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

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

21-DAY EMERGENCY HEARING REQUESTED

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INTRODUCTION

"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 v. J.R.*, 442 U.S. 584, 602 (1979). Parental involvement plays a particularly essential and time-honored role in the realm of medical decision-making. "In medical procedures involving children, ensuring the existence of parental consent is critical, because children rely on parents or other surrogates to provide informed permission for medical procedures that are essential for their care." *Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1207 (10th Cir. 2003), *citing* American Academy of Pediatrics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314-17 (February, 1995). And while that presumption may be rebutted in certain circumstances, they are the exception, not the rule.[1]

The District of Columbia Minor Consent to Vaccinations Act of 2020 sets that presumption on its head. Not only does it allow medical providers to approach children as young as eleven for consent to vaccines, without providing the child's parents any prior notice; it actively *conceals* from parents that such consent is sought from a child, and if a child does "consent" to a vaccine, that fact is further concealed from parents through the creation of two health records: a false record—which omits all information about the vaccines administered—which is accessible by parents, and a true record—which records that the child received vaccines—that *cannot* be shared with parents. Insurance companies are also barred from disclosing information to parents about vaccines administered under the Act.

[1] *See* American Academy of Pediatrics, *Informed Consent in Decision-Making in Pediatric Practice*, PEDIATRICS 138(2), 1 (2016) ("Since the publication of previous American Academy of Pediatrics (AAP) statements on informed consent in 1976 and 1995, obtaining informed permission from parents or legal guardians before medical interventions on pediatric patients has become standard within our medical and legal culture").

Regardless of what one believes about vaccines, the decision of whether to vaccinate a child is tremendously important to parents. As with any medical care, vaccines also carry risks, to the point that Congress *requires* that the parents of minor children be provided with lengthy Vaccine Information Sheets (VISs) before a child can be vaccinated. Parental knowledge and consent is not only an essential component of how the National Vaccine Act works, but a fundamental part of what it means to "care" for a child. *See, e.g., In re Cassandra C.*, 316 Conn. 476, 496-497 (2015) ("At common law, minors generally were considered to lack the legal capacity to give valid consent to medical treatment or services, and consequently a parent, guardian, or other legally authorized person generally was required to provide the requisite consent. In the absence of an emergency, a physician who provided medical care to a minor without such parental or other legally authorized consent could be sued for battery").

While some illegal government interference in the parent-child relationship may be subtle and incremental, the Minor Consent Act interferes with familial decisions in ways that are clear, substantial, and brazen. It creates a legal mechanism to override the lawful exemptions of parents, even if those parents are fit. It offers parents a statutory right to claim a religious exemption with one hand, and then secretly robs them of that right with the other. It imposes duties on medical providers and insurers that directly conflict with the duties that Congress has imposed on those very same providers and insurers in the National Vaccine Act. And it does this not because there is a medical emergency, or because these parents are unfit, but because it disagrees with the decisions of parents who object to childhood vaccines.

There are cases when the liberty interest at stake may be hard to define, or the threat to liberty is subtle and cunning. But the Minor Consent Act does not come clad in sheep's clothing. This wolf comes as a wolf. *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting).

STATEMENT OF FACTS

The District of Columbia Minor Consent to Vaccinations Act of 2020 (hereinafter "the Minor Consent Act"), adopted by the D.C. Council 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 of age or older to consent to receive a vaccine recommended by the United States 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. Ver. Compl. ¶¶ 46-48. 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 the parents, and that insurers shall not send an Explanation of Benefits to parents for any vaccine administered under the Act. Ver. Compl. ¶ 51.

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 (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." Ver. Compl. ¶¶ 53-55. The result is the creation of two conflicting health records for the child. The one given to parents leaves the child's immunization record blank, even though vaccines have in fact been administered to the child. The other, which is kept from parents, records the child's true vaccine history. Ver. Compl. ¶¶ 56-57.

Prior to the adoption of the Minor Consent Act, District law gave parents two choices regarding immunization if they wanted to send their children to public, private, or parochial school: parents could either comply with immunization standards and regulations specified by the Mayor, or they could obtain an exemption from vaccinations, based either on medical reasons

or their sincere religious beliefs. Ver. Compl. ¶¶ 10-13; *see also* D.C. CODE § 38-202(a); D.C. CODE §§ 38-501, 38-502, 38-503, *and* 38-506. To claim a medical exemption, a parent must provide the school with a written certification by a private physician, his or her representative, or the public health authorities that vaccinations are medically inadvisable. Ver. Compl. ¶ 15; D.C. CODE § 38-506(2). A parent may claim a religious exemption by sending a good faith objection in writing to the chief official of the school, stating that vaccinations would violate the parent's religious beliefs. Ver. Compl. ¶ 14; *see also* 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. Ver. Compl. ¶ 14. The statute, which was enacted in 1979, was not amended or repealed by the Minor Consent Act. Ver. Compl. ¶¶ 13, 58, 155, 160.

