NINETEENTH JUDICIAL DISTRICT COURT

PARISH OF EAST BATON ROUGE, STATE OF LOUISIANA

NUMBER: 714146 SECTION: 26

REPRESENTATIVE RAYMOND J. CREWS AND THE STATE OF LOUISIANA THROUGH JEFF LANDRY, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL AND CHIEF LEGAL OFFICER OF THE STATE OF LOUSIANA

VERSUS

GOVERNOR JOHN BEL EDWARDS

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MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF AND *AMICUS CURIAE* OF CHILDREN'S HEALTH DEFENSE AND CONCERNED PARENTS SUPPORTING REPRESENTATIVE RAYMOND J. CREWS AND LOUISIANA ATTORNEY GENERAL JEFF LANDRY

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Respectfully submitted:

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INTRODUCTION

Children's Health Defense and Concerned Parents ("Amicus" or "CHD") respectfully moves for leave to file the incorporated amicus curiae brief[1] as amicus curiae in support of the plaintiffs' request that this Court find that mandatory COVID vaccination of children ages 5 and up is unjustified and unlawful in in the matter of *Representative Raymond J. Crews and the State of Louisiana through Jeff Landry in his official capacity as Attorney General and Chief Legal Officer for the State of Louisiana versus Governor John Bel Edwards* docketed under case number 714146, Section 26. Consent for the filing of this motion was sought but has not yet been obtained. Permitting the filing of the proposed brief would offer an important perspective to this Court on a matter of great public importance: This brief *amicus curiae* is respectfully submitted by Children's Health Defense, a nonprofit organization, and by concerned Louisiana parents to ensure that this Court has accurate scientific data on the efficacy and safety of COVID vaccination for children. The data are clear: mandatory COVID vaccination of children is not scientifically justifiable.

Under a rule promulgated by the Louisiana Department of Health and approved by the Governor, Louisiana has become the only state in America other than California to mandate COVID vaccination as a requirement for school attendance. Louisiana's mandate expressly applies to kindergartens and covers children aged 5 and up. The data demonstrates the position that mandatory COVID vaccination of children is not scientifically justifiable.

Simply put, the COVID vaccines have not been shown to be either effective or safe for children. The benefits to children are minuscule, while the risks—including the risk of potentially fatal heart damage—are "known" and "serious," as the FDA itself has acknowledged.[1] Moreover, it is undisputed that the existing COVID vaccines do not prevent COVID—at best they reduce the incidence of severe disease outcomes—and hence COVID is not a "*vaccine-preventable*" disease; as a result, COVID vaccines cannot be made mandatory for school attendance under express Louisiana statutory law.[2] Finally, with the rise of Omicron, the vaccines have become wholly ineffective at preventing *infection,* and hence vaccination will not prevent children from catching COVID and spreading the disease to others.[3] Indeed, even as of August, 2021, prior to enactment

[1] *See* Point I(B) *infra*.
[2] *See* Point II *infra*.
[3] *See* Point II *infra*.

of Louisiana's mandate, the Director of the CDC itself admitted that "what [the vaccines] can't do anymore is prevent transmission."[4]

Amici also submit this brief to bring to the Court's attention a comprehensive study of *over 365,000 children* aged 5-11 released on February 28, 2022, revealing that the COVID vaccines do not have the 90% effectiveness claimed by their manufacturer; instead, vaccine effectiveness *is now a mere 12%*.[5] As the New York Times reported, the data showed that vaccination offered "virtually no protection against infection,"[6] meaning that *vaccinated children are just as likely as unvaccinated children to spread COVID to others*. As stated by a recently retired FDA senior vaccine regulator, this new finding, in so comprehensive a dataset, "certainly weakens the argument for mandating" a COVID vaccination for children.[7]

AMICI CURIAE

Children's Health Defense (CHD) is a 501(c)(3) non-profit organization dedicated to protecting children's health, with unmatched expertise in pediatric issues related to COVID, especially the effectiveness and safety of the COVID vaccines. CHD has a strong interest in this case because CHD is committed to informing the judiciary of the actual data demonstrating that such a mandate is scientifically unjustifiable. Joining CHD as *amici* are Louisiana parents who are deeply concerned about the lack of data establishing the safety and efficacy of the COVID vaccines for children and who seek to defend the right of all parents in this state to choose for themselves whether or not to have their children vaccinated. *See* Exhibit A hereto for a list of the concerned parents joining this brief.

