IN THE UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

VICTOR M. BOOTH,
individually and as next friend of
L.B. a minor child; and

SHAMEKA WILLIAMS,
individually and as next friend of
K.G. and R.T., minor children;

SHANITA WILLIAMS,
individually and as next friend of
N.W. and M.R., minor children; and

JANE HELLEWELL,
individually and as next friend of
H.B., a minor child,
Plaintiffs,

vs.

MURIEL BOWSER,
in her official capacity as Mayor of the
District of Columbia;

LAQUANDRA NESBITT,
In her official capacity as
Director of the District of Columbia
Department of Health; and

LEWIS FEREBEE,
In his official capacity as
Chancellor of the District of Columbia
Public Schools,

Defendants.

Case No. 21-1857

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

21 DAY EMERGENCY HEARING REQUESTED

Plaintiffs VICTOR M. BOOTH, SHAMEKA WILLIAMS, SHANITA WILLIAMS, and JANE HELLEWELL move for a preliminary injunction as set out below and for the reasons set out in the accompanying *Statement of Points and Authorities* and *Verified Amended Complaint for Declaratory and Injunctive Relief*. Fed. R. Civ. P. 65(a).

As set out more fully in their *Statement of Points and Authorities* and *Verified Amended Complaint for Declaratory and Injunctive Relief*, the plaintiffs challenge the legality and constitutionality of the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 (hereinafter "the Minor Consent Act").

The motion should be granted because the plaintiffs are likely to succeed in showing that the Minor Consent Act violates the Supremacy Clause of the Constitution, in that it contradicts clear commands of Congress in the National Child Vaccine Injury and Compensation Act of 1986 (the National Vaccine Act).

Alternatively, the motion should be granted because the plaintiffs are likely to succeed in showing that the Minor Consent Act substantially burdens their right to freely exercise their religion, in violation of the Religious Freedom Restoration Act (RFRA).

Alternatively, the motion should be granted because the plaintiffs are likely to succeed in showing that the Minor Consent Act violates their right to freedom of religion, which is protected by the First Amendment.

Alternatively, the motion should be granted because the plaintiffs are likely to succeed in showing that the Minor Consent Act violates their right to direct the care and upbringing of their children, which is protected by the due process clause of the Fifth Amendment.

Moreover, if an injunction is not granted, the plaintiffs will suffer an irreparable injury to their statutory and constitutional rights to direct that their children not receive vaccines, which would violate their sincere religious beliefs.

Finally, plaintiffs request an expedited hearing on this matter. As set out in the complaint, the pressure upon the plaintiff's children has reached a critical point. Because the plaintiffs are likely to prevail in their claims against the Minor Consent Act, and because an injunction of this

unconstitutional Act is in the public interest, this Court should enjoin the District from enforcing the D. C. Minor Consent Act.

Respectfully submitted this 14th day of December 2021:

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PLAINTIFFS' STATEMENT OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

21-DAY EMERGENCY HEARING REQUESTED

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PRELIMINARY STATEMENT

The plaintiffs are the parents of minor children, who are students in the D.C. Public School System. The Plaintiffs' challenge the District of Columbia Minor Consent to Vaccinations Act of 2020 (hereinafter "the Minor Consent Act"), which the D.C. Council adopted on October 20, 2020, to amend Title 22-B of the District of Columbia Municipal Regulations (D.C.M.R.) to allow a child eleven years of age or older to consent to any vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) without parents' knowledge or consent. The Minor Consent Act contains multiple provisions designed to deceive parents and prevent them from knowing that their child has been vaccinated without their knowledge and consent. The Minor Consent Act specifically targets the children of parents who have submitted religious exemptions. The Minor Consent Act endangers children by depriving their parents and them of the protections of the National Childhood Vaccine Injury Act of 1986 in violation of Article VI and the Fifth Amendment to the United States Constitution. The Minor Consent Act also violates the Religious Freedom Restoration Act of 1993 and the First and the Fifth Amendments to the United States Constitution.

On August 19, 2021, before the start of the school year, the Plaintiffs filed a complaint and motion for preliminary injunction. The plaintiffs' pleadings were largely based on the fears of what would happen when school reopened. On September 2, three days after school reopened, this Court held a telephonic hearing. The complaint was dismissed without prejudice. In essence, the court expressed that the case was not ripe for decision.

Consistent with Plaintiffs' predictions in the original complaint, Defendants are placing tremendous pressure on children to receive vaccines without parents' knowledge or consent. Defendants are also offering children an escape from the pressure through easily accessible walk-in vaccine clinics. This case is now at a boiling point. One twelve-year-old child in

particular, L.B., seems likely to defy his father to get a COVID-19 vaccine, even though the vaccine violates the family's religious beliefs and may severely injure L.B.'s health. To release the unrelenting pressure on him, L.B. faces imminent harm if the court does not issue a preliminary injunction. This case is now ripe for decision.

STATEMENT OF FACTS

The District of Columbia Minor Consent to Vaccinations Act of 2020 (hereinafter "the Minor Consent Act"), that the D.C. Council adopted on October 20, 2020, amends Title 22-B of the District of Columbia Municipal Regulations (D.C.M.R.) to allow a child who is eleven years old or older to consent to receive a vaccine recommended by the Advisory Committee on Immunization Practices (ACIP), so long as the person administering the vaccine believes the child is capable of providing informed consent, and the child provides such consent. The Act does not require the person administering the vaccine to approach the child's parent for informed consent; on the contrary, it states that medical providers who administer vaccines under the Minor Consent Act shall seek reimbursement directly from the insurer without contacting parents and that insurers shall not send an Explanation of Benefits to parents for any vaccine administered under the Act. Amended Ver. Compl. ¶ 21.

Moreover, the Act states that if a student's parent has claimed a religious exemption from vaccines in general, or an exemption from the vaccine for the Human Papillomavirus Virus vaccine (HPV) in particular, "the healthcare provider shall leave blank Part 3 of the immunization record, and submit the immunization record directly to the minor student's school." Amended Ver. Compl. ¶¶ 22-24. *See* Exhibit 1 to Amended Ver. Compl. This creates two conflicting health records for the child, one for the parents, which leaves the child's immunization record blank, even though vaccines have been administered, and the other, withheld from parents, that records the child's true history. Amended Ver. Compl. ¶¶ 25-26.

Before the adoption of the Minor Consent Act, District law gave parents two choices for immunization if they wanted to their children in public, private, or parochial school: they could either comply with immunization standards and regulations or they could obtain exemptions based on medical reasons or sincere religious beliefs. Amended Ver. Compl. ¶¶ 10-13; *see also* D.C. Code § 38-202(a); D.C. Code §§ 38-501, 38-502, 38-503, *and* 38-506. A parent may claim a religious exemption by sending a good faith objection in writing to the chief school official, stating that vaccinations violate the parent's religious beliefs. Amended Ver. Compl. ¶ 14; D.C. Code § 38-506(1). A good faith statement that a parent has sincere religious beliefs against childhood immunizations is sufficient to claim the exemption. Amended Ver. Compl. ¶ 14. The Minor Consent Act does not amend or repeal the statute, enacted in 1979. Amended Ver. Compl. ¶¶ 13, 25, 309.

Plaintiffs are four parents who live in the District, all of whom send their school-age children to D.C. Public Schools (DCPS). Amended Ver. Compl. ¶¶ 1-4. All are fit parents. Amended Ver. Compl. ¶¶ 167-170. All have claimed exemptions under D.C. Code § 38-506(1) because vaccinating their children violates their sincere religious beliefs.

Several Council members touted the Minor Consent Act in the weeks leading up to its passage as a way to "alter certain behaviors" and to "reduce any and all barriers to these treatments" posed by those who are "choosing not to vaccinate their children based on" the "anti-science belief[]" that "vaccines may cause autism or other harmful health effects." Amended Ver. Compl. ¶¶ 30,31. DCPS's Immunization Attendance Policy for the 2021-2022 school year complies with the Minor Consent Act. Amended Ver. Compl. ¶¶ 52-56.

Defendants are exerting tremendous pressure on Plaintiffs and their children through a mass media marketing campaign to push the COVID-19 vaccine. The intense marketing

campaign includes billboards, posters, fliers, printed ads, online ads, websites, emails, Twitter and other mass media advertising. Mayor Browser hawks "incentives" to receive vaccines, such as $51 gift cards, free ear buds and chances to win other prizes including I-pads and $25,000 scholarships. The mass media blitz contains catchy slogans, such as "Don't Wait. Vaccinate!" Amended Ver. Compl. ¶¶ 76, 77, 78, 85. Defendants' websites contain easy-to-follow instructions on how to locate vaccine walk-in clinics, including at District schools. The walk-in or "pop-up" clinics have been and will continue to be in the schools that Plaintiffs' children attend. Amended Ver. Compl. ¶¶ 79, 80, 84. See Exhibits 2-6 and 12 to Amended Ver. Compl.

Defendants are creating a culture of fear and compliance. The "10-layered mitigation health and safety framework," which includes, masks, saliva tests, nasal swabs, temperature screening, social distancing, self-isolation quarantine protocols and COVID vaccines, fosters this. Amended Ver. Compl. ¶¶ 96, 97, 109. And Defendants impose additional requirements on unvaccinated children. Amended Ver. Compl. ¶¶ 102, 103, 106, 108, 116-118; *see* Exhibit 7 to Amended Ver. Compl.

According to Defendants' contact tracing policy, if an unvaccinated student comes within six feet of a person who tests positive for COVID-19, then the unvaccinated student must isolate at home for 10 days. A vaccinated student is not subject to the same self-isolation requirements, although vaccinated students are also at equivalent risk of infection. Amended Ver. Compl. ¶¶ 102-103; *see COVID-19 Response Protocol FAQ*, #REOPENSTRONG, https://dcpsreopenstrong.com/health/response/, submitted herewith as Exhibit 19[1].

School policies that deny unvaccinated children the opportunity to play sports exert

[1] Plaintiffs submitted Exhibits 1 through 18 with their Amended Verified Complaint. The Appendix of Exhibits submitted with this motion continues Plaintiffs' designation of exhibits to the Amended Verified Complaint and thus begins with Exhibit 19.

additional pressure. On or about November 2021, Defendants issued a document entitled "School Year 2021-22, Student Athletes: COVID-19 Vaccination Religious Exemption Certificate." *See* Exhibit 9 to Amended Ver. Compl. It requires the parent to detail his or her basis for a religious exemption. It further states, "this religious exemption request shall be reviewed by the school leader or designee." In reality, the Vaccination Religious Exemption Certificate is a request form subject to the whims of the same officials pushing the vaccine.

Even if a parent's request for a religious exemption is approved, the child is subject to additional restrictions. On the Vaccination Religious Exemption Certificate, the parent is required to initial the following: "I understand that student athletes with an approved religious exemption must: (1) wear a mask in athletic events (even if the current indoor masking order is rescinded or suspended); (2) be tested weekly for COVID-19: and (3) provide the school a negative COVID-19 test result on a weekly basis in order to report to their school based extracurricular activity." Amended Ver. Compl. ¶¶ 115-118.The additional requirements on student athletes intensify the pressure on Plaintiffs' children to defy their parents.

The pressure on student athletes falls most intensely on L.B. and H.B. Playing baseball with his friends is very important to L.B. and H.B. is an avid tennis player. Tennis is extremely important to H.B.'s life and identity. He is adamant that he will play tennis this year. H.B.'s older sister, who is seventeen, received the COVID-19 vaccine in direct opposition to Jane's parental judgment. Amended Ver. Compl. ¶¶ 283-287.

The overall pressure on L.B., a medically fragile child, is acute. He suffers from autoimmunity, including alopecia (severe hair loss), asthma and eczema. His hair loss is so severe that he is the only child in his class allowed to wear a baseball cap in class to conceal his severe baldness. Based on his medical history, L.B.'s hair loss and eczema appear to be causally

related to childhood immunizations. Amended Ver. Compl. ¶¶ 122, 125, 134-140.

L.B. has been singled out by Defendants' policies on at least two occasions. On September 9, 2021, medical testing teams came to L.B.'s class. The testers ordered all students to remove their things from their desks so they could collect saliva samples. When L.B. told the testers that his parents had not given him permission to take part in the tests, they ordered him to leave the room and stand in the hall. This occurred in full view of his friends and classmates. Amended Ver. Compl. ¶¶ 155-162.

The second time L.B. was singled out began on October 21, 2021. L.B. was forced to quarantine at home for ten days because he came within six feet of his teacher, who later tested positive for COVID-19. To the best of Victor's knowledge, none of the other children in the classroom were forced to remain home. When L.B. learned that he had to stay home for ten days because he was not vaccinated even though he was not sick, he became very upset. He cried and was angry that he could not go to school and take his math test. He does not want to isolate at home. He wants to go to school and be with his friends. L.B. has become increasingly angry, agitated and upset as a result of the pressure. Being isolated from friends places tremendous pressure on L.B. to defy his father and receive the vaccines without Victor's knowledge or consent. Amended Ver. Compl. ¶¶ 188-191.

Shortly before L.B. was forced to stay home from school for ten days for coming into contact with his teacher, who was vaccinated but tested positive for COVID-19, L.B. created the illustration at Exhibit 10 to Amended Ver. Compl. The computer-generated drawing depicts a child in distress. It states, "I feel like I'm being pressured into taking the vaccination because I feel like an outsider since everybody else has the vaccine and not only that but I feel like the vaccination is some sort of hall pass because I need the vaccination to go to certain places which

is very annoying. My parents sometimes fight over me and how mom and dad have different opinions about the vaccines so I am in a very tight space right now." L.B. made the drawing and statement shortly before the school suspended him for not being vaccinated after exposure. L.B. is correct: the vaccine is a "hall pass" "to go to certain places," specifically school. After L.B. was suspended, he created a second drawing entitled, "*PEER Pressure*," which is Exhibit 11 to the Amended Ver. Compl. It states, "C'mon dude" "take it" "Scared" "just do it" "I think" "you should." Both drawings reflect a child under tremendous pressure to submit to vaccination, even in defiance of his parents. Amended Ver. Compl. ¶¶ 194-197.

Before refiling the complaint, L.B. and Victor spoke about the rising level of peer pressure L.B. feels. L.B. said, **"if I were offered a vaccine, I would take it."** Amended Ver. Compl. ¶¶ 198. L.B. is being offered vaccines by the Defendants non-stop. They are advertising vaccine walk-in clinics including at L.B.'s school. He can register to reserve a specific time to receive the vaccine at the walk-in clinics at his school. Other than his own self-restraint, there is absolutely nothing preventing L.B. from receiving vaccines.

The D.C. Minor Consent Act and the available vaccine clinics provide an extremely tempting release from the tremendous pressure on L.B., K.G., N.W., and H.B. to receive vaccinations against their parents' sincere religious beliefs. To prevent this from happening, Plaintiffs brought a complaint for declaratory and injunctive relief.

The Minor Consent Act violates federal law in four respects: (1) it expressly contradicts Congressional mandates contained in the National Vaccine Act; (2) it deprives Plaintiffs of their right to free exercise of religion under the Religious Freedom Restoration Act; (3) it deprives Plaintiffs of their fundamental rights to free exercise of religion under the First Amendment; and (4) it strips them of their fundamental rights under the Fifth Amendment to direct the medical

care of their children. Because the threat to Plaintiffs' rights is both substantial and imminent, they seek a preliminary injunction to enjoin the Minor Consent Act. Furthermore, regardless of whether one or more of the children buckle and get vaccinations against their parents' wishes, the constitutional rights of both the parents and children are being infringed.

ARGUMENT

A preliminary injunction is an extraordinary remedy that may be granted at the discretion of a court sitting in equity. *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008). It may be granted if the movants show that (1) they are likely to succeed on the merits, (2) they will suffer irreparable harm in the absence of preliminary relief, (3) the balance of the equities tips in their favor, and (4) it serves the public interest. *League of Women Voters of the United States v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016). The court then "balance[s] the strengths of the requesting party's arguments in each of the four required areas," and "[i]f the showing in one area is particularly strong, an injunction may issue even if the showings in other areas are rather weak." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). Where the Government is the opposing party, the last two factors merge because "the government's interest *is* the public interest." *Shawnee Tribe v. Mnuchin*, 984 F.3d 94, 102 (D.C. Cir. 2021), *quoting Pursuing America's Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2009) (emphasis in original).

I. PLAINTIFFS' LEGAL CHALLENGES TO THE MINOR CONSENT ACT ARE LIKELY TO SUCCEED ON THE MERITS.

Plaintiffs "need not establish an absolute certainty of success" to obtain injunctive relief. *Population Institute v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986). Instead, "[i]t will ordinarily be enough that the plaintiff has raised serious legal questions going to the merits, so serious, substantial, difficult as to make them a fair ground of litigation and thus for more deliberative investigation." *Washington Metropolitan Area Transit Comm'n v. Holiday Tours,*

Inc., 559 F.2d 841, 844 (D.C. Cir. 1977). Here, Plaintiffs' verified complaint presents substantial claims against the Minor Consent Act under the National Childhood Vaccine Injury and Act of 1986, the Religious Freedom Restoration Act of 1993, the free exercise clause of the First Amendment, and the due process clause of the Fifth Amendment. The motion for preliminary injunction should be granted.

A. The Minor Consent Act directly violates multiple statutory requirements of the National Childhood Vaccine Injury Act of 1986.

The Supremacy Clause declares that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land. . . ." U.S. Const. Art. VI, cl. 2. "The Supremacy Clause, on its face, makes federal law 'the supreme Law of the Land' even absent an express statement by Congress." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 621 (2011).

Whether a federal law preempts a lesser law under the Supremacy Clause hinges on Congress' intent in enacting the statute. *Shaw v. Delta Air Lines, Inc*., 463 U.S. 85, 95 (1983). Federal preemption "may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Id., quoting Jones v. Rath Packing Co*., 430 U.S. 519, 525 (1977).

Congress may engage in implicit preemption either through "field" preemption or "conflict" preemption. *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015). The former occurs when Congress creates "a framework of regulation" that "is 'so pervasive' that it leaves no space for state supplementation, or where the federal interest is 'so dominant' that the existence of a federal scheme can 'be assumed to preclude enforcement of state laws on the same subject.'" *Sickle v. Torres Advanced Enter. Sols., LLC*, 884 F.3d 338, 347 (D.C. Cir. 2018),

quoting Arizona v. United States, 567 U.S. 387, 399 (2012). Conflict preemption "exists when the operation of federal and state law clash in a way that makes 'compliance with both state and federal law . . . impossible,'" or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sickle*, 884 F.3d at 347.

1. The National Vaccine Act's comprehensive regulatory framework for litigating vaccine injuries depends on the accurate recording and reporting of information specified by Congress.

Congress passed the National Childhood Vaccine Injury Act of 1986 ("National Vaccine Act") to shield vaccine manufacturers from liability and to compensate vaccine injured children. As the Supreme Court explained in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011), the National Vaccine Act is based on the premise that vaccine injury is "unavoidable." If a large enough number of children are vaccinated, eventually some children will be seriously injured. Recognized vaccine injuries include severe neurological damage and death.

Through provisions in the National Vaccine Act, Congress created the National Vaccine Injury Compensation Program (VICP) to address these issues, as well as complaints that "obtaining compensation for legitimate vaccine-inflicted injuries was too costly and difficult." *Bruesewitz*, 562 U.S. at 227. As the Supreme Court explained, Congress's solution of "[f]ast, informal adjudication" is "made possible by the Act's Vaccine Injury Table, which lists the vaccines covered under the Act; describes each vaccine's compensable, adverse side effects; and indicates how soon after vaccination those side effects should first manifest themselves." *Id.* at 228.

The Vaccine Injury Table consists of a list of childhood vaccines, recognized injuries, and a time period. If the vaccine injury first manifests during the short time period listed on the table (referred to as a "table injury"), then the vaccine is presumed to have caused the injury and the child is entitled to compensation, unless the Department of Health and Human Services can

prove an alternative cause of injury. *Id.* If the child's injury is not listed on the Vaccine Injury Table, or if the injury is listed on the table, but the injury does not manifest until after the short time period listed on the table, then the petitioner bears the burden of proving causation. *Id.* at 228-29. This is referred to as a "non-table injury." Congress' regulatory scheme is dependent on recognizing vaccine injuries in a timely manner. Not only is timely recognition important for receiving follow-up medical care. It is also a critical element of proving that one is entitled to legal compensation for injuries that may be necessary for a lifetime of care.

The Supreme Court has repeatedly recognized that "state and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mensing*, 564 U.S. at 618, *quoting Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). The Minor Consent Act does just that, by injecting itself into Congress' carefully-crafted and carefully-calibrated regulatory scheme.

In order to achieve the goals of administering vaccines safely and compensating vaccine injured children, the National Vaccine Act contains specific mandates as to the publication and distribution of written vaccine information materials, known as Vaccine Information Sheets (VISs), which must be provided to parents before administration of vaccines. 42 U.S.C. § 300aa-26. The National Vaccine Act also requires health care providers to record specific information in a child's medical records when the child is administered vaccines. 42 U.S.C. § 300aa-25.

Moreover, Congress mandated that "the Secretary [of the U.S. Department of Health] *shall* develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised." 42 U.S.C. § 300aa-26(a) (emphasis added). A "legal representative" is "a

parent or an individual who qualifies as a legal guardian under state law." 42 U.S.C. § 300aa-33(2). Congress went on to declare that:

> The information in such materials shall be based on available data and information, shall be presented in understandable terms and *shall* include
>
> (1) a concise description of the benefits of the vaccine,
> (2) a concise description of the risks associated with the vaccine,
> (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
> (4) such other relevant information as may be determined by the Secretary.

42 U.S.C. § 300aa-26(c) (emphasis added).

Critically, Congress declared in subsection (d), "Health care provider duties," that "each health care provider who administers a vaccine set forth in the Vaccine Injury Table *shall* provide to the *legal representatives of any child* . . . a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. *Such materials shall be provided prior to the administration of such vaccine*." 42 U.S.C. § 300aa-26(d) (emphasis added).