The plaintiffs in this case are four parents who live in the District, all of whom send their school-age children to schools that are part of D.C. Public Schools (DCPS). Ver. Compl. ¶¶ 1-4. All are fit parents. Ver. Compl. ¶¶ 175-178. All have claimed an exemption under D.C. CODE § 38-506(1), because vaccinating their children is contrary to their sincere religious beliefs. Ver. Compl. ¶¶ 156-159, 175-178. Three of them have already been pressured from their schools to have their children vaccinated before DCPS schools resume in-person instruction on August 30, 2021. Ver. Compl. ¶¶ 103-105. And all of them fear that they cannot send their children back to DCPS schools next year, without jeopardizing their lawful decision to object to vaccines and exposing their children to intense pressure to "consent" to vaccines under the Act. Ver. Compl. ¶¶ 102-105.

Their fears are rooted in the plain language of the Minor Consent Act outlined above (which allows unidentified persons to circumvent their lawful objections, as fit parents, to childhood vaccines), as well as the public statements of D.C. Council members and the official

statements and policies made by the named defendants. 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." Ver. Compl. ¶¶ 62-63, 66. DCPS's Immunization Attendance Policy for the 2021-2022 school year states that the Minor Consent Act "allows minors, 11 years of age or older, to receive a vaccine without parental consent if the minor is capable of meeting the informed consent standard," and that "[i]f a minor student is utilizing a religious exemption or HPV opt-out and the student receives a vaccine under [the Minor Consent Act], the healthcare provider shall submit the immunization record directly to the minor student's school" and "the school shall keep the immunization record received from the healthcare provider confidential." Ver. Compl. ¶¶ 92-96. The District has already opened vaccination clinics at DCPS schools, Ver. Compl. ¶ 99, while simultaneously restricting opportunities for remote instruction during the upcoming school year. Ver. Compl. ¶¶ 17-19. And both the plaintiffs and their children have already faced pressure from their local schools. Ver. Compl. ¶¶ 103-105.

To prevent this from happening, the plaintiffs brought a complaint for declaratory and injunctive relief. The Minor Consent Act violates federal law in three respects: it expressly contradicts Congressional mandates contained in the National Vaccine Act, it deprives the plaintiffs of their right to freely exercise their religion under the Religious Freedom Restoration Act, and it strips them of their fundamental right under the Fifth Amendment to direct the medical care of their children. Because the threat to the plaintiffs' rights is both substantial and imminent, they seek a preliminary injunction to prevent the District from employing the Minor Consent Act against them when the school year resumes on August 30, 2021.

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); *see also Nken v. Holder*, 556 U.S. 418, 435 (2009).

I. The 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, the plaintiffs' verified complaint presents substantial claims against the Minor Consent Act under the National Childhood Vaccine Injury

Act of 1986, the Religious Freedom Restoration Act of 1993, 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, *quoting Oneok*, 135 S. Ct. at 1595 *and California v. ARC America Corp.*, 490 U.S. 93, 100 (1989).

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 (hereinafter the "National Vaccine Act") to shield vaccine manufacturers from liability, to promote vaccine safety, 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 upon 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.

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. *See* **Complaint Exhibit C**. 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 228-229. This is referred to as a "non-table injury." Congress's regulatory scheme is dependent on recognizing vaccine injuries in a timely manner: not only is timely recognition important for receiving follow-up medical care, but it is also an element of proving that one is entitled to legal compensation for injuries—compensation 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's 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 prior to the administration of the vaccines.[2] 42 U.S.C. § 300aa-26. The National Vaccine Act also requires the health care provider to record specific information in the 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

[2] Vaccine Information Sheets are also sometimes called "Vaccine Information Materials" or "Vaccine Information Statements." The terms are interchangeable.