ARGUMENT

It is an axiomatic principle of medical law and ethics that every proposed medical intervention must satisfy a simple, well-established test: its benefits must outweigh its risks. *Cf.* LA Code 40:I.2019(C)(2)(b)(iv)(a) ("[R]isk versus benefit should always be evaluated when

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[4] CNN HEALTH, *Fully Vaccinated People Who Get a CoVID-19 Breakthrough Infection Transmit the Virus, CDC Chief Says*, Aug. 6, 2021, https://www.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html.
[5] Dorabawila, V. et al., *Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant*, Feb. 28, 2022, https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.
[6] New York Times, *Pfizer Shot Is Far Less Effective in 5- to 11-Year-Olds Than in Older Kids, New Data Show*, Feb. 28, 2022, https://www.nytimes.com/2022/02/28/health/pfizer-vaccine-kids.html (hereafter New York Times, *Pfizer Shot*).
[7] *Id.*

considering injection therapy."); *State v. Perry*, 610 So. 2d 746 752 (La. 1992) (a "patient's autonomy rights are violated [if] he is not permitted to weigh the benefits and risks of a proposed course of treatment") (citing E. Pellegrino & D. Thomasma, FOR THE PATIENT'S GOOD 37-50 (1988)). In the case of COVID vaccines for children, this simple test has not been met.

I. *The COVID Vaccines Have Not Been Shown To Be Effective or Safe For Children*

No governmental health agency, no pharmaceutical company, and no scientific data have yet shown that the COVID vaccines are either effective of safe for children. On the contrary, the medical benefits of pediatric COVID vaccination are infinitesimal, while the risks of an adverse reaction are extremely serious.

A. **COVID Vaccination is of Infinitesimal Benefit for Children**

It is well-known that COVID poses a miniscule mortality danger to children. Children without serious pre-existing medical conditions are not, as is sometimes said, at "low" risk of dying from COVID; they are, medically speaking, at *zero* risk. A Johns Hopkins study monitoring 48,000 children diagnosed with COVID "found a *mortality rate of zero* among children without a pre-existing medical condition such as leukemia."[8] Similarly, a study published in Nature Medicine showed that children under 18 with no co-morbidities have virtually no risk of death.[9]

Including children with co-morbidities, CDC data indicates that the COVID mortality rate for children aged 5-11, taken to three decimal points, is still *0.000* %:

[8] Marty Makari, *The Flimsy Evidence Behind the CDC's Push to Vaccinate Children*, Wall St. J., Jul. 19, 2021, https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868. The study is available here.

[9] Smith, C. *et al., Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year*, Nat Med 28 (2022):185–192, https://doi.org/10.1038/s41591-021-01578-1.

COVID Population Fatality Ratios By Single Year of Age

Data from January 1, 2020 to October 16, 2021, as of October 20, 2021.

Source: https://data.cdc.gov/resource/3apk-4u4f.csv

Population from CDC Wonder.