When a statute uses the term "shall," it creates mandatory duties. *See, e.g., Lopez v. Davis*, 531 U.S. 230, 231 (2001) ("Congress used 'shall' to impose discretionless obligations"); *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 525 n.32 (1989) ("The process by which Congress changed the District of Columbia Code to provide that impeaching evidence 'shall,' not 'may,' be admitted . . . makes it evident that this mandatory language was intended"). Here, the Minor Consent Act imposes a contradictory set of duties on the very same actors: it is incompatible with the National Vaccine Act, and must yield under the Supremacy Clause. *Mensing*, 564 U.S. at 618.

2. The Minor Consent Act violates 42 U.S.C. § 300aa-26.

Subsection (c) of the Minor Consent Act states, "The Department of Health shall produce

alternative vaccine information sheets, which shall be one or more age-appropriate made available before vaccination of minors to support providers in the informed consent process." 42 U.S.C. § 300aa-26(c) (emphasis added). **Appendix A** contains the Vaccine Information Materials—commonly referred to as Vaccine Information Statements (VISs)—produced by the U.S. Department of Health for the vaccines at issue here.

The word "alternative" is defined as "One or the other of two things: giving an option or choice: allowing a choice between two or more things or acts to be done." *What is Alternative*, THE LAW DICTIONARY (2021), *available at* https://thelawdictionary.org/alternative/ (accessed July 5, 2021). 42 U.S.C. § 300aa-26(d) clarifies that the required VISs may be "supplemented." But an alternative is not a supplement. *See What is Supplemental*, THE LAW DICTIONARY (2021), *available at* https://thelawdictionary.org/supplemental/ (accessed July 5, 2021) (defining "supplemental" as "Something added to supply defects in the thing to which it is added, or in aid of which it is made"). A state or local law, offering an "alternative" to federally mandated vaccine information materials, by definition, is a violation of the doctrine of preemption and the Supremacy Clause of the Constitution.

The National Vaccine Act explicitly mandates that HHS develop and publish vaccine information materials in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the CDC, and the FDA. *See* 42 U.S.C. § 300aa-26(b). The Minor Consent Act usurps the responsibility and authority of the private entities and federal government agencies, which Congress entrusted and assigned the responsibility to develop and publish VISs.

Furthermore, the National Vaccine Act explicitly mandates VISs must be provided to the parents before vaccine administration. By use of the word "alternative," the Minor Consent Act

violates the express written mandates of the National Vaccine Act and abolishes the rights of both the parent and child for the parent to receive the federally mandated VISs. In the process, the Minor Consent Act recklessly places children at risk of serious harm and death.

Vaccine injury is real. *See Brusewitz*, 562 U.S. at 227 (explaining that concerns about vaccines for diphtheria, tetanus, and pertussis (DTP) led to "a massive increase in vaccine-related tort litigation" in the mid-1980s, prompting Congress to create the National Vaccine Act). Since the Vaccine Injury Compensation Program was enacted, the VICP has paid over $4.6 billion in compensation for vaccine injuries. *See* Exhibit 16 to Amended Ver. Compl. The Injuries listed on the Vaccine Injury Table, which is reproduced in Exhibit 14 to Amended Ver. Compl., include encephalopathy (brain injury), paralysis and death. Federally mandated VISs are extremely important in preventing unnecessary vaccine injury.

VISs are designed to provide parents with the minimum amount of information necessary to understand the benefits and risks of administering immunizations to form and give informed consent. *See* Exhibit 17 to Amended Ver. Compl., *DTaP* (*Diptheria, Tetanus, Pertussis*) *Vaccine: What You Need to Know* (warning that risks may include "soreness or swelling where the shot was given, fever, fussiness, feeling tired, loss of appetite, and vomiting," and may also include more serious reactions such as "seizures," "non-stop crying for 3 hours or more," a "high fever," "swelling of the entire arm or leg," "long-term seizures, coma, lowered consciousness, or permanent brain damage"). See Exhibit 17 to Amended Ver. Compl., *Influenza* (*Flu*) *Vaccine (Inactivated or Recombinant): What You Need to Know* (warning that risks may include "soreness, redness, and swelling where shot is given, fever, muscle aches, and headache," as well as "a very small increased risk of Guillain-Barre Syndrome (GBS)," and that "Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTap vaccine at the

same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure"). *See* Exhibit 17 to Amended Ver. Compl., *Pneumococcal Conjugate Vaccine* (*PCV13*)*: What You Need to Know* (warning that risks may include "redness, swelling, pain or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, and chills," and that "Young children may be at increased risk for seizures caused by fever after PCV13 if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information").

The information contained on the mandatory VISs is critical to prevent serious harm, including neurological damage to a child. A primary purpose of the VISs is to educate so that parents are able to recognize vaccine "adverse events." These "adverse events" include encephalopathy (brain injury) and death. If a child receives an immunization without parents' knowledge or consent, they likely will have no way of recognizing if the child has suffered a vaccine injury. Not recognizing that the child has suffered a vaccine adverse reaction can cause serious medical consequences. If the parent has not been provided the minimum information necessary to recognize an adverse event, she will not know to seek immediate medical attention. The parent will also not know that some vaccine adverse reactions are listed as precautions and contraindications to further vaccination. Furthermore, if VISs are not provided, then the parents will not know of the existence of the National Childhood Vaccine Injury Compensation Program.

3. The Minor Consent Act violates 42 U.S.C. § 300aa-25(a).

The Minor Consent Act amended Section 3(a) of the Student Health Care Act of 1985 to add the following:

> (2) If a minor student is utilizing a religious exemption for vaccinations or is opting out of receiving the Human Papillomavirus vaccine, but the minor student is receiving vaccinations under section 600.9 of Title 22-B of the District of Columbia Municipal

> Regulations (22-B DCMR § 600.9), the health care provider shall leave *blank* part 3 of the immunization record, and *submit the immunization record directly to the minor student's school*. The school shall keep the immunization record received from the health care provider confidential; except, that the school may share the record with the Department of Health or the school-based health center.

(Emphasis added.)

The Act's requirement that a health care provider leave a child's immunization record "*blank*" is not only recklessly dangerous to the child, but also blatantly violates 42 U.S.C. § 300aa-25(a), which states:

> Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person *shall record*, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine:
> (1) the date of administration of the vaccine,
> (2) the vaccine manufacturer and lot number of the vaccine,
> (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and
> (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(Emphasis added.) The Minor Consent Act explicitly violates these federal requirements.

The Minor Consent Act also violates an additional command in section 300aa-25(a). It states that health care workers who administer vaccines to a child without the parents' knowledge or consent "shall submit the immunization record directly to the minor's school. The school *shall keep this immunization record confidential*, except it may share the record with the Department of Health or the school-based health center." In contrast, 42 U.S.C. § 300aa-25(a) mandates that "[e]ach health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person *shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request)* with respect to each such vaccine" (emphasis added). A "legal representative" includes parents. 42 U.S.C. § 300aa-33(2). This presents yet another clear

conflict: the Minor Consent Act commands that the immunization record shall be confidential to hide from parents that the child has been vaccinated, while Congress commands that parents "shall have access upon request" to those records. Medical providers cannot comply with both acts at the same time. The Supremacy Clause demands that the Minor Consent Act yield to federal law.

4. The Minor Consent Act violates 42 U.S.C. § 300aa-25(b).

42 U.S.C. § 300aa-25(b) mandates the reporting of vaccine adverse events within specified time periods. However, if a health care provider does not comply with subsection (a) by recording the required information, then it becomes almost impossible to comply with subsection (b), "Reporting adverse events." Section 300aa-25(b) states in pertinent part:

> (1) Each health care provider and vaccine manufacturer shall report to the Secretary—
> (A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
> (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
> (C) such other matters as the Secretary may by regulation require….
>
> (2) A report under paragraph (1) respecting a vaccine **shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine**.

(Emphasis added.)

If a health care provider abides by the Minor Consent Act and leaves the immunization record "blank", then it is impossible to comply with subsection (b) ("the reporting of vaccine adverse events") because the health care provider will not have recorded critical information required to be in any vaccine adverse event report. Also, by hiding the fact that a child has been vaccinated from parents, they likely will never know if the child had a vaccine adverse reaction

and the adverse reaction will not be reported.

5. The Minor Consent Act violates 42 U.S.C. § 300aa-25(c).

Finally, Congress has adopted a specific subsection, titled "Release of information," which governs the disclosure of vaccine information. 42 U.S.C. § 300aa-25(c) "**Release of information"** specifies what information shall or shall not be available to the public. However, the information which is "shall not" be available to the public shall be available to "the legal representative" of "the person who received the vaccine."

A health care provider cannot both record the information listed in the statute *and* leave the child's immunization record "blank." Again, providers cannot comply with both acts at the same time. Moreover, subsection (c) specifically authorizes the release of information to "the legal representative of such person"—the child's parent. The Minor Consent Act says the exact opposite. This not only undermines Congress's intent in creating the National Vaccine Act, but also undercuts the practical mechanism Congress created to deal with vaccine injuries—the Vaccine Adverse Event Reporting System (VAERS)—which assumes that vaccine information will be accurately recorded, not concealed.

By enacting the National Vaccine Act, Congress created "a framework of regulation" that "is 'so pervasive' that it leaves no space for . . . supplementation" by the District. *Sickle*, 884 F.3d at 347. Section 300aa-26 mandates the information that must be provided to parents before children may be vaccinated, while section 300aa-25 mandates what information must be recorded in their permanent medical records and what information must be provided to parents. By ordering health care providers to not record specific information in immunization records, and ordering health care providers, school officials and government agents to conceal immunization records from parents, the Minor Consent Act "makes 'compliance with both state and federal law . . . impossible.'" *Sickle*, 884 F.3d at 347. Plaintiffs are likely to prevail on their

Supremacy Clause claim because the Minor Consent Act imposes contradictory, mandatory duties on those who administer vaccines to children, and those conflicts "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* The District's law must yield.

The COVID-19 vaccine is not covered by the National Vaccine Act, however the logic underlying the need for parental supervision rights is even greater for this Emergency Use Authorization product.

Primarily because the Pfizer-BioNTech COVID-19 vaccine represents novel, experimental technology, it is not covered by the National Vaccine Act. Unlike the childhood vaccines covered by the National Vaccine Act, the Pfizer-BioNTech COVID-19 vaccine has not received FDA approval. It is a biologic countermeasure under Emergency Use Authorization (EUA) in accordance with 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(1-111) of the Federal Food, Drug, and Cosmetic Act and the Public Readiness and Preparedness Act (PREP Act), 42 U.S.C. § 247. Its full range of risks are unknown.

Under the PREP Act, vaccine manufacturers, healthcare providers and government planners cannot be held liable for any injuries, except for "willful misconduct" by a clear and convincing standard. No matter how defective or unreasonably dangerous, vaccine manufacturers cannot be held liable for design or manufacturing defects. In the real world, if there is no liability, there is no incentive for safety.

Pfizer is well aware that its COVID-19 vaccines carry significant risk of myocarditis and pericarditis (inflammation and damage of the heart muscle and the thin sac surrounding the heart). On October 26, 2021, Pfizer-BioNTech acknowledged the risks of myocarditis and pericarditis on page 13 of a key document entitled "*Vaccines and Related Biological Products Advisory Committee Meeting October 26, 2021, FDA Briefing Document, EUA amendment for*

Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age," FDA.GOV, https://www.fda.gov/media/153447/download, a copy of which is submitted herewith as Exhibit 20. The document's purpose was to obtain EUA for the Pfizer-BioNTech COVID-19 vaccine for use in children 5 through 11 years of age.

Page 13 of Pfizer's document states:

> **Myocarditis and pericarditis**
>
> Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of the 2-dose primary series. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and **have been highest in males 12 through 17 years of age.**

On page 14, Pfizer-BioNTech requested authorization to modify the formulation of the Pfizer-BioNTech COVID-19 vaccine by adding tromethamine, a drug commonly used to treat heart attack or cardiac bypass surgery patients. Adding this to the Pfizer-BioNTech COVID-19 vaccine underscores the risk of heart complications in children who receive the Pfizer-BioNTech COVID-19 vaccine.

Vaccine Fact Sheets and Prescribing Information now note the risks of myocarditis and pericarditis. See Exhibit 18 to Amended Ver. Compl. for a copy of the Pfizer-BioNTech COVID-19 vaccine Fact Sheet. The "Fact Sheet" operates much the same as VISs for vaccines covered by the National Vaccine Act and must be provided under the PREP Act EUA provisions. Although the Pfizer-BioNTech COVID-19 vaccine is not covered by the National Vaccine Act, vaccine injured children can receive compensation through the Countermeasures Injury Compensation Program (CICP). *See Countermeasures Injury Compensation Program (CICP)*, HEALTH RESOURCES AND SERVICES ADMINISTRATION, https://www.hrsa.gov/cicp. Like the

National Vaccine Injury Compensation Program, compensation under the CICP is based on an "Injury Table" in which timely recognition of the first manifestation of injury is critical.

Therefore, the need and justification for parental supervision and involvement is even greater with the Pfizer-BioNTech COVID-19 vaccine than routine childhood vaccinations.

B. The Minor Consent Act substantially burdens Plaintiffs' fundamental right to freely exercise religion in violation of the Religious Freedom Restoration Act.

In 1993, a near-unanimous Congress enacted the Religious Freedom Restoration Act (RFRA). Congress found that "laws 'neutral' toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise," and that "governments should not substantially burden religious exercise without compelling justification." 42 U.S.C. § 2000bb(a)(2)-(3). RFRA created a cause of action to vindicate free exercise rights. 42 U.S.C. § 2000bb-1(c). The District is subject to RFRA. 42 U.S.C. § 2000bb-2.

If the Government substantially burdens a plaintiff's free exercise of religion, that plaintiff is entitled to an exemption from the rule unless the Government "demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 695 (2014), *citing* 42 U.S.C. § 2000bb-1(b). The Minor Consent Act does not meet this "exceptionally demanding" standard. *Hobby Lobby*, 573 U.S. at 728.

1. The Minor Consent Act substantially burdens Plaintiffs' right to free exercise of religion.

RFRA defines "religious exercise" to include "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." 42 U.S.C. § 2000bb-2(4), 42 U.S.C. § 2000cc-5(7). "[B]ecause the burdened practice need not be strictly compelled by the religious tradition at issue to merit protection, courts 'focus not on the centrality of the particular activity

to the adherent's religion but rather on whether the adherent's sincere religious exercise is substantially burdened.'" *Capitol Hill Baptist Church v. Bowser*, 496 F. Supp. 3d 284, 293-294 (D.D.C. 2020), *quoting Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008).

Here, Plaintiffs have sincere religious beliefs against vaccinating their minor children and have acted on those beliefs by asserting religious exemptions. The District may disagree with those beliefs—indeed, several District Council members have expressed their disagreements publicly. But the District cannot lawfully "[a]rrogat[e] the authority to provide a binding . . . answer to this religious and philosophical question." *Hobby Lobby*, 573 U.S. at 724. "Repeatedly and in many different contexts, we have warned that courts must not presume to determine the place of a particular belief in a religion or the plausibility of a religious claim." *Employment Div. v. Smith*, 494 U.S. 872, 887 (1990); *see also Thomas v. Review Bd. of Ind. Employment Sec. Div.*, 450 U.S. 707, 715 (1981) ("Intrafaith differences . . . are not uncommon among followers of a particular creed, and the judicial process is singularly ill equipped to resolve such differences in relation to the Religion Clauses"); *Hernandez v. Commissioner*, 490 U.S. 680, 699 (1989) ("It is not within the judicial ken to question the centrality of particular beliefs or practices to a faith, or the validity of particular litigants' interpretations of those creeds"); *West Virginia Bd. of Ed. v. Barnette*, 319 U. S. 624, 642 (1943) ("If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion").

"A 'substantial burden' exists when government action rises above *de minimis* inconveniences and puts 'substantial pressure on an adherent to modify his behavior and to violate his beliefs.'" *Kaemmerling*, 553 F.3d at 678. This occurs even if the government "propose[s] alternatives" that it believes are "sensible substitutes." *Capitol Hill Baptist Church*,

496 F. Supp. 3d at 294.

The Minor Consent Act doesn't place a "*de minimis* inconvenience[]" on parents—it expressly overrides their decisions and violates their religious beliefs. This distinguishes the Act from the more "typical" vaccine cases, like *Doe v. Zucker*, 496 F. Supp. 3d 744, 756 (N.D. N.Y. 2020), where the government merely conditions a benefit—such as in-person school attendance—on the receipt of vaccinations, or where the state has decided to create one category of exemption, but not another. Because such laws "do not force parents to consent to vaccination of their children," courts in cases like that one could frame the substantive due process right at issue differently—a non-fundamental right to be free from "condition[ing] [a] child[]'s right to attend school on vaccination," for example. *Id.* This case is different: the District *already* requires vaccinations for school attendance and has already created an exemption for parents. D.C. Code § 38-506(1).

The Minor Consent Act is an entirely different kind of statute because it allows for the *actual vaccination* of children over parents' objections without parental knowledge. *C.f. B.W.C. v. Williams*, 990 F.3d 614, 621 (8th Cir. 2021) (holding that Missouri's religious exemption form did not violate the free exercise clause because it merely "communicate[d] neutrally to anyone considering opting out on religious grounds that the government discourages it," but said that "'the ultimate decision is yours'—the parents," and did not "force their children to get immunized"). Before the Minor Consent Act, if a parent claimed a religious exemption, the District could not override that decision. Now, it can. And it does so by exerting "substantial pressure" on parents and children to "modify [their] behavior and to violate [their] beliefs,'" *Kaemmerling*, 553 F.3d at 678, and by cutting the parents out of the decision-making process entirely. This is not a "*de minimis*" burden. *Id.* Depriving a religious parent of the right to

meaningfully object to vaccinations damages the right of conscience. *Actually* administering a vaccine to a child, in secret, when the District *knows* that doing so will violate a parent's sincere religious beliefs, is far worse.

2. The District does not have a compelling government interest in offering parents a religious exemption with one hand, and then stripping them of that exemption's protections with the other.

Before it can burden free exercise, "RFRA requires the Government to demonstrate that the compelling interest test is satisfied through application of the challenged law 'to the person' — the particular claimant whose sincere exercise of religion is being substantially burdened." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-31 (2006), *citing* 42 U.S.C. § 2000bb-1(b). As the Supreme Court held this past term, in *Fulton v. City of Philadelphia*, ___ U.S. ___, 2021 U.S. LEXIS 3121 (2021), "Rather than rely on 'broadly formulated interests,' courts must 'scrutinize[ ] the asserted harm of granting specific exemptions to particular religious claimants.' The question, then, is not whether the City has a compelling interest in enforcing its non-discrimination policies generally, but whether it has such an interest in denying an exception…." *Id.* at *26 (internal citations omitted, brackets in original).

When analyzing RFRA claims, courts "look beyond broadly formulated interests justifying the general applicability of government mandates and scrutinize the asserted harm of granting specific exemptions to particular religious claimants." *Gonzales v. O Centro*, 546 U.S. at 431. No such harm is present here. All Plaintiffs have claimed a religious exemption under District law—in some cases, for years. None of their children have caused any outbreaks or public health crises in the past; and there is no reason to believe they will now while attending school under a religious exemption that the District has neither suspended nor eliminated. *See Holt v. Hobbs*, 574 U.S. 352, 368 (2015) ("[T]he Department has not argued that denying petitioner an exemption is necessary to further a compelling interest . . . . At bottom, this

argument is but another formulation of the 'classic rejoinder of bureaucrats throughout history: If I make an exception for you, I'll have to make one for everybody, so no exceptions.' We have rejected a similar argument in analogous contexts, and we reject it again today"), *quoting Gonzales v. O Centro*, 546 U.S. at 436; *see also Capitol Hill Baptist*, 496 F. Supp. 3d at 298 ("The District cannot rely on its generalized interests in protecting public health or combating the COVID-19 pandemic. Rather, RFRA requires the District to 'demonstrate that the compelling interest test is satisfied through application of the challenged law "to the person"—the particular claimant whose sincere exercise of religion is being substantially burdened'").

Nor can the District rely on the generalized compelling interests that courts typically rely on in cases like *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). First, *Jacobson* does not control cases that are brought under RFRA. While *Jacobson* used a more "relaxed standard" to evaluate a Massachusetts smallpox regulation, "Congress incorporated a specific burden-shifting framework into RFRA" that "'did more than merely restore the balancing test used in the [pre-*Smith*] line of cases; it provided even broader protection for religious liberty than was available under those decisions.'" *Capitol Hill Baptist*, 496 F. Supp. 3d at 297, *quoting Hobby Lobby*, 573 U.S. at 695 n. 3. Accordingly, "Courts must respect that decision and dutifully apply its scheme." *Capitol Hill Baptist*, 496 F. Supp. 3d at 297.

More importantly, while *Jacobson* recognized the traditional "power of the states to enact and enforce quarantine laws for the safety and the protection of the health of their inhabitants," Justice Harlan stated repeatedly that the regulation at issue was adopted by the Cambridge Board of Health at a time when smallpox was "prevalent and increasing at Cambridge." *Jacobson*, 197 U.S. at 28. "*If such was the situation*," the regulation would be "justified by the necessities of the case," and the Court would not "usurp the functions of another branch of the government." *Id.*

(emphasis added). But if the "necessities of the case" were different, so too would be the court's deference. "It might be," the Court warned, "that an acknowledged power of a local community to protect itself against an epidemic threatening the safety of all, might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons." *Id.* And if the government adopts an "arbitrary" law—"if a statute *purporting* to have been enacted to protect the public health, the public morals or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law"—then "it is the duty of the courts to so adjudge, and thereby give effect to the Constitution." *Id.* at 31.

The Minor Consent Act is such a law. Whereas *Jacobson* dealt with a uniform, vaccination regulation, which was designed "to meet and suppress the evils of a[n] . . . epidemic that imperilled an entire population," *id.* at 30-31, the Minor Consent Act is aimed squarely at children whose parents have claimed a lawful exemption that the District *created*. Whatever position the District takes on the "opposing theories" of vaccinations, *id.* at 30, its decision to recognize religious exemptions in the first place suggests that such exemptions are not inherently incompatible with the demands of public health.