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." THE LAW DICTIONARY (2021), *available at* https://thelawdictionary.org/alternative/ (accessed July 5, 2021). Subsection 300aa-26(d) clarifies that the required VISs may be "supplemented." But an alternative is not a supplement. *See* 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 shall 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); *see also* **Complaint Exhibit E** (ACIP Recommended Child and Adolescent Immunization Schedule). 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 prior to the administration of vaccines to a child. 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 billion in compensation for vaccine injuries. *See* **Complaint Exhibit B**. The Injuries listed on the Vaccine Injury Table, which is reproduced in **Complaint Exhibit C**, include encephalopathy (brain injury), paralysis and death. Federally mandated VISs are extremely important in preventing unnecessary vaccine injury.

VISs are designed to provide the parents with the minimum amount of information necessary to understand the benefits and risks of administering immunizations to form and give informed consent. *See, e.g.,* **Complaint Exhibit A**, *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"); **Complaint Exhibit A**, *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"); **Complaint Exhibit A**, *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 for the parents to be aware of to prevent serious harm, including neurological damage to the 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 a parents' knowledge or consent, in all probability, the parent will have no way of recognizing that the child has suffered a vaccine injury. Moreover, a child may have other conditions—either at the time a vaccine is administered, or in their personal or family medical history—that could severely increase the risk of a vaccine injury. VISs warn parents of these "precautions" and "contraindications," which would counsel against receiving a vaccine. Failure to timely recognize vaccine allergic reactions, as well as adverse events which are precautions or contraindications, place a child at risk of serious injury or death. The CDC's precautions and contraindications for the childhood vaccines at issue here are found in **Complaint Exhibit D**.

Not recognizing that the child has suffered from a vaccine adverse reaction can cause serious medical consequences. If the parent has not been provided the minimum information necessary to recognize a post vaccination adverse event, the parent will not know to seek immediate medical attention in the event of an adverse reaction. The parent will also not know that some post vaccine adverse events are listed as precautions and contraindications to further vaccinations. In addition, if VISs are not provided to the parent, then the parent 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 Sec. 3. Section (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 that:

> 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.) These demands are expressly undermined by the Minor Consent Act, which requires health care providers to ignore clear federal mandates that they record specific information in the child's permanent medical record.

The Minor Consent Act also violates an additional command in section 300aa-25(a). The Minor Consent Act 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, section 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 in order to hide from the parent the fact 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 the mandates of Congress.

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.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the re- porting requirement.

(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 that is required to be in the vaccine adverse event report. Also, by hiding the fact that a child has been vaccinated from the child's parent, in all probability the parent will never know if the child has a vaccine adverse reaction and the vaccine adverse reaction will never 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) states:

(c) Release of information
(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—
(A) the person who received the vaccine, or (B) the legal representative of such person.
(2) For purposes of paragraph (1), the term 'information which may identify an individual' shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine,

> and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.
>
> (3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

At the risk of stating the obvious, 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 has 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 what information must be provided to parents before their children may be vaccinated, while section 300aa-25 mandates what information must be recorded in the child's permanent medical records, and which information must be provided to the 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 other copies of immunization records from parents, the Minor Consent Act "makes 'compliance with both state and federal law . . . impossible.'" *Sickle*, 884 F.3d at 347. The 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.

B. The Minor Consent Act substantially burdens the plaintiffs' fundamental right to freely exercise their 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, as a "covered entity," 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 the 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, the plaintiffs have sincere religious beliefs against vaccinating their minor children. And they have acted on those beliefs by claiming a religious exemption. 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. 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 the parent's objection, without the parent's 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 Act, if a parent claimed the religious exemption, the District could not override that decision. Now, it can. And it does so by exerting "substantial pressure" on both 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 does significant damage to the rights 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, 430-431 (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 to CSS." *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*, 546 U.S. at 431. No such harm is present here. All the 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 would do so if they return to school under a religious exemption on August 30, 2021—a religious exemption that the District has neither suspended nor eliminated for the 2021-2022 school year. *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 O Centro*, 546 U.S. at 436; *see also Capitol Hill*, 496 F. Supp. 3d at 298 ("The District cannot rely on its generalized interests in protecting public health or combating the COVID-19 pandemic, critical though they may be. 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, as this Court recognized last term in *Capitol Hill Baptist*, *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*, 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*, 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, exemption-less 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 was *created* by the District. 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 as an argument for adopting the Minor Consent Act, the list of vaccines that could be administered without parents' knowledge at the time the Act was adopted in March 2021 did *not* include the vaccine for COVID-19. Instead, the Act is limited to vaccines that are recommended by the United States Advisory Committee on Immunization Practices ("ACIP"). And until May 12, 2021, that list

included only routine childhood vaccines and the HPV vaccine. *See* 22-B D.C.M.R. § 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.