	Deaths With COVID	Population	Deaths With COVID as % of Population
<1 Year	132	3,783,052	0.003%
01 Year	26	3,829,599	0.001%
02 Years	10	3,922,044	0.000%
03 Years	13	3,998,665	0.000%
04 Years	14	4,043,323	0.000%
05 Years	11	4,028,281	0.000%
06 Years	8	4,017,227	0.000%
07 Years	13	4,022,319	0.000%
08 Years	15	4,066,194	0.000%
09 Years	18	4,061,874	0.000%
10 Years	14	4,060,940	0.000%
11 Years	15	4,189,261	0.000%
12 Years	23	4,208,387	0.001%
13 Years	28	4,175,221	0.001%
14 Years	27	4,164,459	0.001%
15 Years	50	4,175,459	0.001%
16 Years	49	4,150,420	0.001%
17 Years	76	4,142,425	0.002%
18 Years	95	4,255,827	0.002%
19 Years	148	4,330,439	0.003%
20 Years	176	4,269,683	0.004%
21 Years	194	4,278,323	0.005%
22 Years	253	4,298,772	0.006%
23 Years	292	4,341,644	0.007%
24 Years	332	4,444,518	0.007%
25 Years	383	4,539,058	0.008%
26 Years	402	4,611,220	0.009%
27 Years	516	4,733,869	0.011%
28 Years	562	4,818,725	0.012%
29 Years	681	4,806,144	0.014%
30 Years	788	4,614,384	0.017%
31 Years	879	4,502,311	0.020%
32 Years	908	4,421,505	0.021%
33 Years	1,003	4,432,973	0.023%
34 Years	1,114	4,460,132	0.025%
35 Years	1,176	4,315,866	0.027%
36 Years	1,265	4,372,444	0.029%
37 Years	1,405	4,361,286	0.032%
38 Years	1,528	4,305,576	0.035%
39 Years	1,683	4,382,349	0.038%
40 Years	1,786	4,105,313	0.044%
41 Years	2,055	4,020,254	0.051%
42 Years	2,223	3,974,741	0.056%
43 Years	2,420	3,854,040	0.063%
44 Years	2,687	3,967,275	0.068%
45 Years	2,897	3,837,909	0.075%
46 Years	3,162	3,889,372	0.081%
47 Years	3,461	4,058,038	0.085%
48 Years	3,919	4,282,657	0.092%
49 Years	4,435	4,329,775	0.102%
50 Years	4,999	4,096,572	0.122%
51 Years	5,054	4,004,343	0.126%
52 Years	5,453	4,001,782	0.136%
53 Years	5,726	4,068,851	0.141%
54 Years	6,217	4,305,603	0.144%
55 Years	6,793	4,374,565	0.155%
56 Years	7,789	4,361,016	0.179%
57 Years	8,193	4,342,385	0.189%
58 Years	8,730	4,385,570	0.199%
59 Years	9,907	4,413,855	0.224%
60 Years	10,523	4,252,663	0.247%
61 Years	11,205	4,215,172	0.266%
62 Years	12,087	4,156,645	0.291%
63 Years	12,909	3,996,088	0.323%
64 Years	13,229	3,950,578	0.335%
65 Years	13,876	3,774,597	0.368%
66 Years	14,248	3,618,069	0.394%
67 Years	14,464	3,464,437	0.417%
68 Years	15,142	3,345,475	0.453%
69 Years	15,667	3,252,423	0.482%
70 Years	16,309	3,136,704	0.520%
71 Years	17,088	3,083,083	0.554%
72 Years	18,129	3,191,048	0.568%
73 Years	19,401	2,334,433	0.831%
74 Years	18,969	2,283,164	0.831%
75 Years	17,405	2,198,286	0.792%
76 Years	18,431	2,222,392	0.829%
77 Years	19,620	1,911,261	1.027%
78 Years	19,925	1,720,817	1.158%
79 Years	18,944	1,599,909	1.184%
80 Years	18,981	1,475,278	1.287%
81 Years	18,883	1,381,641	1.367%
82 Years	19,298	1,241,341	1.555%
83 Years	19,226	1,151,190	1.670%
84 Years	19,076	1,067,757	1.787%
85+ Years	196,633	6,604,958	2.977%

Overall, including children with co-morbidities, the CDC reports that the "crude" rate of "COVID associated" mortality for children aged 5-11 is 2 per million (0.0002%).[10] This number is "crude" because "COVID associated mortality" includes children with a positive COVID diagnosis who die from any cause—*e.g.*, accidents (such as a car crash) or other diseases (such as leukemia)—but even accepting the 2 per million figure, it is important to recognize the miniscule nature of this risk. Every child's life is precious, but the chance of any particular child dying from

[10] CDC, *Leading Causes of Death in Children 5-11 Years of Age*, Nov. 3, 2021, https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-Covid-Jefferson-508.pdf.