While several members of the Council cited the COVID-19 pandemic to justify the Minor Consent Act, the list of vaccines that the District could administer without parents' knowledge when it adopted the act in March 2021 did *not* include the COVID-19 vaccine. Instead, the Act is limited to vaccines the Advisory Committee on Immunization Practices ("ACIP") recommends. And until May 12, 2021, that list included only routine childhood

vaccines. *See* D.C.M.R., Title 22-B, § 600.9(a). If the purpose of the Minor Consent Act was to truly react to the "necessities" of a global pandemic, this reliance on independent action from ACIP is a curious drafting choice.

Perhaps the *real* goal of the Minor Consent Act is not to react to a global pandemic, but to bypass the decisions of religious parents who object to *any* ACIP-recommended vaccinations, whether pre- or post-pandemic. That would be illegal, though, even under *Jacobson's* deferential standard: the District cannot adopt a statute "*purporting* to have been enacted to protect the public health," but which is "beyond all question, a plain, palpable invasion of rights secured by the fundamental law." *Jacobson*, 197 U.S. at 31. The Minor Consent Act does just that. And, of course, laws that "singl[e] out a certain class of citizens for disfavored legal status or general hardships" are constitutionally suspect for many other reasons. *Romer v. Evans*, 517 U.S. 620, 633 (1996); *see also id.* at 634-35 ("[L]aws of the kind now before us raise the inevitable inference that the disadvantage imposed is born of animosity toward the class of persons affected. 'If the constitutional conception of "equal protection of the laws" means anything, it must at the very least mean that a bare . . . desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest'"), *quoting Department of Agriculture v. Moreno*, 413 U.S. 528, 534 (1973).

3. The Minor Consent Act is not narrowly tailored.

"The least-restrictive-means standard is exceptionally demanding"— to prevail, the government must "sho[w] that it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting part[y]." *Holt*, 574 U.S. at 364-65, *quoting Hobby Lobby*, 573 U.S. at 728. "If a less restrictive means is available for the Government to achieve its goals, the Government must use it." *United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 815 (2000).

Plaintiffs contend that the Minor Consent Act does not further any compelling interest rooted in health or safety. There are clearly less-restrictive approaches to accomplish that. One need look no further than the status quo before the Act was adopted. The District required children to have certain vaccines to attend school. D.C. Code § 38-502. The District allowed parents to exempt their children from those requirements based on their sincere religious beliefs. D.C. Code § 38-506(1). And the District respected that choice. There is no doubt that requiring parents to claim a religious exemption in writing, and then respecting that claim, imposes a much lower burden on the free exercise rights of parents than requiring them to claim a religious exemption in writing, and then ignoring that claim based on the sole discretion of non-parents who disagree with it. As the Supreme Court has noted repeatedly in the context of free expression, it is unconstitutional to "make[] the peaceful enjoyment of freedoms which the Constitution guarantees contingent upon the uncontrolled will of an official. . . ." *Shuttlesworth v. Birmingham*, 394 U.S. 147, 151 (1969). Yet that is precisely what the Act does. In so doing, the Minor Consent Act clearly violates the free exercise rights of parents under RFRA.

C. The Minor Consent Act violates the free exercise clause of the First Amendment.

The First Amendment to the Constitution states, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." The First Amendment clearly applies to state and local governments. *Cantwell v. Connecticut*, 310 U.S. 296 (1940). The Minor Consent Act is unconstitutional on its face. Specifically, the Amendment to D.C. Code § 38-602(b)(2) states: "if a minor is utilizing a religious exemption for vaccinations… the health care provider shall leave blank part 3 of the immunization record." This part of the Minor Consent Act is specifically targeting and endangering children whose parents have claimed a lawful religious exemption. This is directly contrary to the religious neutrality the Constitution requires.

"The Constitution commits government itself to religious tolerance, and upon even slight suspicion that proposals for state intervention stem from animosity to religion or distrust of its practices, all officials must pause to remember their high duty to the Constitution and to the rights it secures." *Masterpiece Cakeshop, LTD., v. Colorado Civil Rights Commission* 138 S. Ct. 1719, 1731 (2018) (internal citations omitted).

The State has a "duty under the first amendment not to base laws or regulations on hostility to a religion or religious viewpoint." *Masterpiece Cakeshop.* 138 S. Ct. at 1721, yet this is exactly what the D.C. Minor Consent Act does. As the Supreme Court explained in *Masterpiece Cakeshop*, the government's "hostility was inconsistent with the First Amendment's guarantee that our laws be applied in a manner that is neutral toward religion." *Id.* The D.C. Minor Consent Act is not neutral toward religion; it specifically targets children whose parents have exercised lawful religious rights.

In essence, the Minor Consent Act commands that if a parent files a lawful religious exemption from vaccinations for her child, then not only is her religious exemption ignored, but also the protections of 42 U.S.C. § 300aa-25(a) are stripped away. The Minor Consent Act is clearly hostile to religion, because whether the vaccination record is left "blank" is based upon the parents' religious exemption form. The Minor Consent Act clearly violates the First Amendment because the District disregards very specific rights under the Vaccine Act *because* the parent exercised a lawful religious right.

D. The Minor Consent Act deprives Plaintiffs of their fundamental rights to direct the medical care of their children, in violation of the due process clause of the Fifth Amendment

"The liberty interest at issue in this case—the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000). Citing "extensive precedent," *Troxel*

concluded that "it cannot now be doubted that the Due Process Clause of the Fourteenth Amendment protects the fundamental right of parents to make decisions concerning the care, custody, and control of their children." *Troxel*, 530 U.S. at 66; *see also Santosky v. Kramer*, 455 U.S. 745, 753 (1982) (freedom of personal choice in matters of family life is a fundamental liberty interest protected by the Fourteenth Amendment"); *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972) ("The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition"); *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 639-40 (1974) ("This Court has long recognized that freedom of personal choice in matters of marriage and family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment").

The fundamental right implicated here—the right of fit parents to be informed of and to consent to the immunizations of their minor children in non-emergency situations—lies at the core of this liberty interest. "[T]he custody, care and nurture of the child reside first in the parents, whose primary function and freedom include preparation for obligations the state can neither supply nor hinder." *Troxel*, 530 U.S. at 65-66, *quoting Prince v. Massachusetts*, 421 U.S. 158, 166 (1944). "The right and liberty interest in parenting and the right to refuse unwanted medical procedures are fundamental rights." *Doe v. Zucker*, 496 F. Supp. 3d at 756, *citing Troxel*, 530 U.S. at 66; *see also Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 278 (1990) (finding a "constitutionally protected liberty interest in refusing unwanted medical treatment").

Through the Minor Consent Act, the District has arrogated to itself—and to the unspecified class of persons who may administer vaccines to minors under the Act—the power

to override fit parents' decisions. While parental rights are not absolute, "the Due Process Clause does not permit a State to infringe on the fundamental right of parents to make childrearing decisions simply because a state judge believes a 'better' decision could be made." *Troxel*, 530 U.S. at 72-73. Much more is required, and the Minor Consent Act again falls short.

1. The Minor Consent Act makes no attempt to rebut the presumption that fit parents act in the best interests of their children.

The Supreme Court has consistently recognized that "there is a presumption that fit parents act in the best interests of their children." *Troxel*, 530 U.S. at 68. This presumption extends to medical decisions, as well as other child-rearing decisions. In *Parham v. J.R.*, the Supreme Court held that parents "have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations." *Parham v. J.R.*, 442 U.S. 584, 602 (1979) (brackets in original). "Surely," the Court said, this must "include[] a 'high duty' to recognize symptoms of illness and to seek and follow medical advice." *Id.*

There is no doubt that vaccination carries risk, including of brain damage and death. That is precisely why Congress created the National Vaccine Act, why Congress requires that patients be provided with VISs before vaccination, and why Congress requires that these statements be provided to parents *before* vaccines can be administered to minor children. *See* 42 U.S.C. § 300aa-26(d).

For minors, who *cannot* legally consent to many things, that assumption of risk lies with parents. "The law's concept of the family rests on the presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions." *Parham*, 442 U.S. at 602; *see also Washington v. Harper*, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty. . . . While the therapeutic benefits of

antipsychotic drugs are well documented, it is also true that the drugs can have serious, even fatal, side effects") (internal citations omitted); *Van Emrik v. Chemung County Dep't of Social Servs.*, 911 F.2d 863, 867 (2d Cir. 1990) ("[T]the constitutional liberty interest of parents in the 'care, custody, and management of their child' includes a significant decision-making role concerning medical procedures sought to be undertaken by state authority upon their children") (internal citations omitted); *Wallis ex rel. Wallis v. Spencer*, 202 F.3d 1126, 1142 (9th Cir. 1999) ("[P]arents have a right arising from the liberty interest in family association to be with their children while they are receiving medical attention . . . . Likewise, children have a corresponding right to the love, comfort, and reassurance of their parents while they are undergoing medical procedures, including examinations—particularly those, such as here, that are invasive or upsetting"); *Mann v. Cty. Of San Diego*, 907 F.3d 1154, 1161 (9th Cir. 2018) ("The right to family association includes the right of parents to make important medical decisions for their children, and of children to have those decisions made by their parents rather than the state").

Here, Victor, Shameka, Shanita, and Jane are all fit parents. They have used their own maturity, experience, and capacity for judgment to decide whether to vaccinate their children. They have decided that vaccinating their children would be contrary to their sincere religious beliefs. And they have expressed that to the District by filing religious exemptions, which they have a statutory right to do under D.C. Code § 38-506(1). As fit parents, the Fifth Amendment presumes that their decisions are in the best interests of their children.

The Minor Consent Act takes the opposite approach: if someone disagrees with a parent's decision not to vaccinate his or her child, and believes that the child can provide informed consent, then the parent's decision can be ignored and a vaccine can be administered without the parent's knowledge, much less consent. But a parent's decision not to vaccinate a child does not

make that parent unfit. And even if an eleven-year-old child had the knowledge of vaccine warnings and her own personal medical history to give informed consent, that also wouldn't render his or her parent "unfit."

In short, the Minor Consent Act overlooks the core demand of the Fifth Amendment: the decisions of fit parents cannot be infringed based on "nothing more than a simple disagreement" between the District and parents concerning a child's best interests. *Troxel*, 530 U.S. at 60. "[W]hile the need to protect children from *unfit* parents is a well-recognized compelling reason for burdening family integrity, defendants must make at least some showing of *parental unfitness* in order to establish such a compelling state interest." *De Nolasco v. United States Immigration & Customs Enforcement*, 319 F. Supp. 3d 491, 501 (D.D.C. 2018) (emphasis added), *citing Quillion v. Walcott*, 434 U.S. 246, 255 (1978). Absent a showing of unfitness, the State is simply not on an equal footing with parents when it comes to child rearing decisions. As the Supreme Court held in *Troxel*, "so long as a parent adequately cares for his or her children (*i.e.*, is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children." *Troxel*, 530 U.S. at 68-69.

The Minor Consent Act does not even *account* for the presumption that fit parents act in the best interests of their children, much less *rebut* that presumption. The Act draws no distinction whatever between "fit" and "unfit" parents: *any* parent's decision can be ignored if someone believes that a child can give informed consent. And no parent—no matter how fit—will be told if her child is vaccinated against her wishes. On the contrary, that fact will be *hidden*. D.C. Code § 38-602(a)(2). This violates the Fifth Amendment.

2. The Minor Consent Act does not give special weight to the decisions of fit parents.

In *Troxel*, the "problem" identified by the Supreme Court was that when the Superior Court intervened in the mother's visitation decision, "it gave no special weight to [her] determination of her daughters' best interests." *Troxel*, 530 U.S. at 60. The Court held that "if a fit parent's decision of the kind at issue here becomes subject to judicial review, the court must accord *at least* some special weight to the parent's own determination." *Id.* at 70 (emphasis added).

Here, rather than presuming that fit parents act in the best interests of their children, and then giving special weight to a parent's decision that his or her child should not be vaccinated, the Minor Consent Act does the exact opposite. The parent's decision is not factored into the equation at all, much less given "special weight." *See* D.C.M.R., Title 22, § 600.9(a) And if a child's parent files a religious exemption or an HPV exemption, her decision is *targeted*, not protected. *See* D.C. Code § 38-602(a)(2).

3. The Minor Consent Act is not narrowly tailored to further a compelling state interest.

A fit parent's decision with respect to the care, custody, and control of his or her child cannot be overridden by the government unless it has a compelling interest, and its actions are narrowly-tailored to accomplish that compelling interest. The due process clause "forbids the government to infringe . . . 'fundamental' liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997) (emphasis in original).

Because the liberty interest shared by children and parents is "fundamental," the Minor Consent Act must "promote, in a particular case, compelling governmental interests," and "[i]f there are other, reasonable ways to achieve those goals with a lesser burden on constitutionally

protected activity, a State may not choose the way of greater interference. If it acts at all, it must choose 'less drastic means.'" *Franz v. United States*, 707 F.2d 582, 607 (D.C. Cir. 1983). "This principle has been repeatedly reaffirmed when constitutionally protected familial rights have been threatened." *Id.*, *citing Carey v. Population Services International*, 431 U.S. 678, 686 (1997); *Doe v. Bolton*, 410 U.S. 179, 194-95 (1973); *see also De Nolasco*, 319 F. Supp. at 500 ("Substantial governmental burdens on family integrity are subject to strict scrutiny review, and they survive only if the burden is narrowly tailored to serve a compelling state interest"), *citing Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 702 (D.C. Cir. 2007).

Plaintiffs are likely to prevail on their Fifth Amendment claim for the same reasons they are likely to prevail under RFRA: the Minor Consent Act, as applied, does not further any compelling government interest because the District has no particular reason to deny Plaintiffs the same exemption now that it has given them before—and still offers. Nor is the Minor Consent Act narrowly tailored to accomplish any of the interests that animate traditional vaccination laws. *See supra* at 18-22. The motion should be granted.

II. WITHOUT INJUNCTIVE RELIEF, PLAINTIFFS WILL BE IRREPARABLY HARMED.

Plaintiffs will be irreparably harmed if this Court is satisfied that the injury complained of is "beyond remediation," *League of Women Voters*, 838 F.3d at 7-8, as opposed to "purely financial or economic," *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 555 (D.C. Cir. 2015), and if "[t]he injury complained of is of such imminence that there is a 'clear and present' need for equitable relief to prevent irreparable harm." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). The motion should be granted because the injuries complained of are both irreparable and imminent.

A. The deprivation of statutory and constitutional rights is an irreparable injury.

"It has long been established that the loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Mills v. District of Columbia*, 571 F.3d 1304, 1312 (D.C. Cir. 2009), *quoting Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Because the deprivation of constitutional rights is an irreparable injury, "by extension the same is true of rights afforded under the RFRA, which covers the same types of rights as those protected under the Free Exercise Clause of the First Amendment." *Capitol Hill Baptist*, 496 F. Supp. at 301, *quoting Tyndale House Publishers, Inc. v. Sebelius*, 904 F. Supp. 2d 106, 129 (D.D.C. 2012). The Minor Consent Act substantially burdens the right of parents who have sought and claimed a lawful vaccine exemption because of their sincere religious beliefs. The resulting injury is not merely economic; it is irreparable.

Finally, this Court has recognized that the loss of a clear statutory entitlement is not "merely economic" harm, for the same reason that the loss of a constitutional right is not merely economic: "[o]nce the statutory entitlement has been lost, it cannot be recaptured." *Hi-Tech Pharmacal Co. v. United States FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008), *quoting Apotex, Inc. v. FDA*, 2006 U.S. Dist. LEXIS 20894 at *17 (D.D.C. Apr. 19, 2006) (UNPUBLISHED), *aff'd*, *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). The National Vaccine Act imposes duties on those who administer vaccines, that are commensurate not only with the constitutional rights of parents, but the right to be free from nonconsensual medical care in general. Information about vaccine risks *must* be disclosed to patients before vaccines are administered, and when the patient is a minor child, that information must be disclosed to a parent. The Minor Consent Act is not only inconsistent with the National Vaccine Act—it expressly contradicts it. And in so doing, it will deprive parents of their statutory right to know that their child is about to be vaccinated,

and the risks attendant to that decision. If that opportunity is lost, "it cannot be recaptured." And no amount of economic damages will make up for it. *Hi-Tech Pharmacal*, 587 F. Supp. 2d at 11.

B. The District's threat to the constitutional rights of Plaintiffs is imminent.

An irreparable injury is imminent if a violation of protected rights is "either ongoing or threatened." *Wagner v. Taylor*, 836 F.2d 566, 576 n. 76 (D.C. Cir. 1987). "As a preliminary injunction requires only a likelihood of irreparable injury, Damocles's sword does not have to actually fall on all appellants before the court will issue an injunction." *League of Women Voters*, 838 F.3d at 8-9, *citing Winter v. NRDC, Inc.*, 555 U.S. 7, 22 (2008).

Mills v. District of Columbia, 571 F.3d 1304, is instructive on this point. In *Mills*, citizens of the District challenged a Neighborhood Safety Zones (NSZ) checkpoint program where Metropolitan Police Department (MPD) officers would stop and ask motorists if they had a "legitimate reason" for entry into that zone. *Mills v. District of Columbia*, 584 F. Supp. 2d 47, 50-51 (D.D.C. 2008). The District Court denied the plaintiffs' motion for a preliminary injunction, concluding both that they were unlikely to prevail on the merits and that they could not prove irreparable harm.

On appeal, the D.C. Court of Appeals reversed. After concluding that the plaintiffs were likely to prevail in their Fourth Amendment challenges, the Court "further conclude[d] that appellants have sufficiently demonstrated irreparable injury, particularly in light of their strong likelihood of success on the merits." *Mills*, 571 F.3d at 1312. The myriad problems with the checkpoint program made it "apparent that appellants' constitutional rights are violated," *id.*, and as the Court had held before, a preliminary injunction may issue "where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." *CityFed Fin. Corp. v. Office of Thrift Supervision, United States Dep't of Treasury*, 58 F.3d 738, 747 (D.C. Cir. 1995), *citing McPherson*, 797 F.2d at 1078.

Moreover, "the loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" *Mills*, 571 F.3d at 1312, *quoting Elrod*, 427 U.S. at 373. Faced with a clear constitutional violation, and a stated intention on the part of the District to violate that right in the future, the court concluded that the "appellants have established the requisites for the granting of a preliminary injunction." *Id.*

Here, as in *Mills*, the likelihood that Plaintiffs will succeed on the merits is particularly strong. The Minor Consent Act goes further than any vaccination law any other court has considered. It imposes duties on those who administer vaccines that directly conflict with the duties of the National Vaccine Act. It broadly overrides the consent of both religious and non-religious parents without serving any compelling interest. And the deprivation of such rights is the quintessential example of an irreparable injury.

Additionally, Plaintiffs here face a threat to their rights that is more imminent than the threat posed even in *Mills*. While the *Mills* plaintiffs could not state exactly how they would be harmed, *Mills*, 584 F. Supp. 2d 47 at 63, Plaintiffs here know the Minor Consent Act is depriving them of their rights: The Minor Consent Act, on its face, presents a clear threat to Plaintiffs' decision to decline vaccines.

Defendants are bombarding Plaintiffs' children with a mass media campaign to "take the shot." Defendants have created a pressure cooker environment of direct, state-sponsored peer pressure. Plaintiffs' children are subjected on a daily basis to a carrot-and-stick approach to receive vaccines against their parents' judgment. Plaintiffs and their children have faced pressure from schools to have the children vaccinated. L.B. is very dramatically expressing that he will take the shot if offered it against his father's direct commands.

Whether L.B. or any of the other children "take the shot" or not, the level of pressure

Defendants are placing on Plaintiffs' children is clearly interfering with the parents' fundamental rights and liberty interest to raise their children and the children's right to be raised by their parents.

The Minor Consent Act is designed precisely so that it can be invoked by any doctor's office, clinic, or medical professional at any time, without parents' knowledge. Unless a child self-reports that he has received a vaccine, the parents' constitutional injury may go undiscovered indefinitely. The Minor Consent Act overrides fundamental constitutional rights, in ways that are clear, substantial, and brazen. An injunction from this Court will prevent the irreparable loss of those rights, until such time as the Court can decide its legality. This Court need not wait for Damocles' sword to fall before granting relief. *League of Women Voters*, 838 F.3d at 8-9. The motion should be granted.

III. INJUNCTIVE RELIEF WILL FURTHER THE PUBLIC INTEREST.

Finally, a preliminary injunction may be granted when "the balance of equities tips in [its] favor, and . . . an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. at 20. When the government is the opposing party, these factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). The "enforcement of an unconstitutional law is always contrary to the public interest" because "the Constitution is the ultimate expression of the public interest." *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013).

The Minor Consent Act places an enormous burden on parents. *See League of Women Voters*, 838 F.3d at 12 ("[A]ppellants' extremely high likelihood of success on the merits is a strong indicator that a preliminary injunction would serve the public interest"). In stark contrast, enjoining the District from enforcing the Minor Consent Act places no greater burden on the District than those it has borne since 1985, when it originally created the religious exemption.

"While the public clearly has an interest in controlling the spread of disease, the public also has an interest in honoring protections for religious freedom in accordance with the laws passed by Congress." *Capitol Hill Baptist*, 496 F. Supp. at 302-303. Where "the government has failed to show a compelling interest" in applying a law to Plaintiffs, "the public has little interest in the 'uniform application' of the regulations. The public interest instead weighs in favor of the plaintiffs." *Tyndale House Publishers, Inc.*, 904 F. Supp. 2d at 130.

CONCLUSION

It is impossible to view this case without considering the unique moment of history in which it arises. Vaccines permeate our national discourse in ways that were unimaginable just a few years ago. The hardships of the last two years have made discourse increasingly personal and passionate.

The Minor Consent Act is not a pandemic measure; its scope is far broader than that. Yet even in pandemics, when the necessities of the moment may demand "an energetic response by the political branches to the many uncertainties accompanying the onset of a public health crisis," there comes a time "when a crisis stops being temporary, and as days and weeks turn to months and years, [when] the slack in the leash eventually runs out. 'While the law may take periodic naps during a pandemic, we will not let it sleep through one.'" *Capitol Hill Baptist*, 496 F. Supp. 3d at 297, *quoting Roberts v. Neace*, 958 F.3d 409, 414-15 (6th Cir. 2020) (*per curiam*).

The Minor Consent Act sets the concerns of our time against timeless legal truths: the fundamental right of fit parents to act in the best interest of their children and the freedom to exercise one's sincere religious beliefs without coercion—freedoms that both Congress and the courts have long protected. Those freedoms are now threatened.