There is, of course, another alternative: 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 vaccines, whether pre- or post-pandemic. But that would be illegal, even under *Jacobson's* more 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 634-635 ("[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 364-365, *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).

As argued above, the plaintiffs contend that the Minor Consent Act does not further any compelling interest rooted in health or safety. But there are clearly less-restrictive approaches to accomplish that interest than the one adopted by the Minor Consent Act. 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. And in so doing, it violates not only the free exercise rights of parents under RFRA, but their fundamental constitutional rights under the Due Process Clause.

C. The Minor Consent Act deprives the plaintiffs of their fundamental right 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, 639-640 (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").[3]

The fundamental right implicated here—the right of fit parents to be informed of and 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 744, 756 (N.D. N.Y. 2020), *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 the decisions of fit parents. While parental rights are not absolute, "the Due Process

[3] Though they are separate amendments, the due process components of the Fifth Amendment and the Fourteenth Amendment are identical. *See Propert v. District of Columbia*, 948 F.2d 1327, 1330 n. 5 (1991).

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.*

Regardless of what one believes about vaccines, there is no doubt that being vaccinated carries some degree of risk—that is precisely why Congress created the National Vaccine Act, why Congress requires that patients be provided with VISs before vaccines are administered, and why Congress requires that these statements be provided to parents *before* vaccines can be administered to their minor children. *See* 42 U.S.C. § 300aa-26(d).

For minors, who *cannot* legally consent to a great number of things,[4] 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

[4] See, e.g., D.C. CODE § 46-101 (setting the age of majority in the District at 18 years of age); 22-B D.C.M.R. § 600.1 ("Any person who is eighteen (18) years of age or older may consent to the provision of health services for himself or herself, or for his or her child or spouse"); 22-B D.C.M.R. §600.2 ("Any minor who is seventeen (17) years of age or more may consent to voluntarily donate blood to a nonprofit organization. . . .").

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 decision to the District by filing a religious exemption, 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 or his or her own, then the parent's decision can be ignored and a vaccine can be administered without the parent's knowledge (much less the parent's consent). But a mother's decision not to vaccinate her child does not automatically make that mother 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 her mother "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 they

are—will be told if their children are vaccinated against their wishes. On the contrary, that fact will be *hidden* from the parents. D.C. CODE § 38-602(a)(2). That 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* 22-B D.C.M.R. § 600.9(a) ("A minor, 11 years of age or older, may consent to receive a vaccine if the minor is capable of meeting the informed consent standard, the vaccine is recommended by the United States Advisory Committee on Immunization Practices ("ACIP"), and will be provided in accordance with ACIP's recommended immunization schedule"). And if a child's parent files a religious exemption or an HPV exemption, their decision is *targeted*, not protected. *See* D.C. CODE § 38-602(a)(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 D.C.M.R. § 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").

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).

The 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 to the plaintiffs, 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 them now.

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, the plaintiffs will be irreparably harmed.

The plaintiffs will be irreparably harmed if this Court is satisfied that the injury complained of is "beyond remediation," *League of Women Voters of the United States v. Newby*, 838 F.3d 1, 7-8 (D.C. Cir. 2016), 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). Here, the Minor Consent Act arrogates the power to strip the plaintiffs of their fundamental right to direct the medical care of their children: must *they* consent to non-emergency vaccines for their children, or may their children be vaccinated without their knowledge, much less their consent. As was argued above, this right falls squarely within the Fifth Amendment's core protections.

Similarly, 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 non-consensual 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 the 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 (D.C. Cir. 2009), 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. The Court concluded that injunctive relief "will not be granted against something merely feared as liable to occur at some indefinite time," and "this court is in no position to predict when the factual preconditions for a NSZ roadblock, which are considerable, will again exist, if ever." *Id.* at 63.