COVID is approximately 500,000 to 1—less than the chance of being struck by lightning.[11] It is less than pediatric mortality rate (1 in 200,000) from the seasonal flu[12]—***for which Louisiana does not require vaccination***.[13]

To be sure, COVID can also cause illnesses that, while nonfatal, are serious enough to require hospitalization. But again, for children the danger of hospitalizable illness from COVID is ***lower than that of the flu, for which no vaccination (or other measures, such as masking or social distancing) is legally required***. According to a study specifically of children aged 5-11 published just two weeks ago by the Journal of the American Medical Association, COVID "hospitalizations occurred at a rate of 10.8 per 100,000 children," while the rate of flu hospitalizations is more than one and a half times higher—17.2 per 100,000.[14] It is simply irrational to require pediatric vaccination for COVID, which is less dangerous to children than the flu, when no vaccination is required for the flu.

Moreover, administering a COVID vaccine does not guarantee that a child will be protected against even this minuscule chance of serious COVID disease or death. On the contrary, as noted earlier, the most recent and most comprehensive data on pediatric COVID vaccine effectiveness—a study of over 365,000 children aged 5-11 in New York released less than a week ago—found that the COVID vaccines are *only 12% effective*.[15] These results are not "surprising, given this is a vaccine developed in response to an earlier variant," explained the study's leader, Dr. Eli Rosenberg, deputy director for science at the New York State Department of Health.[16] In short, at the very best, vaccinating a child with the existing COVID vaccines would be extremely ineffective, with at best roughly a *one-in-a-million chance* of saving that child's life. That is a genuinely infinitesimal benefit.

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[11] CDC, *Lightning: Victim Data*, https://www.cdc.gov/disasters/lightning/victimdata.html#:~:text=Lightning%20is%20one%20of%20the,greater%20risk%20for%20being%20struck (chance of being struck by lightning in any given year is 1 in 500,000).

[12] "School-aged children between 5 and 14 have a 1 in 200,000 chance of dying of influenza." *See* https://freopp.org/estimating-the-risk-of-death-from-covid-19-vs-influenza-or-pneumonia-by-age-630aea3ae5a9; *see also* CDC, *Leading Causes of Death*, *supra* (showing that COVID mortality rate for children is lower than that of "influenza and pneumonia").

[13] La. Dep't of Health, *Required Vaccinations To Attend Louisiana Schools*, https://ldh.la.gov/page/3652.

[14] Encinosa, W. et al., *Severity of Hospitalizations from SARS-CoV-2 vs Influenza and Respiratory Syncytial Virus Infection in Children Aged 5 to 11 Years in 11 US States*, Feb. 21, 2022, JAMA PEDIATRICS, https://jamanetwork.com/journals/jamapediatrics/fullarticle/2789353.

[15] Dorabawila, V. et al., *Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant*, Feb. 28, 2022, https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.

[16] New York Times, *Pfizer Shot*, *supra*.

B. **The Full Medical Risks of COVID Vaccination for Children Are Unknown, But the Known Risks Are Extremely Serious**

At the same time, the full medical risks of COVID vaccination for children are entirely unknown. Because the vaccines were authorized in record time, there is no long-term data whatsoever on long-term adverse pediatric health effects. But as the FDA itself has acknowledged, the existing data already show "*known serious risks of myocarditis*"—a potentially fatal heart condition—caused by the COVID vaccines,[17] and this risk is especially pronounced in younger individuals:

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)

	Females			Males		
Age groups	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	2,189,726	0–2	19	2,039,871	0–4	128
18–24 yrs	5,237,262	1–6	23	4,337,287	1–8	219
25–29 yrs	4,151,975	0–5	7	3,625,574	1–7	59
30–39 yrs	9,356,296	2–18	11	8,311,301	2–16	61
40–49 yrs	9,927,773	2–19	18	8,577,766	2–16	34
50–64 yrs	18,696,450	4–36	18	16,255,927	3–31	18
65+ yrs	21,708,975	4–42	10	18,041,547	3–35	11
Not reported	—	—	1	—	—	8

CDC

* Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)
† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

On the above chart, numbers are highlighted in red when the number of people who developed myocarditis within seven days after vaccination significantly exceeded the "expected" number—*i.e.*, the number of cases that would have been expected from other causes, independent of the vaccine—strongly indicating that the vaccines were causally responsible. As the chart shows, the *younger* the recipients of the vaccine, the *more* the vaccines caused serious adverse heart conditions in excess of the expected number. Indeed, among boys aged 12-17, the reported myocarditis rate following vaccination was over 100 times greater than in the over-65 group. Extrapolating, it would be rational to expect even higher myocarditis rates in younger children.