For the foregoing reasons, Plaintiffs' motion for preliminary injunction should be granted.

Respectfully submitted this 14th day of December 2021:

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

VICTOR M. BOOTH,
individually and as next friend of
L.B. a minor child;

SHAMEKA WILLIAMS,
individually and as next friend of
K.G. and R.T., minor children;

SHANITA WILLIAMS,
individually and as next friend of
N.W. and M.R., minor children; and

JANE HELLEWELL,
individually and as next friend of
H.B., a minor child,
Plaintiffs,

vs.

MURIEL BOWSER,
in her official capacity as Mayor of the
District of Columbia;

LAQUANDRA NESBITT,
In her official capacity as
Director of the District of Columbia
Department of Health; and

LEWIS FEREBEE,
In his official capacity as
Chancellor of the District of Columbia
Public Schools,
Defendants.

Case No. 21-1857

APPENDIX OF EXHIBITS SUBMITTED IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

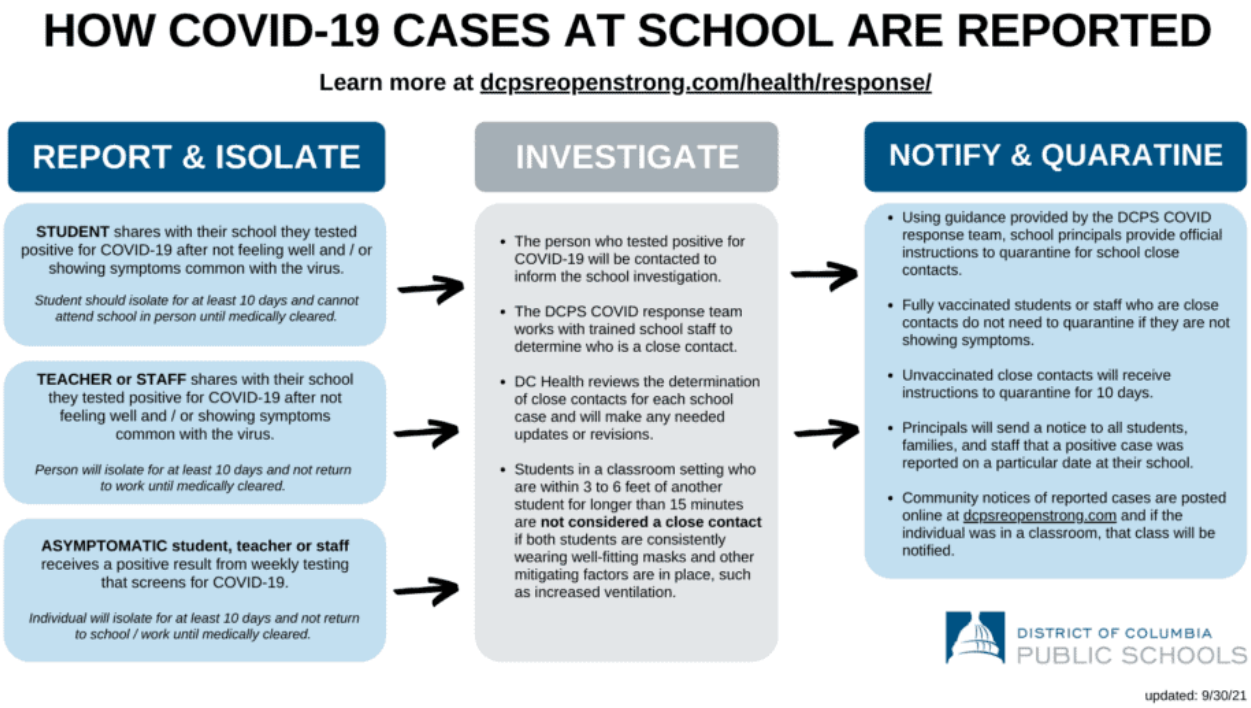
CUMULATIVE INDEX OF EXHIBITS	
Exhibit #	**CITATION**
EXHIBITS PREVIOUSLY SUBMITTED WITH VERIFIED AMENDED COMPLAINT	
1	District of Columbia's Child Health Certificate
2	*Take the Shot, DC., Get Vaccinated*, GOVERNMENT OF THE DISTRICT OF COLUMBIA, MURIEL BOWSER, MAYOR, https://coronavirus.dc.gov/page/get-vaccinated
3	GOVERNMENT OF THE DISTRICT OF COLUMBIA, MURIEL BOWSER, MAYOR, https://coronavirus.dc.gov/node
4	*Vaccine Clinic*, KIPP DC: PUBLIC SCHOOLS, https://www.kippdc.org/vaccine-clinic/ https://www.kippdc.org/vaccine-clinic/#tab-3
5	*Find COVID-19 Vaccines*, VACCINES.GOV, https://www.vaccines.gov/search/
6	*Vaccinations for Students*, DCPSREOPENSTRONG.COM, https://dcpsreopenstrong.com/vaccines/
7	*Healthy Operations*, KIPP DC: PUBLIC SCHOOLS, https://www.kippdc.org/healthy-operations/
8	Nuremberg Code
9	School Year 2021-22, Student Athletes: COVID-19 Vaccination Religious Exemption Certificate
10	Illustration
11	"Peer Pressure" Drawing
12	Hardy Middle School walk in vaccine clinic flyer
13	School Without Walls Letter
14	The Vaccine Injury Table
15	ACIP's Recommended Child and Adolescent Immunization Schedule
16	HRSA $4.6 BILLION VICP (See first page for title; last page for amount.)
17	Collective Exhibit of VISs
18	Pfizer-BioNTech Vaccine Fact Sheet

CUMULATIVE INDEX OF EXHIBITS	
Exhibit #	**CITATION**
EXHIBITS SUBMITTED WITH MOTION FOR PRELIMINARY INJUNCTION	
19	*COVID-19 Response Protocol FAQ*, #ReopenStrong, https://dcpsreopenstrong.com/health/response/
20	*Vaccines and Related Biological Products Advisory Committee Meeting October 26, 2021, FDA Briefing Document, EUA amendment for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age*, FDA.GOV, https://www.fda.gov/media/153447/download

EXHIBIT 19

Select Language

COVID-19 Response Protocol FAQ



Through the DCPS COVID-19 Response Protocol, every staff member will be trained to confidentially report potential exposure in a school building. If there are any confirmed cases of COVID-19 reported to DCPS by a student, family, or staff member — DCPS will follow DC Health's COVID reporting criteria — for contact tracing purposes.

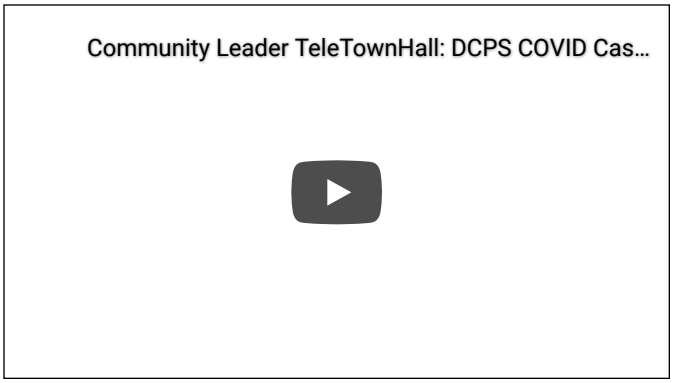
Please use this list of frequently asked questions to help you better understand what happens when there is a positive reported case of COVID-19 at school.

Notices of reported positive cases (https://dcpsreopenstrong.com/health/response/notifications/) will be shared with a school community if a person has been in the building during their infectious period. Note that DCPS will always maintain confidentiality of positive persons.

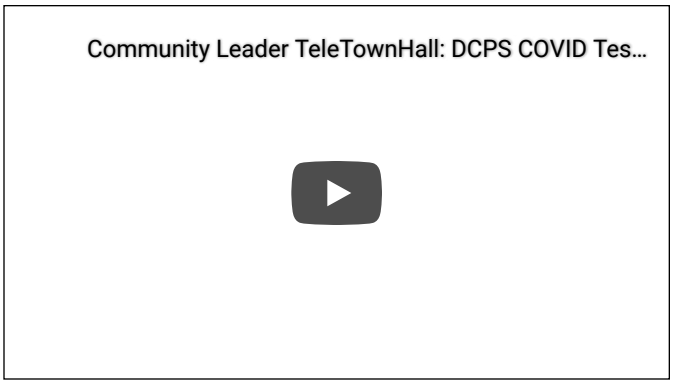
View sample messages alerting a school community of a reported positive case and close contact instructions for students and staff.

- Sample community notice of a reported case at school (https://45biv636w8lm1agg3ozqtqg1-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/FINAL_Community_Notice.pdf)
- Sample staff close contact quarantine instructions (https://45biv636w8lm1agg3ozqtqg1-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/FINAL_Instruction_to_Quarantine_Staff.pdf)
- Sample student close contact quarantine instructions (https://45biv636w8lm1agg3ozqtqg1-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/FINAL_Instruction_to_Quarantine_Student.pdf)

COVID-19 Response Town Halls



On September 29, DCPS help a tele-town hall to share what happens when someone tests positive for COVID-19 while in our school buildings.



On October 6, DCPS held a tele-town hall to share how asymptomatic and symptomatic testing is available for students at school.

The next tele-town hall is on Wednesday, October 20 at 5:00 p.m.

You can RSVP here. (https://www.eventbrite.com/e/dcps-covid-19-protocol-updates-telephone-townhall-series-tickets-175673152127)

Frequently Asked Questions

— What if someone at my student's school tests positive for COVID-19?

If a student or staff member who was in the building during their infectious period and reports a positive test for COVID-19, schools will follow the health and safety guidance released by DC Health (https://coronavirus.dc.gov/sites/default/files/dc/sites/coronavirus/page_content/attachments/COVID-19_DC_Health_Guidance_For_Schools_Reopening_8-20-2021.pdf).

The positive individual will immediately begin working or learning from home and consult their healthcare provider, and DCPS will begin a contact tracing investigation. We will provide self-quarantine instructions to close contacts, notify the school community about the reported positive case if the person was in the building during their infectious period, and follow steps outlined by DC Health and the Centers for Disease Control and Prevention (CDC) for cleaning, disinfecting, and sanitizing of school spaces.

— What is a close contact?

Based on the updated guidance from DC Health, a person in a school setting is considered a close contact if they are within 6 feet of an infected person for more than 15 minutes within a 24-hour window within 2 days prior to illness onset or positive test result.

Please note that students who are within 3 to 6 feet of another student for longer than 15 minutes are not considered a close contact if all students are consistently wearing well-fitting masks and other mitigating factors that part of DCPS' health and safety measures are in place (physical distancing, increased ventilation, etc.). Assigned seating will be utilized in classrooms where students may be seated within 3 feet of each other to assist with contact tracing.

— What is DCPS' COVID-19 testing protocol?

As of August 27, students will now be automatically enrolled in the testing program which supports asymptomatic testing, symptomatic testing and testing for close contacts. Testing programs that screen for COVID-19, alongside other prevention strategies, can detect new positive cases of COVID-19 and work to prevent potential outbreaks. This not only protects the health and wellness of our school communities but supports schools to remain open for in-person instruction safely.

The test will be a non-invasive, saliva-based PCR test. Instead of a nasal swab, students will hold a small vial with a funnel attached and produce a saliva sample.

1. **Asymptomatic Testing —** DCPS will test 10 percent of students each week to screen for COVID-19 as part of our health and safety protocols, targeting unvaccinated students. Families will receive more information from their school and DC Health on how to receive their asymptomatic test results and how to keep their household safe if a student tests positive. Asymptomatic testing will begin on a rolling basis at schools starting September 2, 2021.

2. **Symptomatic Testing —** Will take place in a school's Health Isolation Room is intended for students displaying any red flag symptoms or at least two other COVID-19 symptoms while at school. This service is available daily.

This transition from an opt-in COVID-19 testing model to an opt-out model does not affect a parent's rights concerning their student's participation. **To opt-out, parents/guardians or students over the age of 18 will now need to email or provide their schools with a signed opt-out form available at osse.dc.gov/page/school-based-covid-19-testing (http://osse.dc.gov/page/school-based-covid-19-testing).** On the form, the District is providing detailed information on the testing program so that parents can make an informed decision whether to affirmatively opt out of the program.

— What if my student tests positive for COVID-19?

Anyone who tests positive for COVID-19 should not attend school and should isolate for at least 10 days and show improvement of symptoms, including no fever for 24 hours. Please report the positive result to your school, so the school can work with contact tracers begin their investigation and determine next steps for notifying close contacts for this case.

A contact tracer will interview the individual who reported a positive test to identify other close contacts outside of the school; reach out to all quarantined contacts to provide information on the precautions to follow while in quarantine; and assist individuals in obtaining resources they may need during their quarantine period.

— When is it safe for a student to return to school if they tested positive for COVID-19?

After the quarantine period is concluded, DCPS requires students meet symptom-based criteria to return, have documentation from a healthcare provider or contact tracing force confirming that the student has met criteria to return after illness.

If symptomatic, a student may return only after:

1. At least 24 hours after the fever has resolved without the use of fever-reducing medication (e.g., Motrin, Tylenol) and respiratory symptoms have improved; AND
2. At least 10 days* after symptoms first appeared, whichever is later

**Note: Some individuals, including those with severe illness, may have longer quarantine periods per DC Health or their healthcare provider.*

If asymptomatic, a student may return only after 10 days from the date of a positive test.

— What happens if my student is a close contact?

If your student is identified as a close contact for a reported positive case at school, your principal will provide instructions to quarantine.

If an unvaccinated student or staff member is a close contact to someone who tests positive for COVID-19, they will be required to quarantine for at least 7 days. Students or staff may return to the classroom after 7 days if they take a COVID-19 test on or after day 5 and receive a negative result. Unvaccinated students or staff who do not take a test must quarantine for 10 days.

Vaccinated students and staff who are in close contact to someone who tests positive for COVID-19 do not need to quarantine if they are not showing symptoms but are recommended to take a test between 3 and 5 days after they are exposed.

— How will my student receive instruction if they are quarantining?

Exhibit 19

If a teacher is unable to provide in-person instruction, DCPS will first employ substitutes to continue in-person learning for the class.

Students who are required to quarantine will be provided with a DCPS device for learning at home. Course content will be available via Canvas for students learning at home. Instruction may be fully virtual, a mix of simultaneous in-person and virtual instruction, or self-guided, depending upon the number of students quarantining and the availability of the teacher. Families will be informed by their school about when and how virtual instruction will be provided.

— How will student attendance be reported if they are quarantining?

For students who are required to quarantine but not at the direction of DCPS (e.g., because a family member tested positive for COVID-19 and they were contacted by a contact tracer), the parent/guardian must provide written documentation of the quarantine. The written note must include the date of COVID-19 exposure; the length of time the student has been directed to quarantine by a medical professional or contact tracer; and the name, organization, and contact information of the medical professional or contract tracer.

Please note, students required to quarantine at the direction of DCPS (e.g., because a teacher tested positive for COVID-19) do not need to provide documentation.

— Are teachers and school staff required to receive the COVID-19 vaccine?

Per Mayor's Order 2021-099 (https://coronavirus.dc.gov/page/mayor%E2%80%99s-order-2021-099-covid-19-vaccination-certification-requirement-district-government), DCPS staff and school contractors are required to provide proof of COVID-19 vaccination by September 19, 2021. Any individual staff person who has a religious or medical exemption to the vaccine will be required to take a weekly COVID-19 test.

All students 12 and older are also highly encouraged to get vaccinated, but it is not a requirement to attend school. DC residents can visit vaccinate.dc.gov to find a free school clinic or public vaccination site near them.

— What happens if a student feels unwell with COVID-19 symptoms during the school day?

A Patient Care Technician at the school will escort the student to the Health Isolation Room (HIR). This is a safe identified space within the school building that will keep symptomatic individuals with potential COVID-19 symptoms separate from other people while they receive medical support, including COVID-19 testing, and await pick-up. Once a parent or guardian arrives, the student will be escorted to the entrance to go home or to a health care facility, depending on the severity of symptoms.

— Someone in my household tests positive for COVID-19, what should my student do?

DC Health recommends that students should get tested for COVID-19 if anyone in their household has symptoms of COVID-19, even if the student does not have symptoms. All members of the household should be tested at the same time.

Page updated: October 8, 2021

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Exhibit 19

EXHIBIT 20

Vaccines and Related Biological Products Advisory Committee Meeting
October 26, 2021

FDA Briefing Document

EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age

Exhibit 20

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1 EXECUTIVE SUMMARY

On October 6, 2021, Pfizer submitted a request to FDA to amend its Emergency Use Authorization (EUA) to expand use of Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) for prevention of COVID-19 caused by SARS-CoV-2 in individuals 5 through 11 years of age (hereafter 5-11 years of age). The proposed dosing regimen is a 2-dose primary series, 10 µg mRNA/per dose, administered 3 weeks apart. This EUA request initially included safety data from 1,518 BNT162b2 recipients and 750 placebo (saline) recipients 5-11 years of age who are enrolled in the Phase 2/3 portion (Cohort 1) of an ongoing randomized, double-blinded, placebo-controlled clinical trial, C4591007. Among Cohort 1 participants, 95.1% had safety follow-up ≥2 months after Dose 2 at the time of the September 6, 2021 data cutoff for this cohort. Safety data from an additional 1,591 BNT162b2 recipients and 788 placebo recipients enrolled in the Phase 2/3 portion (Cohort 2) of the trial were provided later during FDA's review of the EUA amendment request to allow for more robust assessment of serious adverse events and other adverse events of interest (e.g., myocarditis, pericarditis, anaphylaxis). The median duration of follow-up in Cohort 2 was 2.4 weeks post Dose 2 at the time of the October 8, 2021 data cutoff for this cohort. Vaccine effectiveness was inferred by immunobridging SARS-CoV-2 50% neutralizing antibody titers (NT50, SARS-CoV-2 mNG microneutralization assay). Neutralizing antibody titers at 1 month post-Dose 2 in children 5-11 years of age were compared to neutralizing antibody titers 1 month post-Dose 2 among a subset of study participants 16-25 years of age randomly selected from efficacy study C4591001 who had previously received two doses of 30 µg BNT162b2. A supplemental descriptive analyses of vaccine efficacy (VE) among Cohort 1 participants (following accrual of 19 total confirmed COVID-19 cases) was also provided during FDA's review of the EUA amendment request.

The immunogenicity analyses evaluated neutralizing antibody titers against the USA_WA1/2020 reference strain, as assessed by microneutralization assay, among study participants with no evidence of prior SARS-CoV-2 infection up to 1 month post-Dose 2. Immunobridging endpoints and statistical success criteria were as follows:

- SARS-CoV-2 neutralizing antibody GMTs measured at 1 month after Dose 2 in study C4591007 Phase 2/3 Cohort 1 participants 5-11 years of age vs. GMTs at 1 month after Dose 2 in a randomly selected subset of study C4591001 Phase 2/3 participants 16-25 years of age, with immunobridging success criteria of >0.67 for the lower bound of the 95% confidence interval around the GMT ratio (5-11 years of age / 16-25 years of age), and a point estimate of the GMT ratio ≥1.0.

- Percentage of participants with seroresponse (≥4-fold rise from baseline [pre-Dose 1]), with immunobridging success criterion of >-10% for the lower bound of the 95% confidence interval around the difference (5-11 years of age minus 16-25 years of age) in seroresponse rates.

Immunobridging statistical success criteria, as described above, were met. Subgroup analyses of immunogenicity by age, gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences as compared with the overall study population, although some subgroups were too small to draw meaningful conclusions. Descriptive immunogenicity analyses, based on an exploratory 50% plaque reduction neutralization test (PRNT), showed that a 10 µg BNT162b2 primary series elicited PRNT neutralizing titers against the reference strain and B.1.617.2 (Delta) strain in participants 5-11 years of age (34 BNT162b2, 4 placebo) with no evidence of SARS-CoV-2 infection up to 1 month post-Dose 2.

In the supplemental descriptive efficacy analysis, VE against symptomatic COVID-19 after 7 days post Dose 2 up to October 8, 2021 (data cutoff) was 90.7% (2-sided 95% CI: 67.4%, 98.3%) in participants 5-11 years of age without evidence of prior SARS-CoV-2 infection. Totals of 3 cases of COVID-19 occurred in the BNT162b2 group and 16 in the placebo group, most of which occurred during July-August 2021 when the Delta variant was prevalent in the United States. At the time of the data cutoff, none of these cases met the criteria for severe COVID-19.

Solicited local and systemic adverse reactions (ARs) reported among Cohort 1 participants generally occurred more frequently after Dose 2, with the most commonly reported solicited ARs being pain at the injection site (71%), fatigue (39.4%), and headache (28%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and most resolved within 1 to 2 days after onset. The most frequently reported unsolicited adverse event (AE) in Cohort 1 BNT162b2 recipients was lymphadenopathy (n=13; 0.9%). More BNT162b2 recipients (n=14; 0.92%) reported hypersensitivity-related AEs (primarily skin and subcutaneous disorder including rash and dermatitis) than placebo recipients (n=4; 0.53%). Overall, from the combined safety database of 3,109 BNT162b2 recipients (Cohorts 1 and 2), 4 participants reported serious adverse events; all were considered by the study investigator and FDA as unrelated to vaccination. There were no reports of myocarditis/pericarditis or anaphylaxis, and no participant deaths. Subgroup safety analyses by gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences as compared with the overall study population, although some subgroups were too small to draw meaningful conclusions.

