating to "a 20,000- or 40,000-death epidemic").

[56] Erika Molteni, et al., *Illness Duration and Symptom Profile in Symptomatic UK School-Aged Children Tested for SARS-CoV-2*, Lancet (Aug. 3, 2021), https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00198-X/fulltext.

infected with COVID-19 and a control group—but omits to mention that the study found dramatically higher rates of *continuous* symptoms.[57]

Given the devastating threat posed by the pandemic and the overwhelming scientific consensus that universal mask policies are a safe and effective way to reduce its spread, the balance of hardships and public interest factors weigh heavily in favor of an injunction. On one side of the scale is an unprecedented pandemic that has killed hundreds of children and put thousands more in the hospital, and which is increasing in severity and transmissibility. On the other is an unfounded fear of unspecified harm, and a purported right to refuse basic precautions and thereby expose both the maskless children and those around them to that pandemic. This balance tilts entirely toward an injunction.

CONCLUSION

For these reasons and those stated in Plaintiffs' briefs, the public interest would be served by enjoining Executive Order No. 84.

[57] Daniel Ayoubkhani, et al., *Technical Article: Updated Estimates of the Prevalence of Post-Acute Symptoms Among People with Coronavirus (COVID-19) in the UK: 26 April 2020 to 1 August 2021*, Office of Nat'l Statistics, U.K. (Sept. 16, 2021), https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/technicalarticleupdatedestimatesoftheprevalenceofpostacutesymptomsamongpeoplewithcoronaviruscovid19intheuk/26april2020to1august2021.

Dated: October 1, 2021

Respectfully submitted,

s/ G.S. Hans

G.S. Hans (TN Bar 037422)
Vanderbilt Law School
131 21st Ave. S.
Nashville, TN 37203

Samara M. Spence (TN Bar 031484)*
Jeffrey B. Dubner (DC Bar 1013399)*
DEMOCRACY FORWARD FOUNDATION
655 15th St. NW, Ste 800
Washington, D.C. 20005
Tel.: (202) 448-9090
sspence@democracyforward.org
jdubner@democracyforward.org
Counsel for *Amici*

* *Pro hac vice* motion pending

CERTIFICATE OF SERVICE

I certify that on October 1, 2021, the above brief was filed using the court's CM/ECF system, which will notify all registered counsel.

Dated: October 1, 2021

Respectfully submitted,

s/ G.S. Hans

Counsel for *Amici*