Myocarditis is an extremely serious disease of the heart. A 10-year tracking study published in 2020 in the Journal of the American Heart Association found that over half of myocarditis patients had a condition called LGE, and 39% of those patients died within ten years—

[17] FDA, Letter to Pfizer Inc., Aug. 23, 2021, p. 6, https://www.fda.gov/media/151710/download (hereafter FDA Letter to Pfizer).

for an overall ten-year mortality rate among myocarditis patients of approximately 20%.[18] As stated in the Journal of the American Medical Association, the rate of reported myocarditis following COVID vaccination is 70.7 per million among boys aged 12-15 and 105.9 per million among boys aged 16-17.[19] While all must profoundly hope for a different result, if the 20% 10-year mortality rate holds true of these boys, then the COVID vaccines will over the next ten years cause the death of approximately 14 per million boys aged 12-15 and approximately 21 per million boys aged 16-17.

This conclusion is alarming to a degree impossible to overstate. It means that while the COVID vaccines can at most save the lives of 2 children of *all* ages per million (because only 2 children per million die from COVID), those vaccines may at the same time cause within ten years the deaths of 14 per million 12- to 15-year-old boys and 21 per million 16- to 17-year-old boys. Needless to say, this benefit-risk ratio makes pediatric COVID vaccination utterly unjustified.

The true scope of the myocarditis risks of COVID vaccination will not be known for years. In August, 2021, the FDA, acknowledging that the existing data were insufficient, instructed Pfizer to conduct studies of the cardiac effects of the COVID vaccines, including in children, with final reports to be submitted in 2024 or 2025.[20] Given (1) the infinitesimal benefits of the COVID vaccines for children, (2) the just-released data showing mere 12% effectiveness of the COVID vaccines for children aged 5-11, (3) "the known serious risk of myocarditis" those vaccines cause in younger individuals, and (4) the lack of any data showing that myocarditis will not prove fatal for these children, it is unjustifiable—indeed unconscionable—to mandate pediatric COVID vaccination.

II. ***COVID Is Not a Vaccine-Preventable Disease***

By statute, Louisiana expressly restricts mandatory immunization of children as a condition of school attendance to "*vaccine-preventable diseases*." La. R.S. 17-170(A)(1)(a),(b) (emphasis added). The plain meaning, common understanding, and widely-accepted definition of that term is straightforward: "Vaccine preventable diseases (VPDs) are infectious diseases caused by viruses

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[18] Greulich, S. et al., *Predictors of Mortality in Patients With Biopsy-Proven Viral Myocarditis: 10-Year Outcome Data*, J. Am. Heart Assoc. 2020; 9:e015351, https://www.ahajournals.org/doi/10.1161/JAHA.119.015351.

[19] Oster, M. et al., *Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021*, J. Am. Med. Assoc., 2022; 327(4):331-340, https://jamanetwork.com/journals/jama/fullarticle/2788346.

[20] FDA Letter to Pfizer, *supra*.

or bacteria that can be *prevented* with vaccines."[21] According to the CDC's webpage on "vaccine-preventable adult diseases," the latter are "serious diseases that can be *prevented* by vaccines."[22]

The CDC also provides a list of "vaccine-preventable diseases," and COVID is not on that list.[23] The reason is simple. The existing COVID vaccines do not prevent COVID. At best, they reduce the incidence of severe disease outcomes such as hospitalization and death.

As is now common knowledge, "breakthrough" COVID infections—*i.e.*, COVID infections in fully vaccinated people—are extremely widespread. Rampant COVID outbreaks among in vaccinated populations were scientifically established as of September 2021, when the Delta variant became prominent.[24] Today, with the rise of the Omicron variant, copious data indicate that vaccination is actually associated with *higher rates of COVID infection*.[25] And as noted earlier, a just-released study of hundreds of thousands of children aged 5-11 confirms that COVID vaccination offers "virtually no protection against infection."[26]

Thus the hard data are indisputable: the COVID vaccines do not prevent COVID. Accordingly, COVID is not at present a "vaccine-preventable disease" and therefore cannot, under Louisiana law, be included on the list of diseases for which children must show proof of immunity as a condition of school attendance.