FDA conducted a quantitative benefit-risk analysis to evaluate predicted numbers of symptomatic COVID-19 cases, hospitalizations, ICU admissions, and deaths that would be prevented per million fully vaccinated children 5-11 years of age over a 6-month period, as compared with predicted numbers of vaccine-associated excess myocarditis cases, hospitalizations, ICU admissions and deaths per million fully vaccinated children 5-11 years of age. The model conservatively assumed that the risk of myocarditis/pericarditis associated with the 10 µg dose in children 5-11 years of age would the same as the estimated risk associated with the 30 µg dose in adolescents 12-15 years of age from Optum healthcare claims data. While benefits of vaccination were highly dependent on COVID-19 incidence, the overall analysis predicted that the numbers of clinically significant COVID-19-related outcomes prevented would clearly outweigh the numbers of vaccine-associated excess myocarditis cases over a range of assumptions for COVID-19 incidence. At the lowest evaluated COVID-19 incidence (corresponding to the June 2021 nadir), the predicted number of vaccine-associated myocarditis cases was greater than the predicted number of COVID-19 hospitalizations prevented for males and for both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine-associated myocarditis, and benefits related to prevention of non-hospitalized cases of COVID-19 with significant morbidity, the overall benefits of the vaccine may still outweigh the risks under this low incidence scenario. If the myocarditis/pericarditis risk in this age group is lower than the conservative assumption used in the model, the benefit-risk balance would be even more favorable.

This October 26, 2021 VRPBAC meeting is being held to discuss whether, based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age.

2 SARS-COV-2 VIRUS AND COVID-19 DISEASE

SARS-CoV-2 is a zoonotic coronavirus that emerged in late 2019 and was identified in patients with pneumonia of unknown cause. The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for severe acute respiratory syndrome (SARS-CoV, a lineage B betacoronavirus). SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA virus sharing more than 70% of its sequence with SARS-CoV, and ~50% with the coronavirus responsible for Middle Eastern respiratory syndrome (MERS-CoV). SARS-CoV-2 is the causative agent of COVID-19, an infectious disease with respiratory and systemic manifestations. Disease symptoms vary, with many persons presenting with asymptomatic or mild disease and some progressing to severe respiratory tract disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death. Symptoms associated with SARS-CoV-2 infection in individuals less than 18 years of age are similar to those in adults, but are generally milder, with fever and cough most commonly reported.[1,2] Other symptoms in children include nausea and vomiting, diarrhea, dyspnea, nasal symptoms, rashes, fatigue and abdominal pain.[3] Most children with COVID-19 recover within 1 to 2 weeks. Estimates of asymptomatic infection in children vary from 15 to 50% of infections.[4,5] However, COVID-19 associated hospitalizations and deaths have occurred in children (see below), and for some children, COVID-19 symptoms may continue for weeks to months after their initial illness.[6]

The SARS-CoV-2 pandemic continues to present a challenge to global health and, as of October 15, 2021, has caused approximately 239 million cases of COVID-19, including 4.8 million deaths worldwide.[7] In the United States, more than 44 million cases have been reported to the Centers for Disease Control and Prevention (CDC), with over 722,000 deaths. [8,9] Of the total COVID-19 cases reported in the United States to date, 22.3% occurred among individuals <18 years of age, with 8.7% occurring among 5-11-year-olds.[10] Following emergency use authorization of COVID-19 vaccines in December 2020, COVID-19 cases and deaths in the United States declined sharply during the first half of 2021; however, beginning in late June 2021 a rise in cases was observed, including in children, associated with the highly transmissible Delta variant that is now predominant in the United States.[11] As of the week ending October 2, 2021, the Delta variant comprised greater than 99% of tested strains in the United States.[12] During the last week in August 2021, new COVID-19 infections in individuals less than 18 years of age surpassed those in adults 18 to 64 years of age for the first time during the pandemic.[13] In the United States, COVID-19 cases occurring in children 5-11 years now constitute 39% of cases in individuals younger than 18 years of age.[14] Among cases of COVID-19 in individuals less than 18 years of age from the COVID-NET network[a], approximately 4,300 have resulted in hospitalization.[15] As of October 17, 2021, 691 deaths from COVID-19 have been reported in the United States in individuals less than 18 years of age, with 146 deaths in the 5-11 year age group.[16]

The most common underlying medical conditions among hospitalized children were chronic lung disease (29%), obesity (25%) and neurologic disorders (23%). A total of 68% of hospitalized children had more than one underlying condition. Obesity and feeding tube dependence were associated with increased risk of severe disease. Available evidence suggests that highest risk groups include children with special healthcare needs, including genetic, neurologic, metabolic

[a] COVID-NET covers approximately 10% of the U.S. population; The current network covers nearly 100 counties in the 10 Emerging Infections Program (EIP) states (CA, CO, CT, GA, MD, MN, NM, NY, OR, and TN) and four additional states through the Influenza Hospitalization Surveillance Project (IA, MI, OH, and UT); see https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html.

conditions, or with congenital heart disease.[17] As in the adult population, COVID-19 in children disproportionally affects underrepresented racial and ethnic groups, with hospitalizations and deaths more frequent among Native American/Alaskan, Hispanic or Latin American, and non-Hispanic Black children than among White children.[18,19]

Following observation of an increased incidence of myocarditis in 2020 compared with 2019, several studies have suggested an association between COVID-19 and myocarditis.[20,21] While the overall incidence of myocarditis following COVID-19 infection is low, persons with COVID-19 have a nearly 16-fold increase in risk for myocarditis, compared to individuals without COVID-19. The risk is lowest among individuals 25-39 years and higher in persons less than 16 years and older than 50 years of age.[22] Myocarditis may also present as part of the Multisystem inflammatory syndrome in children (MIS-C), usually 3 to 5 weeks after a SARS-CoV-2 infection. MIS-C is a rare but serious COVID-19-associated condition that occurs in less than 1% of children with confirmed SARS-CoV-2 infection.[23] MIS-C presents with persistent fever, laboratory evidence of inflammation, and at least 2 affected organs. In severe cases, hypotension and shock can occur. Most patients have laboratory markers indicating damage to the heart.[24] During the pandemic, a rise in MIS-C cases has generally lagged behind a rise observed in COVID-19 infections by several weeks,[25] with one study demonstrating the peak in MIS-C cases occurring 31 days following the peak in laboratory-confirmed COVID-19 cases.[26] Between May 2020 and October 4, 2021, the CDC received reports of 5,217 cases and 46 deaths that met the definition for MIS-C; the median age of participants was 9 years with half of the cases occurring in children ages 5 to 13 years. Males comprised 60% of cases, and 61% were reported in children who were reported as Hispanic or Black.[27] Up to 66.7% of patients with MIS-C had cardiac involvement, [28] including left ventricular dysfunction, mitral or tricuspid regurgitation, coronary artery aneurysms, and/or arrhythmias.[29] One study of outcomes in children with MIS-C followed up to 9 months found that while 76% children with MIS-C required ICU admission and therapy with inotropes or pressors; most symptoms, including cardiovascular manifestations, resolved within 1 to 4 weeks.[30] Limited data are available on long-term outcomes in MIS-C.

While children and adolescents appear less susceptible to SARS-CoV-2 infection and generally have a milder COVID-19 disease course as compared with adults,[31,32] adolescents and adults have similar SARS-CoV-2 viral loads in their nasopharynx, so adolescents may play a role in community transmission.[33,34] Transmission of SARS-CoV-2 virus from children can occur in both household and school settings.[35,36] In schools, transmission depends on the transmission rates locally, variants circulating in the community, vaccination rates, and other preventive mitigation strategies. Transmission between school staff members may be more common than transmission involving students.[37] There is evidence that SARS-CoV-2 transmission is greater in secondary and high schools than elementary schools.[38,39] Outbreaks of COVID-19 have been reported in settings where children congregate, such as summer youth camps.[40,41]

In addition to morbidity and mortality on an individual level, the continuing spread of SARS-CoV-2 has caused significant challenges and disruptions in worldwide healthcare systems, economies, and many aspects of human activity (travel, employment, education). Other impacts of COVID-19 on children include limited access to basic services such as healthcare and child protective services, and social isolation due to disruption of school, sports, and social group gatherings. The emergence of the Delta variant, variable implementation of public health measures designed to control spread, and continued transmission among unvaccinated individuals are major factors in the recent resurgence of COVID-19. While recently reported cases appear to be declining relative to the Delta variant-associated peak globally and in the

United States, the longer-term effect of the Delta variant and the potential role of other variants on the future course of the pandemic is uncertain.

3 AUTHORIZED AND APPROVED VACCINES AND THERAPIES FOR COVID-19

FDA has issued EUAs for three COVID-19 vaccines as shown in Table 1 below. The Pfizer-BioNTech COVID-19 Vaccine is also FDA approved for use as a 2-dose primary series in individuals 16 years of age and older, under the trade name COMIRNATY (see Section 4).

Table 1. Emergency Use Authorizations of COVID-19 Vaccines

Sponsor	Authorized Use (Interval)	Indicated Population	Date of EUA or EUA Amendment
Pfizer-BioNTech	2-dose primary series (3 weeks apart)	Individuals ≥16 years of age Individuals ≥12 years of age	December 11, 2020 May 10, 2021
Pfizer-BioNTech	3rd primary series dose (at least 1 month after the second dose)	Individuals ≥12 years of age with compromised immune systems due to solid organ transplantation or conditions considered to have an equivalent level of immunocompromise	August 12, 2021
Pfizer-BioNTech	Booster dose (at least 6 months after completing a primary series of COMIRNATY and/or Pfizer-BioNTech COVID-19 Vaccine)	• Individuals 65 years of age and older • Individuals 18 through 64 years of age and at high risk of severe COVID-19 • Individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2	September 22, 2021
Moderna	2-dose series (4 weeks apart)	2-dose primary series in adults ≥18 years of age	December 18, 2020
Moderna	3rd dose (at least 1 month after the second dose)	Individuals ≥12 years of age with compromised immune systems due to solid organ transplantation or conditions considered to have an equivalent level of immunocompromise	August 12, 2021
Moderna	Booster dose (at least 6 months after completing a primary series of Moderna COVID-19 Vaccine	• Individuals 65 years of age and older • Individuals 18 through 64 years of age and at high risk of severe COVID-19 • Individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2	October 20, 2021
Janssen	Single dose	Individuals ≥18 years of age	February 27, 2021
Janssen	Booster dose	Individuals ≥18 years of age	October 20, 2021
Pfizer, Moderna and Janssen	Single heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19	Same population(s) as those eligible to receive a booster dose of the vaccine used for primary vaccination	October 20, 2021

Sponsor	Authorized Use (Interval)	Indicated Population	Date of EUA or EUA Amendment
	vaccine (same interval as authorized for a booster dose of the vaccine used for primary vaccination)		

Remdesivir is the only product currently approved by the FDA for treatment of COVID-19 requiring hospitalization, and its approved use is limited to individuals 12 years of age and older. Prior to its approval, remdesivir was authorized for emergency use in adults and pediatric patients and remains authorized for emergency use in hospitalized pediatric patients who are not included in the indicated population under licensure.

Emergency use authorizations of COVID-19 pharmacological products for post-exposure prophylaxis and/or treatment of COVID-19 are as follows:

Table 2. Emergency Use Authorized Pharmacological Products for Post-exposure Prophylaxis and/or Treatment of COVID-19

Product	Date of EUA	Authorized Use and Population
SARS-CoV-2-targeting Monoclonal Antibodies		
• Bamlanivimab/etesevimab • Sotrovimab • Casirivimab/imdevimab	Reissued September 16, 2021 May 26, 2021 Reissued September 9, 2021	All three products are indicated for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older at high risk for progressing to severe COVID-19[a] Casirivimab/imdevimab is also authorized for post-exposure prophylaxis (prevention) for COVID-19 in patients at high risk for progressing to severe COVID-19[b]
Antiviral Drugs		
• Remdesivir	Reissued October 22, 2020 (following FDA approval in adults and some pediatric patients)	Treatment of COVID-19 in hospitalized pediatric patients weighing at least 3.5 kg to <40 kg, or <12 years of age weighing at least 3.5 kg, or ≥12 years and weighing at least 40 kg
Immune Modulators		
• Baricitinib • Actemra	Reissued July 29, 2021 June 24, 2021	Treatment of COVID-19 in hospitalized patients[b] receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO
COVID-19 Convalescent Plasma	Reissued March 9, 2021	Treatment of hospitalized patients with COVID-19

a Indicated for adults and pediatric patients 12 years of age and older weighing at least 40 kg
b Indicated for adults and pediatric patients 2 years and older
ECMO extracorporeal membrane oxygenation, EUA emergency use authorization
Source: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs Accessed August 2, 2021.

4 COMIRNATY (COVID-19 VACCINE, mRNA)

On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) made by BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.). COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine is administered IM as a series of two doses (0.3 mL each) 3 weeks apart, with each dose containing 30 µg mRNA. COMIRNATY contains a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2 that is formulated in lipid particles. COMIRNATY is the only vaccine or medical product that is FDA approved for prevention of COVID-19. COMIRNATY is also authorized under EUA for use as a 2-dose primary series in individuals 12 years of age and older, for use as a third primary series dose in individuals 12 years of age and older with certain immunocompromising conditions, and for use as a single booster dose administered at least 6 months after completion of a primary series to individuals 65 years of age and older, individuals 18 through 64 years of age at increased risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. The vaccine authorized under EUA is also known as the Pfizer-BioNTech COVID-19 Vaccine. During clinical development, the vaccine was called BNT162b2.

COMIRNATY is supplied as a concentrated multi-dose liquid formulation (0.45 mL volume) stored frozen at -90°C to -60°C in a 2 mL Type 1 glass vial. A sterile diluent, 0.9% Sodium Chloride Injection, USP, is supplied separately and is stored at 20°C to 25°C. The COMIRNATY Multiple Dose Vial is thawed in a refrigerator (2°C to 8°C) for 2 to 3 hours or at room temperature (up to 25°C) for 30 minutes. Once at room temperature, the COMIRNATY Multiple Dose Vial is diluted with 1.8 mL of the diluent. After dilution, each vial of COMIRNATY contains six doses of 0.3 mL of vaccine. COMIRNATY does not contain preservative.

4.1 Efficacy of a 2-dose primary series of COMIRNATY in individuals 16 years of age and older

Efficacy of BNT162b2 for the prevention of COVID-19 occurring at least 7 days after completion of a 2-dose primary series was evaluated in an ongoing Phase 3 study, C4591001, in approximately 44,000 participants randomized 1:1 to receive two doses of either BNT162b2 or placebo, 3 weeks apart. Participants were enrolled with stratification by age (younger adults: 18 through 55 years of age; older adults: over 55 years of age). The population for the vaccine efficacy analysis that supported approval of COMIRNATY included participants 16 years of age and older who had been enrolled from July 27, 2020, and who were followed for the development of COVID-19 during blinded placebo-controlled follow-up through as late as March 13, 2021. Overall, 60.8% of participants in the BNT162b2 group and 58.7% of participants in the placebo group had ≥4 months of follow-up time after the primary series in the blinded placebo-controlled follow-up period. The overall VE against COVID-19 in subjects without evidence of prior SARS-CoV-2 infection was 91.1% (95% CI: 88.8 to 93.1). The overall VE against COVID-19 in subjects with or without evidence of prior SARS-CoV-2 infection was 90.9% (95% CI: 88.5 to 92.8).

4.2 Safety of a 2-dose primary series of COMIRNATY in individuals 16 years of age and older

In study C4591001, the most commonly reported solicited adverse reactions (occurring in ≥10% of participants) among BNT162b2 vaccine recipients 16 through 55 years of age following any dose were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain

(45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%). The most commonly reported solicited adverse reactions in BNT162b2 vaccine recipients 56 years of age and older following any dose were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

Among participants 16 through 55 years of age, SAEs from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 0.8% of BNT162b2 recipients and 0.9% placebo recipients. In a similar analysis, in participants 56 years of age and older serious adverse events (SAEs) were reported by 1.8% of BNT162b2 recipients and 1.7% of placebo recipients who received at least 1 dose of BNT162b2 or placebo, respectively. In these analyses, 58.2% of study participants had at least 4 months of follow-up after the primary series. There were no notable patterns between treatment groups for specific categories of SAEs (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2. From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the BNT162b2 group and 17 in the placebo group. None of the deaths were considered related to vaccination.

4.3 Effectiveness and safety of a 2-dose primary series of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12-15 years of age

On May 10, 2021, FDA authorized the use of Pfizer-BioNTech COVID-19 Vaccine in individuals 12-15 years of age based on safety and effectiveness data from an ongoing Phase 2/3 randomized, double-blinded and placebo-controlled trial of the Pfizer-BioNTech COVID-19 Vaccine in 2,260 participants 12-15 years of age.

Vaccine effectiveness in the adolescent age group was inferred by immunobridging based on a comparison of SARS-CoV-2 50% neutralization antibody titers (SARS-CoV-2 mNG microneutralization assay) at 1 month after Dose 2 in participants 12-15 years of age with those of young adults 16-25 years of age (the most clinically relevant subgroup of the study population in whom VE has been demonstrated). In the planned immunobridging analysis, the geometric mean ratio (GMR) of neutralizing antibody titers (adolescents to young adults) was 1.76 (95% CI: 1.47, 2.10), meeting the success criterion (lower bound of the 95% CI for the GMR >0.67). In a descriptive immunogenicity analysis, seroresponse rates among participants without prior evidence of SARS-CoV-2 infection were seen in 97.9% of adolescents and 100% of young adults (difference in seroconversion rates: -2.1%; 95% CI: -6.0%, 0.9%). Immunogenicity outcomes were consistent across demographic subgroups, such as baseline SARS-CoV-2 status, comorbidities, ethnicity, race and sex. In the supplemental efficacy analysis, VE after 7 days post Dose 2 was 100% (95% CI 75.3; 100.0) in participants 12-15 years of age without prior evidence of SARS-CoV-2 infection and 100% in the group of participants with or without prior infection. VE between Dose 1 and Dose 2 was 75.0% (95% CI 7.4; 95.5), with divergence of cumulative incidence of COVID-19 cases in BNT162b2 vs. placebo groups beginning at approximately 14 days after Dose 1. Although based on a small number of cases in descriptive analyses, the supplementary VE data provided compelling direct evidence of clinical benefit in addition to the immunobridging data.

Safety data from a total of 2,260 adolescents 12-15 years of age randomized to receive vaccine (N=1,131) or placebo (N=1,129) with a median of greater than 2 months of follow-up after the second dose suggest a favorable safety profile, with no specific safety concerns identified that would preclude issuance of an EUA. The most common solicited adverse reactions after any dose included injection site pain (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%),

muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), all of which were generally mild to moderate and lasted a few days. Severe solicited local and systemic adverse reactions occurred in up to 2.4% of 12-15-year-old BNT162b2 recipients, were more frequent after Dose 2 (most common: fatigue 1.3%, headache 1.0%, chills 0.4%) than after Dose 1 (most common: fatigue 2.4%, headache 2.0%, chills 1.8%) and more frequent after any dose in BNT162b2 recipients than age-matched placebo recipients. Among recipients of BNT162b2, severe solicited adverse reactions/events in 12-15-year-olds occurred less frequently than in 16-25-year-olds. No deaths were observed in this age group during the follow-up period. SAEs, while uncommon (<0.5%), represented medical events expected to occur among individuals in this age group and with the underlying conditions represented in the study population, and available data do not suggest a causal relationship to BNT162b2. There were no notable patterns or numerical imbalances between treatment groups for specific categories of non-serious AEs among study participants 12-15 years of age that would suggest a causal relationship to BNT162b2 vaccine.

4.4 Cases of myocarditis/pericarditis reported in BNT162b2 recipients in ongoing clinical trials of BNT162b2

Two cases of myocarditis have been reported in BNT162b2 recipients in study C4591001:

- A male participant ≥55 years of age, with no medical history, reported myocarditis 28 days after Dose 2 of BNT162b2; the event was assessed by the investigator as not related to the study intervention and was ongoing at the time of the data cutoff.
- A male participant who was randomized to blinded placebo group at age 15 years and subsequently unblinded and crossed over to open label BNT162b2 at age 16 years was diagnosed with myopericarditis beginning 2 days after Dose 2 of BNT162b2. He was hospitalized on Day 3 and treated with IVIG, non-steroidal anti-inflammatory medications and steroids, and discharged the following day. He was followed by a cardiologist and seen for follow-up 2 months after vaccination. At that time the cardiologist recommended limited activity. The investigator concluded that the there was a reasonable possibility that the myopericarditis was related to vaccine administration due to the plausible temporal relationship. FDA agrees with this assessment.

4.5 Post-EUA and post-licensure surveillance

As of October 21, 2021, more than 240 million doses of the Pfizer-BioNTech COVID-19 Vaccine have been administered in the U.S. (CDC COVID Data Tracker, accessed on October 22, 2021). Among all COVID-19 vaccines, 205,046 individuals less than 12 years of age have received at least one dose and 125,656 are fully vaccinated (CDC COVID Data Tracker, accessed on October 22, 2021).

The Vaccine Adverse Event Reporting System (VAERS) was queried for adverse event (AE) reports following administration of the Pfizer-BioNTech COVID-19 Vaccine, and the results are summarized below. Spontaneous surveillance systems such as VAERS are subject to many limitations, including underreporting, variable report quality and accuracy, inadequate data regarding the numbers of doses administered, and lack of direct and unbiased comparison groups. Reports in VAERS may not be medically confirmed and are not verified by FDA. Also, there is no certainty that the reported event was actually due to the vaccine.

As of October 18, 2021, VAERS received 442,763 reports (including 270,342 U.S. reports), of which 854 U.S. reports were in children 5-11 years of age, 9,523 U.S. reports were in children

12-15 years of age, and 5,821 U.S. reports were in adolescents 16-17 years of age. The top ten most frequently reported MedDRA preferred terms (PTs) included:

- Overall most frequent PTs: headache, fatigue, pyrexia, SARS-CoV-2 test, dizziness, pain, nausea, chills, pain in extremity, dyspnoea
- Most frequent PTs in in persons ≤17 years of age: dizziness, syncope, headache, pyrexia, nausea, product administered to patient of inappropriate age, chest pain, fatigue, vomiting, loss of consciousness.

Note that a report may have one or more PTs. An additional query of VAERS for U.S. reports by dose number retrieved the following: 127,747 reports after Dose 1; 100,730 reports after Dose 2; and 5,223 reports after dose 3 (data as of October 18, 2021).

Safety concerns identified from post-authorization safety surveillance data in VAERS are summarized below. Anaphylaxis, myocarditis, and pericarditis are existing safety concerns that have been added to the product Fact Sheets. Review of passive surveillance AE reports and the Sponsor's periodic safety reports does not indicate any new safety concerns, including in adolescents. Most AEs are labeled events and consistent with the safety profile for this vaccine. No unusual frequency, clusters, or other trends for AEs were identified that would suggest a new safety concern.