The district court's reasoning was expanded in an explanatory footnote. "Plaintiffs argue that they will suffer irreparable harm," the court began, "because, as licensed drivers residing in the District, they retain a substantial risk of being stopped at a NSZ checkpoint again as long as the NSZ checkpoint program remains in effect, particularly given that the District 'reserves the right to redeploy' the NSZ checkpoint program at will." *Id.* at 63 n. 10. But by the time the plaintiffs' motion was heard, there were no checkpoints left in effect, *see id.* at 52-53, leading the court to conclude that "whether (and when) MPD will again implement a NSZ remains speculation." *Id.* at 63 n. 10. Because "NSZ checkpoints are not implemented at the whim of any given officer," and "can only be established in limited circumstances ('solely in response to documented crimes of violence'), upon a specific showing of proof, and at the sole discretion of the Chief of Police or the Chief's designee," *id.*, the court was "not convinced that the risk that MPD will implement additional NSZ roadblocks during the pendency of this litigation would be great enough to satisfy plaintiffs' required showing on irreparable harm for a preliminary injunction. . . ." *Id.* at 63-64.

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 NSZ 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. This was sufficient to overcome the primary objection raised by the district court: the fact that the checkpoints could "only be established in limited circumstances ('solely in response to documented crimes of violence'), upon a specific showing of proof, and at the sole discretion of the Chief of Police or the Chief's designee." *Mills*, 584 F. Supp. 2d at 63 n. 10. "Granted, the District is not currently imposing an NSZ checkpoint," the Court of Appeals reasoned, "but it has done so more than once, and the police chief has expressed her intent to continue to use the program until a judge stops her." *Mills*, 571 F.3d at 1312. 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 the plaintiffs will succeed on the merits is particularly strong. The Minor Consent Act goes further than any vaccination law considered by

any other court. It imposes duties on those who administer vaccines that directly conflict with the duties imposed by 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, the 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 "whether (and when) MPD will again implement a NSZ" in a way that would impact them, *Mills*, 584 F. Supp. 2d 47 at 63, the plaintiffs here know when the Minor Consent Act will deprive them of their rights: on August 30, 2021, when in-person schooling resumes in the District. The writing is on the wall. The Minor Consent Act, on its face, presents a clear threat to the plaintiffs' decision to decline vaccines. Several members of the D.C. Council justified the Act as a way to "alter certain behaviors," Ver. Compl. ¶ 66, 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." Ver. Compl. ¶¶ 62-63. Chancellor Ferebee has since told parents, "[i]f you want to see students back in school, then it is our responsibility as a community for everyone to receive the COVID-19 vaccine when it's available to them." Ver. Compl. ¶ 89. DCPS's Immunization Attendance Policy for the 2021-2022 school year stresses the importance of "identify[ing] students that are non-compliant," that religious exemptions "are generally rare in the District," that the Minor Consent Act "allows minors, 11 years of age or older, to receive a vaccine without parental consent if the minor is capable of meeting the informed consent standard," and that "[i]f a minor student is utilizing a religious exemption or HPV opt-out and the student receives a vaccine under [the Minor Consent Act], the healthcare provider shall submit the immunization record directly to the minor student's school"

and "the school shall keep the immunization record received from the healthcare provider confidential." Ver. Compl. ¶¶ 92-96. The District has already opened vaccine clinics at DCPS schools, Ver. Compl. ¶ 99, while simultaneously restricting opportunities for remote instruction during the upcoming school year. Ver. Compl. ¶¶ 17-19. And both the plaintiffs and their children have already faced pressure from their local schools to have the children vaccinated. Ver. Compl. ¶¶ 103-105.

Moreover, while the plaintiffs in *Mills* had a temporary reprieve from NSZ checkpoints, the Minor Consent Act is currently on the books. And it is designed precisely so that it can be invoked by any doctor's office, clinic, or medical professional at any time, without the knowledge of parents. Unless a child self-reports that he has received a vaccine against the express wishes of his mother, the constitutional injury may go undiscovered indefinitely. The Minor Consent Act overrides fundamental constitutional rights, in ways that are clear, substantial, and brazen. Its reach will increase exponentially at a date certain in August. And an injunction from this Court will prevent the irreparable loss of those rights, until such time as its legality can be decided. This Court need not wait for Damocles' sword to fall before granting relief to the plaintiffs. *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*, 555 U.S. at 20. When the government is the opposing party, these factors merge. *Nken*, 556 U.S. at 435. 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).

As has already been argued, the Minor Consent Act violates the statutory and constitutional rights of parents in ways that are clear, substantial, and brazen. The burden it places on parents is enormous. *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 the 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 consider this case apart from the unique moment of history in which it arises. Vaccines permeate our national discourse in ways that were unimaginable just a few short years ago. And the hardships of the last year have made that 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 made medical decisions 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. The wolf is off the leash.

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

Respectfully submitted this 12th day of July, 2021:

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