III. *Mandatory COVID Vaccination for Children Cannot Be Justified as a Measure to Prevent the Spread of the Disease*

Apart from the health and best interests of the children themselves, backers of the vaccine mandate in this case might claimed that vaccinating children against COVID is necessary to prevent the spread of the disease to others—*i.e.*, to prevent children from being infected by COVID and then transmitting it to teachers, family members, and so on. But this justification has no scientific basis. There is no evidence whatsoever that the COVID vaccines prevent infection or transmission against the virus we now face—the Omicron variant. On the contrary, the existing

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[21] D.C. HEALTH, *Vaccine Preventable Diseases*, https://dchealth.dc.gov/page/vaccine-preventable-diseases (emphasis added).
[22] CDC, *Vaccine Preventable Adult Diseases*, https://www.cdc.gov/vaccines/adults/vpd.html (emphasis added).
[23] *Id*.
[24] NEW ENGLAND JOURNAL OF MEDICINE, *Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce*, N. ENGL. J. MED. 2021; 385:1330-1332, Sept. 30, 2021, https://www.nejm.org/doi/full/10.1056/NEJMc2112981.
[25] *See* Point III *infra*.
[26] *See* New York Times, *Pfizer Shot*, *supra*.

evidence indicates that vaccination has *negative effectiveness* against Omicron—*i.e.*, vaccinated people are *more likely* to be infected than unvaccinated people.

Vaccine effectiveness can refer to many different outcome measures. For example, the term "vaccine effectiveness" can refer to a vaccine's ability to reduce mortality from a disease. As shown above, the COVID vaccines have infinitesimal mortality-reducing effects for children. But for a vaccine mandate supposedly justified as a measure preventing children from spreading the disease to others, the crucial form of vaccine effectiveness is the ability of a vaccine to prevent *infection or transmission* of the disease. As the World Health Organization (WHO) states, a vaccine mandated to prevent spread of a disease must be shown to be effective against "*infection and/or transmission*," because if a vaccine does not protect against infection and/or transmission, then vaccination cannot prevent the spread of the disease to other people.[27] As the world's leading scientific journal, Nature, puts it, a COVID vaccine cannot prevent spread of the disease unless it "*stop[s] people from getting infected and passing on the SARS-CoV-2 virus.*"[28]

Until late 2021, the Delta variant of the COVID virus comprised the overwhelming majority of US COVID cases.[29] Today, however, Delta is all but gone. It was replaced by a new variant, called Omicron. From November 27, 2021 to January 1, 2002, Omicron exploded from 0% to over 95% of all US COVID cases.[30] By February 1, 2022, Omicron represented over 99% of US COVID cases.[31]

Omicron is a radically mutated form of COVID, "with upwards of 50 mutations in its genome, 30 of which exist in the gene encoding Spike—the SARS-CoV-2 surface protein responsible for binding to human ACE2 receptors to facilitate infection, and the immunogen used in all vaccines currently authorized for general use."[32] Because some of Omicron's "deletions and mutations are known to lead to increased transmissibility, higher viral binding affinity, and higher

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[27] WHO, *COVID-19 and mandatory vaccination: Ethical considerations and caveats*, Apr. 13, 2021, at p. 2, https://www.who.int/ publications/i/item/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2021.1 ("if mandatory vaccination is considered necessary to interrupt transmission chains and prevent harm to others, there should be sufficient evidence that the vaccine is efficacious in *preventing serious infection and/or transmission*") (emphasis added).
[28] Nature, *Can COVID vaccines stop transmission? Scientists race to find answers*, Feb. 19, 2021, https://www.nature.com/articles/d41586-021-00450-z.
[29] *See* CDC, COVID Data Tracker: Variant Proportions, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (chart showing that approximately 99% of all US COVID cases were B.1.6172 (Delta) infections from Sept. 25, 2021 through Nov. 6, 2021).
[30] *Id.*
[31] *Id.*
[32] AMERICAN SOCIETY OF MICROBIOLOGY, *How Ominous Is the Omicron Variant* (*B.1.1.529*)?, Dec. 16, 2021, https://asm.org/Articles/2021/December/How-Ominous-is-the-Omicron-Variant-B-1-1-529.

antibody escape,"[33] because the effects of many of its other mutations remain unknown, and because of its rapid spread in highly vaccinated populations, Omicron immediately created "a high level of uncertainty" about the ability of the existing COVID vaccines to protect against it.[34]

As the FDA has acknowledged, the federal authorizations and approvals of the COVID vaccines were based on data "accrued before the Omicron variant emerged."[35] And no subsequent data shows vaccine efficacy against Omicron infection or transmission. Indeed, preliminary experiments, studies, and case data suggest the contrary.