Anaphylaxis

Post-authorization surveillance has identified a risk of anaphylaxis, occurring at a rate similar to reported rates of anaphylaxis following licensed preventive vaccines, primarily in individuals with history of prior severe allergic reactions to other medications or foods.[42][43] Anaphylaxis is an important identified risk in the pharmacovigilance plan (PVP) and included in the Warnings sections of the vaccine Fact Sheets and Prescribing Information. The estimated crude reporting rate for anaphylaxis in the U.S. is 6.1 cases per million doses at this time based on the above VAERS data.

Myocarditis and pericarditis

Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of the 2-dose primary series. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and have been highest in males 12 through 17 years of age (~71.5 cases per million second primary series doses among males age 16-17 years and 42.6 cases per million second primary series doses among males age 12-15 years as per CDC presentation to the ACIP on August 30, 2021). In an FDA analysis of the Optum healthcare claims database, the estimated excess risk of myocarditis/pericarditis approached 200 cases per million fully vaccinated males 16-17 years of age and 180 cases per million fully vaccinated males 12-15 years of age.[44] Although some cases of vaccine-associated myocarditis/pericarditis have required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae and outcomes in affected individuals, or whether the vaccine might be associated initially with subclinical myocarditis (and if so, what are the long-term sequelae). A mechanism of action by which the vaccine could cause myocarditis and pericarditis has not been established. Myocarditis and pericarditis were added as important identified risks in the PVP and included in the Warnings sections of the vaccine Fact Sheets and Prescribing Information. The Sponsor is conducting additional post-authorization/post-marketing

studies to assess known serious risks of myocarditis and pericarditis as well as to identify an unexpected serious risk of subclinical myocarditis.

5 EUA AMENDMENT REQUEST FOR THE PFIZER-BIONTECH COVID-19 VACCINE FOR USE IN CHILDREN 5-11 YEARS OF AGE

On October 6, 2021, Pfizer and BioNTech submitted a request to amend this EUA to include use of a 2-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine (10 µg each dose, administered 3 weeks apart) in individuals 5-11 years of age for active immunization to prevent COVID-19 caused by severe acute coronavirus 2 (SARS-CoV-2).

The request is accompanied by safety data from 1,518 BNT162b2 and 750 placebo (saline) Phase 2/3 participants 5-11 years of age in ongoing clinical study, C4591007, of which a total of 1,444 (95.1%) had safety follow-up ≥2 months after Dose 2 at the time of a September 6, 2021 data cutoff, and data from an additional 1,591 BNT162b2 and 788 placebo participants with a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of an October 8, 2021 data cutoff. Vaccine effectiveness in children 5-11 years of age was inferred by immunobridging SARS-CoV-2 50% neutralizing antibody titers (NT50, as assessed by SARS-CoV-2 mNG microneutralization assay) among C4591007 study participants 5-11 years of age following completion of a primary series to antibody titers of those of young adults 16-25 years of age who received two doses of 30 µg BNT162b2 in study C4591001. Efficacy against COVID-19 disease was assessed descriptively in study C4591007 participants 5-11 years of age.

Vaccine formulation

Authorization is being requested for a modified formulation of the Pfizer-BioNTech COVID-19 Vaccine. Each dose of this formulation contains 10 µg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 that is formulated in lipid particles and supplied as a frozen suspension in multiple dose vials.

To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11 years of age uses tromethamine (Tris) buffer instead of the phosphate-buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride. The packaged vials for the new formulation are stored frozen at -90°C to -60°C. The frozen vials may be thawed and stored at refrigerator at 2°C to 8°C for up to 10 weeks.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex. For the 10-µg RNA dose, each 1.3-mL filled via vial must be diluted with 1.3mL 0.9% sodium chloride for injection to provide 10 doses at 10 µg RNA / 0.2 mL Injection volume. After dilution, the vials should be stored at 2°C to 25°C and should be used within 12 hours.

6 EUA REQUIREMENTS, GUIDANCE AND CONSIDERATIONS PERTAINING TO COVID-19 VACCINES

6.1 U.S. requirements to support issuance of an EUA for a biological product

Based on the declaration by the Secretary of the U.S. Department of Health and Human Services (HHS) that the COVID-19 pandemic constitutes a public health emergency with a significant potential to affect national security or the health and security of United States citizens

living abroad, FDA may issue an EUA after determining that certain statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)).

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2, or to mitigate a serious or life-threatening disease or condition caused by an FDA-regulated product used to diagnose, treat, or prevent a disease or condition caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

If these criteria are met, under an EUA, FDA can allow unapproved medical products (or unapproved uses of approved medical products) to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. FDA has been providing regulatory advice to COVID-19 vaccine manufacturers regarding the data needed to determine that a vaccine's benefit outweigh its risks. This includes demonstrating that manufacturing information ensures product quality and consistency.

6.2 FDA guidance for industry related to COVID-19 vaccines

An EUA allowing for rapid and widespread deployment of the vaccine to millions of individuals, including healthy people, would need to be supported by clear and compelling evidence of effectiveness and adequate safety follow-up to make a determination of favorable benefit/risk (see guidance for industry "Emergency Use Authorization for Vaccines to Prevent COVID-19" February 2021, originally issued October 2020).[45] These expectations would apply to age-group specific data to support an EUA amendment for use of an unapproved COVID-19 vaccine in children 5-11 years of age. The timing, design, and appropriate endpoints for pediatric studies are discussed in the context of specific vaccine development programs as described in the guidance for industry "Development and Licensure of Vaccines to Prevent COVID-19" from June 2020.[46]

6.3 Regulatory considerations for clinical development of COVID-19 vaccines in children

The Vaccines and Related Biological Products Advisory Committee convened on June 21, 2021 to discuss, in general, the data needed to support authorization and/or licensure of COVID-19 vaccines for use in pediatric populations.

Effectiveness

Regulatory precedent with other preventive vaccines provides a basis for inference of vaccine effectiveness in pediatric populations based on immunobridging to a young adult population in which clinical disease endpoint vaccine efficacy has been demonstrated for the same prototype vaccine. The immune marker(s) used for immunobridging do not need to be scientifically established to predict protection but should be clinically relevant to the disease. Based on

available data in humans and animal models, FDA considers neutralizing antibody titers (a functional measure of the vaccine immune response against SARS-CoV-2) to be clinically relevant for immunobridging to infer effectiveness of COVID-19 vaccines in pediatric age groups. Because no specific neutralizing antibody titer has been established to predict protection against COVID-19, two immunogenicity endpoints (geometric mean titer [GMT] and seroresponse rate) are considered appropriate for comparing the range of neutralizing antibody responses elicited by the vaccine in pediatric vs. young adult populations.

Safety

The size of the safety database sufficient to assess risks of COVID-19 vaccines for EUA in pediatric age groups would generally be the same as for other preventive vaccines for infectious diseases, provided that no specific safety concern is identified that could reasonably be evaluated in pre-authorization clinical trials. These safety data would include characterization of common adverse reactions (reactogenicity, including injection site and systemic adverse reactions), and less common but medically important adverse reactions. Depending on prior experience with the vaccine in adults, and prior experience with licensed vaccines based on the same or similar platforms, FDA has accepted an overall pediatric safety database in the range of ~500 to ~3,000 trial participants exposed to the age-appropriate dose and regimen intended for licensure and have at least 6 months of follow-up evaluations after completion of the vaccination regimen. Since COVID-19 vaccines represent a new class of vaccines, with many of the lead candidates based on new platform technologies, an appropriate overall pediatric safety database would approach the upper end of this range, with adequate representation across all pediatric age groups, in particular younger age groups (e.g., <12 years) that are less physiologically similar to adults. A control group (ideally placebo control) would be important to inform interpretation of safety data and to comply with the expectation for adequate and well-controlled studies to support licensure. If another COVID-19 vaccine is licensed or authorized for use in the age group(s) enrolled in the trial, recommended by public health authorities, and widely available such that it is unethical to use a placebo control, the licensed or authorized COVID-19 vaccine could serve as a control.

Within the overall pre-licensure safety database, solicited reactogenicity could be adequately characterized among several hundred trial participants in each relevant age group. Additionally, safety evaluation in all trial participants would include collection of all AEs through at least 1 month after each study vaccination and collection of serious and other medically attended AEs for the duration of the trial. Although longer-term follow-up (through 1 year or longer post-vaccination) of trial participants would be important to ongoing assessment of both benefits and risks, completion of such longer-term follow-up would not be a prerequisite to licensure unless warranted by a specific safety concern. Post-licensure/post-authorization safety surveillance and observational studies in pediatric populations would be needed to evaluate for adverse reactions that occur too rarely to be detected in clinical trials.

7 FDA REVIEW OF CLINICAL SAFETY AND EFFECTIVENESS DATA

7.1 Overview of study C45910007

The EUA amendment request contains safety, immunogenicity, and descriptive efficacy data from children 5-11 years of age enrolled in C4591007, an ongoing Phase 1/2/3, randomized, placebo-controlled study. The comparator group for the immunobridging analyses to support vaccine effectiveness in this age group was a random subset of Phase 2/3 participants 16-25 years of age enrolled in study C4591001, the study in which vaccine efficacy against COVID-19 was established in individuals 16 years of age or older.

Data from study C4591007

- Phase 2/3: a total of 3,109 BNT162b2 (10 µg) recipients and 1528 placebo recipients 5-11 years of age

  – Cohort 1: 1,518 BNT162b2 (10 µg) recipients and 750 placebo recipients, of whom 1,444 (95.1%) and 714 (95.2%), respectively, had at least 2 months of safety follow-up after completing a 2-dose primary series (data cutoff September 6, 2021). Summary tables for solicited adverse reactions (ARs) and immunogenicity analyses are based on this cohort of subjects. A descriptive efficacy analysis was also based on this cohort; at the time of this Briefing Document was prepared, FDA has not fully verified the underlying data or Pfizer-BioNTech's conclusions from this analysis.

  – Cohort 2: A second cohort of 1,591 BNT162b2 (10 µg) recipients and 778 placebo recipients had a median duration of follow-up of 2.4 weeks post-Dose 2 at the time of data cutoff (October 8, 2021). Safety data from this cohort were provided for further assessment of SAEs and AEs of clinical interest. Data verification is in process, but not yet finished at the time this briefing book was completed.

- Phase 1 data to support dosage selection for Phase 2/3 portion of the study

Table 3. Study C4591007*: Participants 5-11 Years of Age (10 µg BNT162b2)

Study Number/ Countries	Description	BNT162b2 N	Placebo (Saline) N	Study Status
C4591007 United States, Finland, Poland, and Spain	Phase 1/2/3 randomized, placebo-controlled; to evaluate safety, immunogenicity and efficacy of COVID-19 vaccine	Phase 1: 16 Phase 2/3: 3,109	Phase 1:0 Phase 2/3: 1,528	Ongoing

N=Number of randomized participants as of data cutoff dates July 16, 2021 (all Phase 1 participants), September 6, 2021 (Phase 2/3 Cohort 1: 1,518 BNT162b2, 750 placebo; includes participants starting March 24, 2021) and October 8, 2021 (Phase 2/3 cohort 2: 1,591 BNT162b2, 788 placebo; first subject in this second cohort randomized August 15, 2021).
*First participant, first visit was March 24, 2021.

7.2 Study design

Study C4591007 is an ongoing Phase 1/2/3 randomized, observer-blinded, placebo-controlled safety, immunogenicity, and efficacy study. This section presents the design for the Phase 2/3 portion of the study in children 5-11 years of age. Please see Appendix 1 for Phase 1 study design.

Phase 2/3 is being conducted in the United States, Finland, Poland, and Spain. The Phase 2/3 portion of the study did not exclude children with a history of prior SARS-CoV-2 infection or clinical symptoms/signs of COVID-19, children with known HIV, hepatitis B or hepatitis C, or stable pre-existing disease (defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment).

Participants were randomized 2:1 to receive two doses of 10 µg BNT162b2 or placebo (saline), 3 weeks apart. Participants who turned 12 years of age during the study would have the opportunity to receive the EUA-authorized dose level of 30 µg (12-15 years of age) if they originally received placebo.

Immunogenicity evaluation

Immunobridging was based on SARS-CoV-2 neutralizing antibody responses in study C4591007 Phase 2/3 (Cohort 1) participants 5-11 years of age compared to neutralizing antibody responses in a random subset of study C4591001 participants 16-25 years of age, as measured by 50% neutralizing antibody titers (NT50, SARS-CoV-2 mNG microneutralization assay) against the reference strain (USA_WA1/2020) at 1 month after a primary series. The primary analysis is based on the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 2.

Primary endpoints and statistical success criteria

- Immunobridging success based on GMT was declared if the lower limit (LL) of the 95% CI for the GMT ratio (5-11 years of age / 16-25 years of age) was >0.67, and the point estimate of the GMT ratio was ≥1.0.
- Immunobridging success based on the seroresponse rate was declared if the LL of the 95% CI for the difference in seroresponse rates (5-11 years of age minus 16-25 years of age) was >-10%. Seroresponse was defined as a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination (pre-Dose 1) to 1 month after Dose 2.

Efficacy evaluation

A secondary objective is to evaluate efficacy of BNT162b2 against laboratory-confirmed symptomatic COVID-19 occurring from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection and in participants with or without evidence of prior SARS-CoV-2 infection. A descriptive analysis was conducted once 19 confirmed cases had accrued.

Safety evaluation

Reactogenicity (solicited local and systemic adverse reactions)

The participants' parents or participants themselves recorded reactogenicity assessments and antipyretic/pain medication use from Day 1 through Day 7 after each dose in an e-diary. Reactogenicity assessments included solicited injection site reactions (pain, redness, swelling) and systemic AEs (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain).

Unsolicited adverse events

Other safety assessments included: AEs occurring within 30 minutes after each dose, non-serious unsolicited AEs from Dose 1 through 1 month after Dose 2, and SAEs from Day 1 to 6 months after Dose 2, or the data cutoff date (Phase 1: of July 16, 2021; Phase 2/3: September 6, 2021). AEs were categorized by frequency and maximum severity according to system organ class (SOC) and preferred term (PT), according to MedDRA, and relationship to the study intervention was assessed. Deaths are recorded to the end of the study.

Adverse events of clinical interest

The occurrence of certain AEs including lymphadenopathy and myocarditis/pericarditis were assessed as part of the safety review, as well as additional AEs requested by FDA (including anaphylaxis, Bell's palsy, appendicitis, pregnancy exposures and outcomes, and MIS-C cases).

Analysis populations

Pertaining to participants 5-11 years of age

- Safety: All participants who receive at least 1 dose of the study intervention.

- All-available immunogenicity: All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after vaccination.
- Evaluable immunogenicity: All eligible randomized participants who receive two doses of the vaccine to which they are randomized with Dose 2 received within the predefined window, have at least 1 valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and have no other important protocol deviations as determined by the clinician.
- Evaluable efficacy: All randomized participants who receive all vaccinations as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

Data analysis cutoff dates:

- All Phase 1 participants: July 16, 2021
- Phase 2/3 Cohort 1: September 6, 2021; includes participants starting March 24, 2021
- Phase 2/3 Cohort 2: October 8, 2021; first subject in this cohort was randomized August 15, 2021

7.3 Disposition of Phase 2/3 participants

Cohort 1

Cohort 1 was comprised 1,528 BNT162b2 10 µg participants and 757 placebo participants; 11 (0.7%) BNT162b2 and 6 (0.8%) placebo participants did not receive any study agent. Two BNT162b2 participants (0.1%) and two placebo participants (0.3%) discontinued vaccination before the 1 month post-Dose 2 follow-up; none resulted from an AE. Three participants turned 12 years of age during the course of the study and became eligible to receive 30 µg BNT162b2 under EUA; two of these participants received two doses of 10 µg BNT162b2 prior to being unblinded, and the other participant received both doses of placebo before being unblinded and withdrew to receive a COVID-19 vaccine outside of the study; data from these participants were included in endpoint analyses up to the point at which they were unblinded.

Safety population: solicited ARs, unsolicited AEs, SAEs and AEs of clinical interest were assessed in a total of 2,268 (1,518 10 µg BNT162b2, 750 placebo) participants 5-11 years of age; 95% of participants in each study group completed at least 2 months of safety follow-up after Dose 2. Five BNT162b2 recipients and six placebo recipients withdrew from the study, mainly due to voluntary withdrawal.

Comparator group for immunogenicity: The comparator group for immunobridging analyses consisted of 300 evaluable participants 16-25 years of age who received both doses of BNT162b2 30 µg and were randomly selected from study C4591001 Phase 2/3.

Table 4. Disposition of Immunogenicity Populations, Phase 2/3, Participants 5-11 Years of Age (Study C4591007 Cohort 1) and Participants 16-25 Years of Age (Study C4591001)

Disposition	5-11 years of age BNT162b2 (10 µg) n (%)	5-11 years of age Placebo n (%)	16-25 years of age BNT162b2 (30 µg) n (%)
Randomized to receive BNT162b2[a]	322 (100.0)	163 (100.0)	300 (100.0)
All-available immunogenicity population	311 (96.6)	156 (95.7)	286 (95.3)
Excluded because they did not have at least 1 valid and determinate immunogenicity result after vaccination	11 (3.4)	7 (4.3)	13 (4.3)
Evaluable immunogenicity population	294 (91.3)	147 (90.2)	273 (91.0)
Without evidence of infection up to 1 month after Dose 2[b]	264 (82.0)	130 (79.8)	253 (84.3)
Subjects excluded from evaluable immunogenicity population	28 (8.7)	16 (9.8)	27 (9.0)
Reason for exclusion (subjects may have been excluded for >1 reason)			
Did not receive 2 doses of the vaccine as randomized	3 (0.9)	1 (0.6)	0
Did not receive Dose 2 within 19 to 42 days after Dose 1	3 (0.9)	2 (1.2)	3 (1.0)
Did not have at least 1 valid and determinate immunogenicity result within 28 to 42 days after Dose 2	13 (4.0)	14 (8.6)	21 (7.0)
Did not have blood draw at 1 month after Dose 2 visit	7 (2.2)	6 (3.7)	8 (2.7)
1 Month after Dose 2 blood draw outside of window (28-42 days after Dose 2)	6 (1.9)	8 (4.9)	13 (4.3)
Had important protocol deviation(s) as determined by the clinician	10 (3.1)	0	4 (1.3)

%:n/N. n = number of participants with the specified characteristic. N = number of randomized participants in the specified group; this value is the denominator for the percentage calculations.

a. Participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding ant body [serum] negative at Visit 1 and Visit 4 (C4591007) or Visit 3 (C4591001), SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visit prior to the 1-month post-Dose 2 blood sample collection) and had no medical history of COVID-19 were included in the analysis.

b. Participants may have been excluded for more than 1 reason.

Cohort 2

In the Phase 2/3 safety expansion, 1,598 participants were randomized to receive BNT162b2 and 796 were randomized to placebo. At the time of the October 8, 2021 cutoff, most participants (98.7%) had received both Dose 1 and Dose 2. Seven participants in the BNT162b2 group did not receive vaccine, for a Safety Population of 1,591. One participant in the BNT162b2 group discontinued from the vaccination period due to AEs of pyrexia and neutropenia that worsened from baseline (see Section 7.6.7, AEs leading to withdrawal). Two participants (0.1%) in the BNT162b2 group withdrew from the study before the 1 month period. Neither withdrawal was due to an AE.

Comorbidities at baseline

Comorbidities were defined as described in Kim et al. MMWR 2020.[47] Participants with any comorbidity, including obesity, constituted 20.6% of the BNT162b2 group and 20.3% of placebo group. The most common comorbidities at baseline in the Cohort 1 BNT162b2 group were obesity (11.5%), asthma (7.8%), neurologic disorders (1.3%), and congenital heart disease

(1.0%). Other comorbidities included diabetes in 2 participants (0.2%), and one participant each (0.1%) for acute lymphocytic leukemia (immunocompromising conditions), cystic fibrosis, and sickle cell disease.

Demographic characteristics were similar in Cohort 2 as Cohort 1. Overall, 11.1% of participants were obese. Comorbidities including obesity were found in 19.9% of participants. As in Cohort 1, the most common comorbidities were asthma, neurologic disorders and congenital heart disease.

7.4 Demographic and baseline characteristics

Demographic characteristics for the safety population of participants who received BNT162b2 10 µg in Phase 2/3 study C4591007 Cohort 1 are summarized in Table 5 below. Participants were predominately White, with a mean age of approximately 8 years. Of the BNT162b2 recipients, 11.5% met the definition of obesity, 8.8% had evidence of prior SARS-CoV-2 infection and 20.6% had comorbidities placing them at increased risk of severe COVID-19. More than 70% of participants were enrolled in the United States.

Table 5. Demographic and Baseline Characteristics, Phase 2/3, Participants 5-11 Years, Safety Population, Study C4591007 Cohort 1

Characteristic	C4591007 BNT162b2 10 µg (N[a]=1518) n[b] (%)	C4591007 Placebo (N[a]=750) n[b] (%)
Sex: Male	799 (52.6)	383 (51.1)
Sex: Female	719 (47.4)	367 (48.9)
Race: White	1204 (79.3)	586 (78.1)
Race: Black or African American	89 (5.9)	58 (7.7)
Race: American Indian or Alaska Native	12 (0.8)	3 (0.4)
Race: Asian	90 (5.9)	47 (6.3)
Race: Multiracial	109 (7.2)	49 (6.5)
Race: Not reported	9 (0.6)	7 (0.9)
Ethnicity: Hispanic or Latino	319 (21.0)	159 (21.2)
Ethnicity: Not Hispanic or Latino	1196 (78.8)	591 (78.8)
Age: Mean years (SD)	8.2 (1.93)	8.1 (1.97)
Age: Median (years)	8.0	8.0
Obese[c]: Yes	174 (11.5)	92 (12.3)
Obese[c]: No	1343 (88.5)	658 (87.7)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative[e]	1385 (91.2)	685 (91.3)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive[f]	133 (8.8)	65 (8.7)
Comorbidities[d]: Yes	312 (20.6)	152 (20.3)
Comorbidities[d]: No	1206 (79.4)	598 (79.7)
Country: Finland	158 (10.4)	81 (10.8)
Country: Poland	125 (8.2)	60 (8.0)
Country: Spain	162 (10.7)	78 (10.4)
Country: United States	1073 (70.7)	531 (70.8)

Abbreviations: BMI = body mass index; COVID-19 = coronavirus disease 2019; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Demographic and baseline characteristic categories with 0 participants in any treatment group are not shown to avoid inadvertent unblinding through public disclosure.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile).
e. Negative N-binding antibody result and negative NAAT result at Visit 1 and no medical history of COVID-19.
f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

Demographic characteristics in Cohort 2 were similar to Cohort 1.

Comparator group for immunogenicity: The 300 participants ages 16-25 years from study C4591001 were from sites in the United States (64%), Argentina (18%), Brazil (12%), and South Africa/Turkey/Germany (6% combined total).

Less than 0.8% of participants in either group received non-COVID-19 vaccines during the study; most were routine pediatric immunizations including diphtheria, pertussis, tetanus, human papillomavirus vaccine, and meningococcal vaccine.

7.5 Immunogenicity results

7.5.1 Primary immunogenicity objective

Immunogenicity of BNT162b2 was assessed based on analyses of GMTs and seroresponse rates for neutralizing antibody titers to the reference strain (USA_WA1/2020).

GMTs of neutralizing antibody titers to the reference strain

Among participants in the evaluable immunogenicity population without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2, the ratio of SARS-CoV-2 50% neutralizing GMT in children 5-11 years (10 µg each dose) compared to individuals 16-25 years (30 µg each dose) was 1.04. (95% CI: 0.93, 1.18). The lower bound of the 2-sided 95%CI for GMR was >0.67 and the point estimate was ≥1, which met FDA's requested criteria; see Table 6, below.

Table 6. SARS-CoV-2 Neutralizing GMTs (NT50)[a] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[b]

GMT (95% CI) 5-11 Years of Age Study C4591007 N[c] = 264	GMT (95% CI) 16-25 Years of Age Study C4591001 N[c] = 253	GMT Ratio (95% CI) (5-11 Years of Age / 16-25 Years of Age)[d]
1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)

a. SARS-CoV-2 mNeonGreen virus microneutralization assay (SARS-CoV-2 mNG NT), reference strain: recombinant USA_WA1/2020. NT50= 50% neutralizing titer.
b. Evaluable immunogenicity population pertaining to Phase 2/3 BNT162b2 participants 5-11 years of age (study C4591007) and Phase 2/3 BNT162b2 participants 16-25 years of age (study C4591001).
c. N = Number of Phase 2/3 participants with valid and determinate assay results for the specified assay at the given dose/sampling time point within specified window.
d. Immunobridging statistical success is declared if the lower limit of the 2-sided 95% CI for the GMT ratio is greater than 0.67 and the point estimate of the GMT ratio is ≥1.0.

Rates of neutralizing antibody seroresponse to the reference strain

Seroresponse rates among participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 2 are displayed in Table 7 below. Children 5-11 years of age had similar seroresponse (as measured from before vaccination to 1 month after Dose 2) rate as individuals 16-25 years of age. The difference between the two age groups was 0.0% (95% CI: -2.0%, 2.2%). The lower limit of the 95% CI for the difference in seroresponse rate was -2.0%, which was greater than the prespecified margin of -10% and thus immunobridging based on seroresponse rate was met, see Table 7 below.

Table 7. Seroresponse Rates[a,b] at 1 Month Post-Primary Series in Phase 2/3 BNT162b2 (10 µg) Recipients 5-11 Years of Age and Study C4591001 Phase 2/3 Cohort 1 BNT162b2 (30 µg) Recipients 16-25 Years of Age[b] Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2, Evaluable Immunogenicity Population[c]

Seroresponse 5-11 Years of Age Study C4591007 %[d] (95% CI) N= 264	Seroresponse 16-25 Years of Age Study C4591001 %[d] (95% CI) N= 253	% Difference in Seroresponse Rate (Age Group 5-11 Years minus Age Group 16-25 Years)[e] (95% CI)
99.2 (97.3, 99.9)	99.2 (97.2, 99.9)	0 (-2.0, 2.2)

a. SARS-CoV-2 mNeonGreen virus microneutralization assay-NT50, reference strain: recombinant USA_WA1/2020.
b. Seroresponse defined as at least 4-fold rise relative to pre-Dose 1; if the baseline measurement was below LLOQ, a postvaccination titer of ≥4 × LLOQ was considered a seroresponse.
c. Evaluable immunogenicity population pertaining to Phase 2/3 BNT162b2 participants 5-11 years of age (study C4591007) and Phase 2/3 BNT162b2 participants 16-25 years of age (study C4591001).
d. %: n/N. n = number of participants with seroresponse for the given assay at the given dose/sampling time point. N = Number of subjects with valid and determinate assay results for the specified assay within the specified window for blood samples collected at baseline (pre-Dose 1) and 1 month after primary series.
e. Immunobridging statistical success is declared if the lower limit of the 2-sided 95% CI for the difference in percentages of participants with seroresponse is >-10%.

Subgroup Analyses of Geometric Mean Titers

GMTs of SARS-CoV-2 neutralizing titers and seroresponse rates at 1 month after Dose 2 did not vary by demographic subgroup, although some subgroups were too small to evaluate by protocol-specified methods. Specifically, no notable differences in GMTs or seroresponse rates were observed by age (i.e., 5-6 year-old vs. 7-8 year-old vs. 9-11 year-old), sex, race, ethnicity, obesity (Y/N), or SARS-CoV-2 status.

In descriptive post hoc analyses of immunogenicity data based on the presence or absence of comorbidities (defined as described in Kim et al. MMWR 2020[47]), GMT and seroresponse rates among those with comorbidities were comparable to those without comorbidities.

7.5.2 Exploratory immunogenicity analyses against the Delta Variant

In response to FDA's request for immunogenicity data to support effectiveness of a 10 µg BNT162b2 primary series against the Delta variant, Pfizer submitted exploratory descriptive analyses of data from a randomly selected subset of participants (34 BNT162b2 recipients, 4 placebo recipients) with no evidence of infection up to 1 month post-Dose 2. These data were generated using non-validated SARS-CoV-2 plaque reduction neutralization assays with the

reference strain (USA-WA1/2020) and the Delta variant; the relative sensitivity of the two assays is not known.

Table 8. SARS-CoV-2 Neutralizing GMTs[a] at Pre-Dose 1 and 1 Month Post-Primary Series in C4591007 Phase 2/3 Cohort 1 Participants 5-11 Years of Age Without Evidence of SARS-CoV-2 Infection up to 1 Month After Primary Series, Evaluable Immunogenicity Population[b]

Assay Target	Time Point	BNT162b2 10 µg N=34 GMT (95% CI)	Placebo N=4 GMT (95% CI)
Reference strain	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	365.3 (279.0, 478.4)	10.0 (10.0, 10.0)
Delta variant	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	294.0 (214.6, 405.3)	10.0 (10.0, 10.0)

a. SARS-CoV-2 plaque reduction neutralization assay, SARS-CoV-2 strains: recombinant USA_WA1/2020 (reference), B.1.617.2 (Delta).
b. N = number of participants with valid and determinate assay results for the specified assays at the given dose/sampling time point. Participants with no serological or virological evidence of SARS-CoV-2 infection: defined as N-binding ant body [serum] negative from pre-Dose 1 to 1 month post-Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] prior to Dose 1 and Dose 2, and negative NAAT [nasal swab] result at any unscheduled visit prior to 1-month post-Dose 2, and no medical history of COVID-19.

7.5.3 Efficacy evaluation

Pfizer submitted supplemental, descriptive efficacy data for Phase 2/3 Cohort 1 participants 5-11 years of age, based on a total of 19 confirmed symptomatic COVID-19 cases occurring at least 7 days post-Dose 2, accrued up to the data cutoff of October 8, 2021. The evaluable efficacy population included 1,450 participants randomized to BNT162b2 and 736 participants randomized to placebo.

In participants 5-11 years of age without evidence of SARS-CoV-2 infection prior to Dose 2, the observed VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 90.7% (95% CI: 67.4%, 98.3%), with 3 COVID-19 cases in the BNT162b2 group compared to 16 in the placebo group (2:1 randomization BNT162b2 to placebo). All cases of COVID-19 occurred in children without prior history of infection. None of these cases met the criteria for severe infection. Most of the cases occurred in July-August 2021. Comorbidities at baseline (including obesity) were present in total of 20.1% of cases. No virus sequence analyses were available to determine whether these cases were caused by the Delta variant or another variant.

7.6 Safety results

Please see the Appendix for Phase 1 study results.

Overview of adverse events: Phase 2/3

In C4591007 Phase 2/3 Cohort 1, e-diary data were collected on 1,511 participants for reactogenicity (local and systemic reactions). Overall, injection site reactions occurring within 7 days of vaccination with BNT162b2 were common, occurring in approximately 75% of participants after either Dose 1 or Dose 2. Systemic AEs occurred in approximately 50% of BNT162b2 recipients.

No participants withdrew because of AEs, and there were no deaths reported. SAEs occurred in one participant each from the BNT162b2 and placebo groups, and neither were considered by the investigator or FDA to be related to the investigational agent. Immediate unsolicited AEswere rare in this study, occurring in 0.3% or less after either Dose 1 or Dose 2. See Table 9 below.

Table 9. Safety Overview, Phase 2/3 Cohorts 1 and 2, Participants 5-11 Years, Safety Population, Study C4591007

Event	BNT162b2 10 µg n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination		
Dose #1	3/1518 (0.2)	3/750 (0.4)
Dose #2	4/1515 (0.3)	2/746 (0.3)
Solicited injection site reaction within 7 days		
Dose #1	1150/1511 (76.1)	254/749 (33.9)
Dose #2	1096/1501 (73.0)	237/741 (32.0)
Solicited systemic AR within 7 days		
Dose #1	715/1511 (47.3)	334/749 (44.6)
Dose #2	771/1501 (51.4)	272/741 (36.7)
From Dose 1 through 1 month after Dose 2		
Any AE	166/1518 (10.9)	69/750 (9.2)
Unsolicited non-serious AE	166/1518 (10.9)	68/750 (9.1)
SAE	0/1518 (<0.1)	1/750 (0.1)
From Dose 1 through cutoff date[a] or participant unblinding[b]		
Withdrawal due to AEs	1/3109 (<0.1)	0/1538 (0.0)
SAE	4/3109 (0.1)	1/1538 (0.1)
Deaths	0/3109 (0.0)	0/1538 (0.0)

Note: MedDRA (v24.0) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
%:n/N. n = Number of participants with the specified characteristic. N = number of administered participants in the specified group; this value is the denominator for the percentage calculations.
a. Sept 13, 2021 for 1,518 BNT162b2 and 750 placebo; Oct 8, 2021 for the additional 1,591 BNT162b2 and 788 placebo.
b. Three participants (2 BNT162b2, 1 placebo) turned 12 years of age during the course of the study and elig ble to received 30 µg BNT162b2 under EUA; for this reason, the participants were unblinded to their treatment assignment.

7.6.1 Immediate AEs

Among the 1,518 Cohort 1 participants who received BNT162b2 Dose 1, a total of 3 reported any immediate AE, and all were injection site pain. Following Dose 2, 4 participants experienced an immediate AE, including 1 with nausea, 1 with injection site pain, 1 with injection site erythema, and 1 with erythema (skin and subcutaneous disorder).

7.6.2 Solicited adverse reactions

Solicited local adverse reactions generally occurred more commonly after Dose 2 and included pain at the injection site (71%), redness (18.5%) and swelling (15.3%). Systemic adverse reactions also occurred more frequently after Dose 2 and included fatigue (39.4%), headache (28%), and muscle pain (11.7%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and resolved within 1 to 2 days after onset. Adverse reactions in BNT162b2 recipients that were graded as severe included 4 local reactions (3 participants with redness, 1 participant with swelling) and 1 systemic reaction (1 participant with muscle pain).

Rates of local and systemic adverse reactions in children 5-11 years of age were generally similar to those in individuals 12 years of age or older enrolled in study C4591001, with pain at the injection site slightly lower in the 5-11 year-old group, but redness and swelling slightly higher. Systemic adverse reactions such as fever, fatigue, headache, chills, and muscle pain were generally reported less frequently and were milder in severity in the 5-11 year-old group compared to individuals 12 years of age or older.

The frequencies of local and systemic adverse reactions within 7 days after each vaccination in participants with evaluable e-diary data are summarized in Tables 10, 11, and 12 below.

Table 10. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Severity, Phase 2/3 Cohort 1 Participants 5-11 Years of Age, Safety Population[a], Study C4591007

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Pain at the injection site[b]				
Any[d]	74.1	31.3	71.0	29.5
Mild	58.9	27.3	52.8	25.9
Moderate	14.9	4.0	17.8	3.5
Severe	0.3	0.0	0.3	0.0
Redness[c]				
Any[d]	14.7	5.7	18.5	5.4
Mild	9.5	4.9	9.5	4.2
Moderate	5.2	0.8	8.8	1.2
Severe	0.0	0.0	0.2	0.0
Swelling[c]				
Any[d]	10.5	2.7	15.3	2.7
Mild	5.6	1.7	7.8	2.0
Moderate	4.8	0.9	7.5	0.7
Severe	0.1	0.0	0.0	0.0

%:n/N. n=number of participants in the specified age group with the specified reaction. N=number of participants in the specified age group reporting at least 1 yes or no response for the specified reaction after the specified dose.
[a] All participants in the specified age group who received at least 1 dose of the study intervention.
[b] Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.
[c] Mild: 0.5 to ≤2.0 cm; moderate: 2.0 to ≤7.0 cm; severe: >7.0 cm.
[d] Any local reaction: any redness >0.5 cm, any swelling >0.5 cm, or any pain at the injection site.

Table 11. Frequency of Solicited Systemic Reactions Within 7 Days After Dose 2 by Severity, Phase 2/3 Cohort 1 Participants 5-11 Years of Age, Safety Population, Study C4501007

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Fever				
≥38.0°C	2.5	1.3	6.5	1.2
≥38.0°C to 38.4°C	1.5	0.5	3.4	0.7
>38.4°C to 38.9°C	0.8	0.7	2.5	0.4
>38.9°C to 40.0°C	0.2	0.1	0.5	0.1
>40.0°C	0.0	0.0	0.1	0.0
Fatigue[b]				
Any[e]	33.6	31.3	39.4	24.3
Mild	22.0	20.1	21.4	13.0
Moderate	11.3	11.1	17.3	11.2
Severe	0.3	0.1	0.7	0.1

Event	BNT162b2 Dose 1 N=1,511 %	Placebo Dose 1 N=749 %	BNT162b2 Dose 2 N=1,501 %	Placebo Dose 2 N=741 %
Headache[b]				
Any[e]	22.4	24.1	28.0	18.6
Mild	16.5	17.5	18.7	12.6
Moderate	5.8	6.0	9.1	6.1
Severe	0.1	0.5	0.2	0.0
Chills[b]				
Any[e]	4.6	4.7	9.8	4.3
Mild	3.6	4.0	7.0	3.2
Moderate	1.1	0.7	2.7	0.9
Severe	0.0	0.0	0.1	0.1
Vomiting[c]				
Any[e]	2.2	1.5	1.9	0.8
Mild	1.7	1.5	1.8	0.8
Moderate	0.5	0.0	0.1	0.0
Severe	0.0	0.0	0.0	0.0
Diarrhea[d]				
Any[e]	5.9	4.1	5.3	4.7
Mild	5.2	4.1	4.8	4.3
Moderate	0.7	0.0	0.5	0.4
Severe	0.0	0.0	0.0	0.0
New or worsened muscle pain[b]				
Any[e]	9.1	6.8	11.7	7.4
Mild	6.4	4.7	7.7	5.1
Moderate	2.6	2.1	3.9	2.3
Severe	0.1	0.0	0.1	0.0
New or worsened joint pain[b]				
Any[e]	3.3	5.5	5.2	3.6
Mild	2.3	4.1	3.8	2.7
Moderate	1.1	1.3	1.4	0.9
Severe	0.0	0.0	0.0	0.0
Use of antipyretic or pain medication[f]	14.4	8.3	19.7	8.1

%: n/N. n = Number of participants with the specified reaction. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
[a] All participants in the specified age group who received at least 1 dose of the study intervention.
[b] Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
[c] Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
[d] Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
[e] Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
f Severity was not collected for use of antipyretic or pain medication.

Table 12. Characteristics of Solicited Local and Systemic Adverse Reactions, Phase 2/3 Cohort 1, Participants 5-11 Years, Safety Population, Vaccine Group as Administered, Study C4591007

Event	BNT162b2 10 µg Dose 1 n[a]/N[b]	Placebo Dose 1 n[a]/N[b]	BNT162b2 10 µg Dose 2 n[a]/N[b]	Placebo Dose 2 n[a]/N[b]
Any solicited local reaction				
Day of onset: median (min, max)	1.0 (1, 6)	1.0 (1, 6)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 10)	1.0 (1, 10)	2.0 (1, 11)	1.0 (1, 12)
Persisted beyond 7 days	11/1511	9/749	8/1501	5/741

	BNT162b2 10 µg Dose 1	Placebo Dose 1	BNT162b2 10 µg Dose 2	Placebo Dose 2
Redness				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 5)	2.0 (1, 6)	1.0 (1, 5)
Duration: median (min, max)	1.0 (1, 10)	1.0 (1, 8)	2.0 (1, 10)	1.0 (1, 11)
Persisted beyond 7 days	4/1511	1/749	2/1501	1/741
Swelling				
Day of onset: median (min, max)	2.0 (1, 4)	1.0 (1, 7)	2.0 (1, 4)	1.0 (1, 5)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 9)	2.0 (1, 10)	1.0 (1, 12)
Persisted beyond 7 days	1/1511	1/749	2/1501	2/741
Pain at injection site				
Day of onset: median (min, max)	1.0 (1, 6)	1.0 (1, 6)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 10)	1.0 (1, 10)	2.0 (1, 11)	1.5 (1, 12)
Persisted beyond 7 days	7/1511	8/748	6/1501	5/740
Any solicited systemic reaction				
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 22)	1.0 (1, 19)	1.0 (1, 51)	1.0 (1, 10)
Persisted beyond 7 days	29/1511	15/749	30/1501	13/741
Fever				
Day of onset: median (min, max)	2.0 (2, 7)	2.5 (1, 7)	2.0 (1, 7)	6.0 (2, 7)
Duration: median (min, max)	1.0 (1, 3)	1.0 (1, 3)	1.0 (1, 5)	1.0 (1, 5)
Persisted beyond 7 days	0	0	0	0
Fatigue				
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 21)	2.0 (1, 9)	1.0 (1, 14)	1.0 (1, 10)
Persisted beyond 7 days	16/1511	7/748	17/1501	6/740
Headache				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 22)	1.0 (1, 19)	1.0 (1, 51)	1.0 (1, 9)
Persisted beyond 7 days	12/1511	9/748	10/1501	6/740
Chills				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 10)	1.0 (1, 7)	1.0 (1, 8)	1.0 (1, 8)
Persisted beyond 7 days	3/1511	0	1/1501	1/740
Vomiting				
Day of onset: median (min, max)	4.0 (1, 7)	4.0 (1, 6)	2.0 (1, 6)	3.0 (2, 6)
Duration: median (min, max)	1.0 (1, 5)	1.0 (1, 1)	1.0 (1, 2)	1.0 (1, 5)
Persisted beyond 7 days	0	0	0	0
Diarrhea				
Day of onset: median (min, max)	3.0 (1, 7)	3.0 (1, 7)	3.0 (1, 7)	4.0 (1, 7)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 6)	1.0 (1, 28)	1.0 (1, 9)
Persisted beyond 7 days	1/1511	0	2/1501	2/740
New or worsened joint pain				
Day of onset: median (min, max)	2.0 (1, 6)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 7)	1.0 (1, 4)	1.0 (1, 18)	1.0 (1, 6)
Persisted beyond 7 days	0	0	1/1501	0

	BNT162b2 10 µg Dose 1	Placebo Dose 1	BNT162b2 10 µg Dose 2	Placebo Dose 2
New or worsened muscle pain				
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 9)	1.0 (1, 8)	1.0 (1, 9)	1.0 (1, 6)
Persisted beyond 7 days	1/1511	1/748	3/1501	0

a. n = Number of participants with the specified reaction persisted beyond 7 days.
b. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

7.6.3 Subgroup analyses of solicited adverse reactions

Subgroup analyses were performed for solicited adverse reactions, comparing BNT162b2 and placebo groups by sex, race, ethnicity, and baseline SARS-CoV-2 status at baseline. No notable differences were observed among the study groups, although certain subgroups such as Black or African American race and Hispanic/Latino ethnicity had too few participants to draw meaningful conclusions.

7.6.4 Unsolicited adverse events

Information about unsolicited AEs was collected from Dose 1 to 1 month post-Dose 2. No unsolicited AEs were reported by ≥1% of participants.

In Cohort 1, the most common unsolicited AE was lymphadenopathy, which was reported in 13 (0.9%) participants in the BNT162b2 group, and 1 participant in the placebo group (0.1%). Additional unsolicited AEs reported more commonly in the BNT162b2 group than in the placebo group included otitis externa in 7 participants (0.5%), arthropod bite, nasal congestion, oropharyngeal pain, and rash in 5 participants (0.3%), each. In BNT162b2 recipients, the following AEs were considered Grade 3 in severity: 1 tic, 1 rash (bilateral pleomorphic light eruption on arms). No Grade 4 (life-threatening AEs) were observed in the study. In Cohort 2, lymphadenopathy was reported in 6 (0.4%) vaccine recipients and 3 placebo recipients (0.4%).

7.6.5 SAEs

In Cohort 1, SAEs occurred at frequency of 0.1% in both BNT162b2 and placebo recipients. For BNT162b2 recipients, only one SAE was reported, an upper limb fracture. In Cohort 2, 3 BNT162b2 recipients (0.2%) reported a SAE: 1 infection of the knee, 1 foreign body ingestion, and 1 epiphyseal fracture. All SAEs reported in the study were considered by the study investigator to be unrelated to vaccination. FDA agrees with this assessment.