In vitro experiments show "severely reduced" vaccine effectiveness against Omicron: "*[I]n vitro* findings using authentic SARS-CoV-2 variants indicate that in contrast to the currently circulating Delta variant, the neutralization efficacy of vaccine-elicited sera against Omicron was severely reduced."[36] Of the first 43 reported Omicron cases in the U.S., the CDC reports that 79% of those infected were fully vaccinated.[37]

Just days ago, as stated above, a study of hundreds of thousands of children in New York revealed that the COVID vaccines offered "virtually no protection against infection, even within a month after full immunization."[38] Another study similarly found that after only thirty days, in people of all ages, the COVID vaccines had *no statistically significant positive effect* against Omicron infection (their effect became statistically indistinguishable from zero), and after 90 days the vaccines showed *negative effectiveness*, meaning that vaccinated individuals were *more* likely to be infected.[39]

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[33] *See, e.g.*, THE LANCET, *Omicron SARS-CoV-2 variant: a new chapter in the COVID-19 pandemic*, Dec. 11, 2021, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02758-6/fulltext.

[34] *Id*. ("Importantly, the effects of most of the remaining omicron mutations are not known, resulting in a high level of uncertainty about how the full combination of deletions and mutations will affect viral behaviour and susceptibility to natural and vaccine-mediated immunity."); SCIENCE, *COVID-19 vaccine breakthrough infections*, Dec. 23, 2021, https://www.science.org/doi/full/10.1126/ science.abl8487 (noting "[c]ontinued transmission in highly vaccinated populations").

[35] FDA, *Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[36] A. Wilhelm et al., *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera*, Dec. 13, 2021, https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v4.

[37] CDC, SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021 (Dec. 17, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w#contribAff.

[38] New York Times, *Pfizer Shot Is Far Less Effective in 5- to 11-Year-Olds Than in Older Kids, New Data Show*, Feb. 28, 2022, https://www.nytimes.com/2022/02/28/health/pfizer-vaccine-kids.html.

[39] C.H. Hanson et al., *Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study* (Dec. 23, 2021), https://www.medrxiv.org/content/10.1101/2021.12.20.

Official health authority data from many governments all over the world confirm this *negative effectiveness* finding with respect to Omicron infection rates. In Ontario, Canada, the rate of COVID infection after December 25, 2021, became *higher* among vaccinated individuals than among unvaccinated, and is still higher today.[40] The same is true in Denmark, where almost 90% of Omicron cases are in vaccinated individuals.[41] The same is true in Scotland, where as of January 31, 2022 official age-standardized population-wide data show that the triply vaccinated have a substantially higher COVID infection rate than the unvaccinated.[42] And the same is true in the United Kingdom, where official data show vaccinated, boosted adults being infected with Omicron at *over twice the rate* of unvaccinated adults.[43]

In other words, the official government data from health authorities in four major population bases—each of which is known for producing especially reliable COVID data—show *negative vaccine effectiveness* against Omicron infection. And negative effectiveness means that vaccination does not *protect against* Omicron infection, but is instead associated with *higher infection rates* or *increased susceptibility to Omicron*. This disturbing data was never considered by the governmental actors or health authorities that issued the vaccine mandate in this case, for the simple reason that Omicron had not yet been discovered.

On this basis alone, the vaccine mandate in this case should be vacated and remanded to the appropriate governmental actors for reconsideration in light of changed circumstances. For examples of such remands in federal administrative law cases, *see, e.g.*, *Burlington Truck Lines v. United States*, 371 U.S. 156, 171 (1962) (the "intervening facts [have] so changed the complexion of the case" that "the reviewing equity court, in the exercise of its sound discretion, should not

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21267966v3.full-text (preprint) (figure and table showing higher rates of infection for vaccinated versus unvaccinated).