Deaths: No deaths have occurred during the study in either Cohort 1 or 2.

7.6.6 AEs of clinical interest

FDA conducted Standardized MedDRA Queries (SMQs) to evaluate for constellations of unsolicited AEs among recipients 5-11 years of age in study C4591007 Phase 2/3 Cohort 1 through the September 6, 2021 cutoff date. SMQs (narrow and broad in scope) were conducted on AE Preferred Terms (PTs) that could represent various conditions, including but not limited to angioedema, arthritis, cardiomyopathy, ischaemic heart disease, cardiac arrhythmia, cardiac failure, central nervous system (CNS) vascular disorders, convulsions, demyelination, embolic and thrombotic events, hearing and vestibular disorders, hematopoietic cytopenias, hypersensitivity, peripheral neuropathy, thrombophlebitis, and vasculitis. For example, the cardiomyopathy SMQ includes PTs that may be related to myocarditis and pericarditis, such as

chest pain, palpitations, dyspnea, syncope, troponin elevation, ECG with ST elevation or PR depression, pericardiac rub, or echocardiographic findings.

For Cohort 1, the SMQ analyses resulted in identification of 19 participants with AEs of interest in the SMQs (narrow and broad in scope) in the BNT162b2 group and 6 in the placebo group. The SMQ analyses revealed an imbalance of AEs potentially representing allergic reactions, with 14 participants in the vaccine group (0.92%) reporting hypersensitivity-related AEs (primarily skin and subcutaneous disorder including rash and dermatitis) compared with 4 participants in the placebo group (0.53%). See Table 13, below.

As in Cohort 1, SMQ analyses in Cohort 2 showed an imbalance of AEs in the BNT162b2 group compared to the placebo with respect to hypersensitivity, with 9 participants in the vaccine group (0.57%) and 4 in the placebo group (0.51%) reporting unsolicited AEs in this category, primarily skin and subcutaneous disorders of rash and dermatitis. Angioedema was reported in 3 (0.19%) in the vaccine group compared to 1 (0.13%) in the placebo group. These events included one participant with both angioedema and urticaria, and 3 participants with urticaria.

One participant, a 6-year-old female in the BNT162b2 group, had a non-serious AE of Henoch-Schonlein purpura which was diagnosed 21 days after Dose 1 and was considered non-serious.

No new or unexpected adverse reactions were identified based on these SMQ results.

Table 13. Standard MedDRA Query of Adverse Events by System Organ Class and Preferred Terms, Phase 2/3, Participants 5-11 Years, Safety Population, Vaccine Group as Administered, Cohort 1, Study C4591007

SMQ	Overall SMQ System Organ Class Preferred Term	BNT162b2 10 µg (N[a]=1,518) n[b] (%)	Placebo (N[a]=750) n[b] (%)
Any	Participants with any unsolicited AEs within SMQ	19 (1.25)	6 (0.80)
Angioedema (SMQ)	Any unsolicited AEs within Angioedema (SMQ)	4 (0.26)	3 (0.40)
	Eye disorders	0	1 (0.13)
	Periorbital oedema	0	1 (0.13)
	General disorders and administration site conditions	1 (0.07)	0
	Swelling face	1 (0.07)	0
	Skin and subcutaneous tissue disorders	3 (0.20)	3 (0.40)
	Urticaria	3 (0.20)	3 (0.40)
Arthritis (SMQ)	Any unsolicited AEs within Arthritis (SMQ)	1 (0.07)	0
	Musculoskeletal and connective tissue disorders	1 (0.07)	0
	Synovitis	1 (0.07)	0
Convulsions (SMQ)	Any unsolicited AEs within Convulsions (SMQ)	0	0
Demyelination (SMQ)	Any unsolicited AEs within Demyelination (SMQ)	0	0
Hypersensitivity (SMQ)	Any unsolicited AEs within Hypersensitivity (SMQ)	14 (0.92)	4 (0.53)
	Eye disorders	1 (0.07)	1 (0.13)
	Conjunctivitis allergic	1 (0.07)	1 (0.13)
	General disorders and administration site conditions	1 (0.07)	0
	Injection site rash	1 (0.07)	0
	Immune system disorders	0	1 (0.13)
	Hypersensitivity	0	1 (0.13)
	Skin and subcutaneous tissue disorders	12 (0.79)	2 (0.27)
	Dermatitis	1 (0.07)	0

SMQ	Overall SMQ System Organ Class Preferred Term	BNT162b2 10 µg (N[a]=1,518) n[b] (%)	Placebo (N[a]=750) n[b] (%)
	Dermatitis allergic	1 (0.07)	0
	Dermatitis contact	3 (0.20)	0
	Eczema	1 (0.07)	1 (0.13)
	Rash	5 (0.33)	0
	Rash erythematous	0	1 (0.13)
	Rash macular	1 (0.07)	0
	Rash pruritic	1 (0.07)	0
Peripheral neuropathy (SMQ)	Any unsolicited AEs within Peripheral neuropathy (SMQ)	0	0
Vasculitis (SMQ)	Any unsolicited AEs within Vasculitis (SMQ)	0	0

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any unsolicited AEs within SMQ," n = the number of participants reporting at least 1 occurrence of any unsolicited AEs within SMQ.

In Cohorts 1 and 2, “chest pain” was reported in a total of 12 participants: 6 assigned to the BNT162b2 group and 6 assigned to placebo. Chest pain resolved in all participants within 1-2 days of onset. No participants required a cardiac evaluation or ER visit, and none were hospitalized. In each case the AE was considered to be noncardiac in origin.

7.6.7 AEs leading to study withdrawal

In C4591007 Phase 2/3 Cohort 1, there were no AEs leading to withdrawal. In Cohort 2 with a follow-up cutoff of October 8, 2021, 1 participant was withdrawn due to AEs of fever 2 days after Dose 1 and worsening of neutropenia (previously diagnosed as benign transient neutropenia. Dose 2 was not administered.

7.7 Study C4591007 Phase 2/3 summary

This EUA request included safety data from 1,518 BNT162b2 recipients and 750 placebo (saline) recipients 5-11 years of age in the Phase 2/3 portion (Cohort 1) of an ongoing clinical trial, C4591007; Among Cohort 1 participants, 95.1% had safety follow-up ≥2 months after Dose 2 at the time of the September 6, 2021 data cutoff. Safety data from an additional 1,591 BNT162b2 recipients and 788 placebo recipients from the Phase 2/3 portion of the trial (Cohort 2) were provided for assessment of SAEs and other AEs of interest (e.g., myocarditis, pericarditis, anaphylaxis); the median duration of follow-up was 2.4 weeks post Dose 2 at the time of the October 8, 2021 data cutoff for Cohort 2.

Immunobridging success criteria were met for geometric mean neutralizing antibody titers and seroresponse rates at 1 month post-Dose 2 against the USA_WA1/2020 reference strain, as assessed by 50% mNG microneutralization assay, among children 5-11 years of age in study C4591007 Cohort 1 compared to study participants 16-25 years of age randomly selected from study C4591001. Subgroup immunogenicity analyses by age, gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences compared to the overall study population, although some subgroups were too small to draw meaningful conclusions. Descriptive immunogenicity analyses, based on 50% plaque reduction neutralization test (PRNT), showed that a 10 µg BNT162b2 primary series elicited PRNT neutralizing titers against the reference strain and B.1.617.2 (Delta) strain in participants 5-11 years of age (34 BNT162b2, 4 placebo). Lastly, in a supplemental descriptive efficacy analysis,

VE against symptomatic COVID-19 after 7 days post Dose 2 as of the October 8, 2021 data cutoff was 90.7% (2-sided 95% CI: 67.4%, 98.3%) in participants 5-11 years of age without prior evidence of SARS-CoV-2 infection; 3 cases of COVID-19 occurred in the BNT162b2 group and 16 in the placebo group. All cases of COVID-19 occurred in participants 5-11 years of age without prior history of SARS-CoV-2 infection, and most occurred during July-August 2021. At the time of data cutoff, no cases met the criteria for severe COVID-19 infection.

Solicited local and systemic ARs generally occurred more frequently after Dose 2, and the most commonly reported solicited ARs were pain at the injection site (71%), fatigue (39.4%), and headache (28%). Most local and systemic reactions were mild to moderate in severity, with median onset 2 days post-vaccination, and resolved within 1 to 2 days after onset. The most frequently reported unsolicited AE in BNT162b2 recipients was lymphadenopathy (n=13; 0.9%). More BNT162b2 recipients (n=14; 0.92%) reported hypersensitivity-related AEs (primarily rash and dermatitis) than placebo recipients (n=4; 0.53%). Overall, from the combined safety database of 3,109 BNT162b2 participants, 4 BNT162b2 participants reported a SAE, and all of the SAEs were considered unrelated to vaccination. One BNT162b2 recipient withdrew from the study due to fever (40.1ºC) that occurred 2 days after Dose 1 and neutropenia that had worsened from baseline; the neutropenia was related to a pre-existing condition. There were no reports of myocarditis/pericarditis or anaphylaxis, and no participant deaths. Subgroup safety analyses by gender, race and ethnicity, obesity and baseline SARS-CoV-2 status showed no notable differences compared to the overall study population, although some subgroups were too small to draw meaningful conclusions.

8 BENEFIT-RISK ASSESSMENT FOR CHILDREN 5-11 YEARS OF AGE

FDA conducted a benefit-risk assessment for use of a Pfizer-BioNTech COVID-19 Vaccine 2-dose primary series in children 5-11 years of age. The key benefits assessed include preventable COVID-19 cases, hospitalizations, intensive care unit (ICU) visits and deaths due to COVID-19. The key risks include excess myocarditis/pericarditis cases, and related hospitalizations, ICU admissions, and deaths attributable to myocarditis/pericarditis. The benefits and risks are assessed per million fully vaccinated individuals with and without stratification by sex, and with comparison to age groups 12-15 years and 16-17 years.

The model assesses the benefits of vaccine protection in a 6-month period after completion of the primary series. The model assumes vaccine efficacy of 70% against COVID-19 cases and 80% against COVID-19 associated hospitalization based on real-world data for ages 20+ years during circulation of the Delta variant.[48] The incidence rates of COVID-19 cases for the week of September 11, 2021 are obtained from COVID-NET for all sex/age groups. COVID-NET covers approximately 10 percent of the U.S. population. Four-week averages of incidence rate for hospitalizations (week ending on 8/21/2021 to week ending on 9/11/2021) are used due to the variability in rates given the small numbers of hospitalizations per age/sex group. Estimates for the percentage of hospitalizations resulting in ICU admission and the percentage of hospitalized patients who die are based on cumulative rates of hospitalizations, ICU admissions, and deaths for each sex/age groups reported in COVID-NET since March 2020. The death rate among 5-11 year-olds is lower in COVID-NET than in other national data sources such as the CDC COVID-19 Data Tracker. This could be due to geographic differences between COVID-NET's reporting areas and the recent trajectory of the pandemic. This difference will lead to a conservative estimate of benefits in the model. The model assumes the incidence rates of COVID-19 cases and hospitalizations remain constant over the assessment period of 6 months. The estimates for excess myocarditis/pericarditis among fully vaccinated individuals ages 12-15 years and ages 16-17 years are based on data from Optum health claim database for the period 12/10/2020 –

07/10/2021, which is a conservative approach that includes non-confirmed cases. For this analysis the estimate for ages 12-15 years is applied to ages 5-11 years because vaccine-associated myocarditis/pericarditis data is not available for this age group. The proportions of vaccine-attributable myocarditis/pericarditis hospitalizations and ICU admissions are obtained from Vaccine Safety Datalink (12-17 year-old group[49]). Some of these hospitalizations and ICU admissions may be precautionary and therefore not clinically equivalent to COVID-19 hospitalizations and ICU admissions. The dose intended for use in children 5-11 years of age (10 µg), is lower than the dose used under EUA in adolescents 12-15 years of age (30 µg), and the observed systemic reactogenicity associated with the respective antigen contents in clinical trials is lower for children 5-11 years of age as well. Thus, assuming the same rate of vaccine-associated myocarditis for children 5-11 years of age as has been observed for adolescents 12-15 years of age in Optum may be a conservative overestimate.

The model results indicate that the benefits of the vaccine are highly dependent on the incidence of COVID-19. To account for uncertain dynamics of the pandemic, the benefits and risks were assessed under six scenarios: Scenario 1 with COVID-19 incidence as of September 11, 2021, Scenario 2 with COVID-19 incidence close to the recent peak of the Delta variant surge at the end of August 2021, Scenario 3 with COVID-19 incidence close to the lowest recorded incidence in June 2021, Scenario 4 with the same COVID-19 incidence as Scenario 1 and an assumption of 90% vaccine efficacy against cases and 100% efficacy against hospitalizations based on the preliminary descriptive efficacy analysis from study C4591007 Phase 2/3 Cohort 1, Scenario 5 with a 3x multiple of the death rate to more closely match the cumulative death rate for 5-11 years old seen in CDC Data Tracker, and Scenario 6 with the same COVID-19 incidence and assumed vaccine efficacy as Scenario 1 but 50% of the myocarditis cases as Scenario 1.

The results of the benefit-risk assessment are summarized in Table 14 below. The results predict that under Scenarios 1 (Sept 11, 2021 Incidence), 2 (Delta surge peak incidence), 4 (high efficacy), and 5 (higher COVID-19 death rate, per the CDC COVID-19 Data Tracker), the benefits of the Pfizer-BioNTech COVID-19 Vaccine 2-dose primary series clearly outweigh the risks for ages 5-11 years. Under Scenario 3 (lowest incidence), the model predicts more excess hospitalizations due to vaccine-related myocarditis/pericarditis compared to prevented hospitalizations due to COVID-19 in males and in both sexes combined. However, in consideration of the different clinical implications of hospitalization for COVID-19 versus hospitalization for vaccine-associated myocarditis/pericarditis, and benefits related to prevention of non-hospitalized cases of COVID-19 with significant morbidity, the overall benefits of the vaccine may still outweigh the risks under this lowest incidence scenario. If the myocarditis/pericarditis risk in this age group is lower than the conservative assumption used in the model, the benefit-risk balance would be even more favorable.

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	**Prevented COVID-19 Cases**	**Prevented COVID-19 Hospitalizations**	**Prevented COVID-19 ICU Admissions**	**Prevented COVID-19 Deaths**	**Excess Myocarditis Cases**	**Excess Myocarditis Hospitalizations**	**Excess Myocarditis ICU Admissions**	**Excess Myocarditis Deaths**
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0
Females only								
Scenario 1	45,063	172	54	1	32	18	10	0
Scenario 2	54,345	250	78	2	32	18	10	0
Scenario 3	2,639	21	7	0	32	18	10	0
Scenario 4	57,938	215	67	2	32	18	10	0
Scenario 5	45,063	172	54	4	32	18	10	0
Scenario 6	45,063	172	54	1	16	9	5	0

Scenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 2: COVID-19 incidence at peak of U.S. Delta variant surge at end of August 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 3: COVID-19 incidence as of nadir in June 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
Scenario 4: COVID-19 incidence as of September 11, 2021, VE 90% vs. COVID-19 cases and 100% vs. COVID-19 hospitalization.
Scenario 5: COVID-19 case incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19. hospitalization, COVID-19 death rate 300% that of Scenario 1.
Scenario 6: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization, excess myocarditis cases 50% of Scenario 1.

9 PHARMACOVIGILANCE ACTIVITIES

Pfizer submitted a revised Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with BNT162b2 in individuals 5-11 years of age. The PVP includes the following safety concerns:

- Important Identified Risks: anaphylaxis, myocarditis, and pericarditis
- Important Potential Risks: Vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD).

Pfizer-BioNTech plans to conduct passive and active surveillance to monitor the post-authorization safety for the Pfizer-BioNTech COVID-19 Vaccine, including:

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- Mandatory reporting by the Sponsor under the EUA for the following events to VAERS within 15 days: SAEs (irrespective of attribution to vaccination); COVID-19 disease resulting in hospitalization or death; multisystem inflammatory syndrome (MIS)
- Adverse event reporting in accordance with regulatory requirements for the licensed vaccine, COMIRNATY
- Additionally, following approval of COMIRNATY, the Sponsor was also asked to submit reports of myocarditis and pericarditis as 15-day reports to VAERS.
- Periodic safety reports containing an aggregate review of safety data including assessment of AEs; vaccine administration errors, whether or not associated with an AE; and newly identified safety concerns.
- Post-authorization observational studies, that would be modified to encompass the evaluation of children 5-11 years of age include active surveillance safety studies using large health insurance claims and/or electronic health record database(s):

  – Study C4591009: A non-interventional post-approval safety study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States

    Objective: To assess the occurrence of safety events of interest, including myocarditis and pericarditis, in the general U.S. population of all ages, pregnant women, the immunocompromised, and persons with a prior history of COVID-19 within selected data sources participating in the U.S. Sentinel System.

  – Study C4591021: Post-conditional approval active surveillance study among individuals in Europe receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

    Objective: To assess the potential increased risk of AESIs, including myocarditis/pericarditis, after being vaccinated with at least one dose of the Pfizer-BioNTech COVID-19 Vaccine.

  – Study C4591021 Substudy: Substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY

    Objective: To describe the natural history of post-vaccination myocarditis/pericarditis, including recovery status, risk factors, and/or identification of serious cardiovascular outcomes within one year of myocarditis/pericarditis diagnosis among individuals vaccinated with BNT162b2 as well as individuals not vaccinated with a COVID-19 vaccine.

  – Study C4591036: Prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network [PHN]). Working title: *Myocarditis/pericarditis follow-up study within the Pediatric Heart Network*

    Objective: To characterize the clinical course, risk factors, resolution, long-term sequelae, and quality of life in children and young adults <21 years with acute post-vaccine myocarditis/pericarditis.

Pfizer-BioNTech also plans to include vaccine effectiveness analyses among individuals 5-11 years of age in Study C4591014 entitled “Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study Kaiser Permanente Southern California.”

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10 TOPIC FOR VRBPAC DISCUSSION

The VRBPAC will convene on October 26, 2021, to discuss whether based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age.

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12 APPENDIX: C4591007 PHASE 1 (DOSE RANGING) – SUMMARY OF SAFETY AND IMMUNOGENICITY

During study C4591007 Phase 1, BNT162b2 was evaluated in U.S. children who were not at high risk of SARS-CoV-2 exposure, did not have medical conditions that represented risk factors for severe COVID-19, and did not have serologic/virologic evidence of SARS-CoV-2 infection. BNT162b2 dosages of 10 µg, 20 µg, then 30 µg were evaluated sequentially (n=16 participants per dosage) based upon the safety evaluation and recommendation by the internal review committee (IRC) to either advance to the subsequent dosage or terminate a specific dosage. Safety evaluation was the same as for Phase 2/3. SARS-CoV-2 50% neutralizing GMTs (SARS-CoV-2 mNG microneutralization assay) were assessed at 7 days after Dose 2.

Altogether, 48/49 (98%) of participants (assigned to the 10 µg, 20 µg, or 30 µg dosage groups combined) received two doses of BNT162b2 and completed the 1 month follow-up visit after Dose 2. One BNT162b2 participant (20 µg dosage group) did not receive study vaccine. Following safety review of reactogenicity data from the initial 4 participants in the BNT162b2 30 µg dosage group, the IRC recommended to discontinue the 30 µg dosage, due to high frequencies of solicited ARs, and recommended that the remaining 12 participants receive the

dosage selected for Phase 2/3 (i.e., 10 μg) at Dose 2. No participants from Phase 1 withdrew or discontinued from the study.

The frequencies of local and systemic adverse reactions were generally dose number and dosage dependent. Across dosages, systemic adverse reactions were generally mild and moderate in severity and resolved within 1 day of onset. No SAEs, deaths or AEs leading to withdrawal occurred at the time of data cutoff on July 16, 2021, with approximately 3 months of follow-up. No participants reported anaphylaxis, myocarditis/pericarditis, or MIS-C. One BNT162b2 (30 μg) recipient reported Grade 1 axillary lymphadenopathy, which started 3 days after Dose 2 and resolved 17 days later; the AE was considered by the study investigator to be related to study intervention.

All four participants who received 30 μg for both doses developed mild-moderate redness and pain at the injection site, and 2 of the 4 participants developed swelling. In addition, all four subjects reported fevers to 38.9ºC with mild to moderate fatigue, and 2 of the 4 developed muscle pain of moderate severity following the second dose. One participant in the 20 μg group reported Grade 3 pyrexia (temperature to 39.7º C, also reported as a systemic adverse reaction, on Day 2 post-Dose 2), which resolved by Day 3. Both 10 and 20 μg dosages elicited similar immune responses 7 days after Dose 2. In participants 5-11 years of age without evidence of SARS-CoV-2 infection up to 1 month post-Dose 2, the neutralizing antibody GMTs (NT50) at 1 month after Dose 2 were similar in the BNT162b2 10 μg and 20 μg groups (4163 and 4728, respectively).

The higher frequencies of solicited adverse reactions in participants receiving the 20 μg and 30 μg dosages, the favorable AE profile at the 10 μg dosage in participants 5-11 years of age followed for approximately 3 months after Dose 2, and the immunogenicity results demonstrating similar neutralizing antibody responses at the 10 and 20 μg dosages informed the Internal Review Committee’s decision to discontinue the 30 μg dosage and proceed to Phase 2/3 at the 10 μg dosage.

Exhibit 20

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

VICTOR M. BOOTH,
individually and as next friend of
L.B. a minor child; and

SHAMEKA WILLIAMS,
individually and as next friend of
K.G. and R.T., minor children;

SHANITA WILLIAMS,
individually and as next friend of
N.W. and M.R., minor children; and

JANE HELLEWELL,
individually and as next friend of
H.B., a minor child,
Plaintiffs,

vs.

MURIEL BOWSER,
in her official capacity as Mayor of the
District of Columbia;

LAQUANDRA NESBITT,
In her official capacity as
Director of the District of Columbia
Department of Health; and

LEWIS FEREBEE,
In his official capacity as
Chancellor of the District of Columbia
Public Schools,
Defendants.

Case No. 21-1857

ORDER

Upon consideration of Plaintiffs' Motion for Preliminary Injunction, and for good cause shown, the motion is GRANTED.

Ordered this _____ day of _____, 20___,

_____
District Judge