[40] ONTARIO, COVID-19 Vaccination Data, https://covid-19.ontario.ca/data (graph entitled "COVID-19 cases by vaccination status").

[41] According to Danish government data, 89.7% of the country's Omicron cases are in vaccinated individuals (many with a booster shot). STATEN SERUM INSTITUT, *COVID-19 Rapport om omikronvarienten* at 6, table 4 (Dec. 21, 2021), https://www.docdroid.com/C9UY7Ef/dk-serum-institut-rapport-omikronvarianten-21122021-14tk-pdf. Because that figure is higher than the percentage of vaccinated individuals in the population as a whole, *see* Johns Hopkins Univ. Coronavirus Resource Center, Denmark, https://coronavirus.jhu.edu/region/denmark (79% of Denmark population vaccinated), the rate of Omicron infection among the vaccinated is higher than among the unvaccinated.

[42] PUBLIC HEALTH SCOTLAND, COVID-19 & Winter Statistical Report As At 31 January 2022, at 41 (Table 14), https://web.archive.org/web/20220207172220/https://publichealthscotland.scot/media/11597/22-02-02-covid19-winter_publication_report.pdf.

[43] UK HEALTH SECURITY AGENCY, COVID Vaccine Surveillance Report, Week 7, Feb. 17, 2022 at 44 (Table 13) (showing infection rates for vaccinated adults over *twice as high* as infection rates for unvaccinated adults), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1055620/Vaccine_surveillance_report_-_week_7.pdf.

have affirmed the order, as it did, but *should have vacated it and remanded it to the Commission for further consideration in the light of the changed conditions*"); *Quincy Cable TV, Inc. v. FCC*, 730 F.2d 1549 (D.C. Cir. 1984); *American Optometric Ass'n v. FTC*, 626 F.2d 896, 907 (D.C. Cir. 1980) (vacating and remanding to agency in light of change to "core circumstances"); *cf. Air Products & Chemicals, Inc. v. Federal Energy Regulatory Com.*, 650 F.2d 687 (5th Cir. 1981) (adopting the "core circumstances" doctrine, under which agency regulations or orders are to be remanded in the event of changes to core circumstances).

To the extent that the vaccine mandate in this case was premised on the factual presumption that vaccination would prevent children from being infected and passing on COVID to others, that factual premise has been rendered obsolete by the explosive rise of Omicron. There is no data showing that the COVID vaccines are effective against Omicron infection; on the contrary, the data we have shows the opposite—vaccination is associated with higher rates of Omicron infection and transmission.

Thus there is no rational, scientific basis for requiring children to receive a COVID vaccination as a condition for entering school. The vaccines have not been shown to be effective or safe for children, and because they do not stop Omicron infection, they cannot be justified as a means of preventing children from catching the disease and spreading it to others.

CONCLUSION

For the reasons stated above, amicus respectfully ask that this Court order this pleading into the record of these proceedings and that this Court find that mandatory COVID vaccination of children ages 5 and up is unjustified and unlawful.

Respectfully submitted:

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CERTIFICATE OF SERVICE

I do hereby certify that I have on this 16th day of March, 2022, served a copy of the foregoing pleading on counsel for all parties to this proceeding, by electronic mail.

/s/ *Laura Cannizzaro Rodrigue*
Laura Cannizzaro Rodrigue

NINETEENTH JUDICIAL DISTRICT COURT

PARISH OF EAST BATON ROUGE, STATE OF LOUISIANA

NUMBER: 714146 SECTION: 26

REPRESENTATIVE RAYMOND J. CREWS AND THE STATE OF LOUISIANA THROUGH JEFF LANDRY, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL AND CHIEF LEGAL OFFICER OF THE STATE OF LOUSIANA

VERSUS

GOVERNOR JOHN BEL EDWARDS

ORDER

CONSIDERING THE FOREGOING MOTION of Children's Health Defense and Concerned Parents to file the incorporated amicus curiae brief in this matter;

IT IS HEREBY ORDERED that the amicus curiae brief be filed into the record of this matter.

Baton Rouge, Louisiana, this _____day of _____, 2022.

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JUDGE