

February 29, 2024

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## **Opposition to Minor Consent:** Please find our written comments attached, for the legislative record. Thank you.

## Vermont Senate Health & Welfare Committee:

Senator Virginia Lyons, Chair <u>vlyons@leg.state.vt.us</u> Senator David Weeks, Vice-Chair <u>dweeks@leg.state.vt.us</u> Senator Ruth Hardy <u>rhardy@leg.state.vt.us</u> Senator Martine Gulick <u>mgulick@leg.state.vt.us</u> Senator Terry Williams <u>tkwilliams@leg.state.vt.us</u> Kiki Carasi-Schwartz, Committee Assistant <u>kcarasi-schwartz@leg.state.vt.us</u>

Dear Esteemed Members of the Senate Health & Welfare Committee:

It was recently brought to the attention of Children's Health Defense (CHD), that now pending in Vermont is a bill, S. 151 (Minor Consent for Preventative Services & Treatment), that will expand children's access to, among other things, human papillomavirus (HPV) vaccines without parental knowledge or consent.

We appreciate the opportunity to submit our written opposition to S. 151. We are Mary Holland, Esq., President of CHD, and Kim Mack Rosenberg, Esq., General Counsel of CHD. We, along, with co-author, Eileen Iorio, are authors of a book entitled *HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed* (Skyhorse Publishing 2018). Additionally, Ms. Mack Rosenberg is among counsel representing plaintiffs in a multi-district litigation against Merck, the manufacturer of Gardasil and Gardasil 9 HPV vaccines.

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"We will fight for you and your children." Robert F. Kennedy, Jr., Chairman on Leave



## HPV VACCINES NEVER HAVE BEEN SHOWN TO PREVENT CANCER

Contrary to claims by proponents of the bill, there is no conclusive evidence that HPV vaccines have prevented a single case of cancer worldwide. In examining data available from the National Cancer Institute, for young and mid-aged women in particular, there has been little change in the incidence and death since the introduction of HPV vaccines in the United States. In fact, generally speaking a greater reduction occurred between 2000 and 2006 – prior to the vaccine's introduction – than since.<sup>1, 2</sup> The median age of diagnosis with cervical cancer in the United States is fifty and the median age of death is 59.<sup>3</sup> Thankfully, only 0.7% of U.S. women are diagnosed with cervical cancer and many of those diagnosed do not receive regular screening.<sup>4</sup> Moreover, the greatest decreases in cervical cancer incidence rates were seen in older women – who likely never received an HPV vaccine. **The statistics show that screening works and efforts should be made to ensure that young women receive regular gynecologic care**, such as PAP smears, which are inexpensive and effective. However, sadly, data also suggests that girls who receive the vaccine are less likely to be screened regularly.<sup>5</sup> As shown by the data below, the incidence rate actually rose for the youngest, most vaccinated women between 2011 and 2019 back to the level at the time the vaccines first were approved.

The following data shows the delay adjusted incidence rate of cervical cancer by age cohort (the numbers are per 100,000 women): <sup>6, 7, 8, 9, 10</sup>

<sup>&</sup>lt;sup>1</sup> NCI's data is available through 2020 but the NCI notes that because of the COVID-19 pandemic, 2020 incidence data is "anomalous" and may bias estimates. Thus we have included 2019 incidence and death data. https://seer.cancer.gov/data/covid-impact.html

<sup>&</sup>lt;sup>2</sup> https://seer.cancer.gov/statfacts/html/cervix.html

<sup>&</sup>lt;sup>3</sup> https://seer.cancer.gov/statfacts/html/cervix.html

<sup>&</sup>lt;sup>4</sup> https://seer.cancer.gov/statfacts/html/cervix.html

<sup>&</sup>lt;sup>5</sup> D. M. Harper and L. R. DeMars, "HPV vaccines—A review of the First Decade," Gynecologic Oncology, 146(1):196–204, July 2017.

<sup>&</sup>lt;sup>6</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=62&hdn\_stage=101&advopt\_precisi on=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

<sup>&</sup>lt;sup>7</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=122&hdn\_stage=101&advopt\_precision=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2 <sup>8</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=141&hdn\_stage=101&advopt\_preci sion=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2 <sup>9</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=160&hdn\_stage=101&advopt\_precision=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

<sup>&</sup>lt;sup>10</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=166&hdn\_stage=101&advopt\_preci sion=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

Year Age	15-39	40-64	50-64	65-74	75+
2000	7.4	17.2	16.6	17.0	15.8
2006	6.8	14.2	13.2	14.3	11.5
2007	6.7	14.4	13.4	14.0	11.6
2011	6.0	13.6	12.4	12.6	10.4
2019	6.8	14.0	12.6	9.8	9.5

The following data shows the death rate from cervical cancer by age cohort (the numbers are per 100,000 women):<sup>11, 12, 13, 14, 15</sup>

Year Age	15-39	40-64	50-64	65-74	75+
2000	1.1	4.7	5.6	6.8	8.5
2006	0.9	4.3	4.9	5.8	6.9
2007	1.0	4.2	5.0	5.8	6.8
2011	0.9	4.1	4.5	5.7	6.6
2019	0.8	4.0	4.5	4.9	5.4

<sup>&</sup>lt;sup>11</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=62&hdn\_stage=101&advopt\_precisi on=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

<sup>&</sup>lt;sup>12</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=122&hdn\_stage=101&advopt\_preci sion=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2 <sup>13</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=141&hdn\_stage=101&advopt\_precision=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

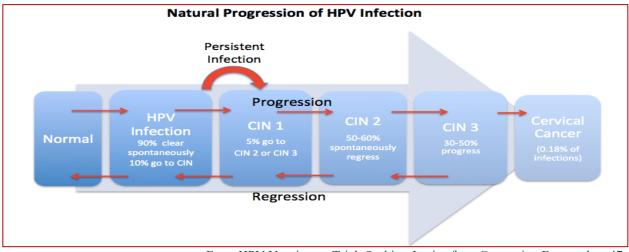
<sup>&</sup>lt;sup>14</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=160&hdn\_stage=101&advopt\_precision=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

<sup>&</sup>lt;sup>15</sup>https://seer.cancer.gov/statistics-

network/explorer/application.html?site=57&data\_type=9&graph\_type=2&compareBy=rate\_type&chk\_rate\_type\_1 =1&chk\_rate\_type\_2=2&chk\_rate\_type\_3=3&hdn\_sex=3&race=1&age\_range=166&hdn\_stage=101&advopt\_preci sion=1&advopt\_show\_ci=on&hdn\_view=0&advopt\_show\_apc=on&advopt\_display=2

Importantly, the need for vaccines – particularly in higher resource countries such as the U.S. is questionable because, in addition to effective and inexpensive screening methods, it is well-understood that the vast majority of HPV infections clear on their own. As the graphic below shows, only 0.18% of HPV infections worldwide (including in lower resource countries with less screening and more significant exposures to co-factors that contribute to cervical cancer) ever become cervical cancer.



From HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed, at 47.

# **HPV VACCINE INJURIES**

By contrast, there have been significant reports of injury from HPV vaccines. More than one hundred cases against Merck are now pending in the multi-district litigation in the United States District Court for the Western District of North Carolina, for serious, life altering injuries, many of which are autoimmune in nature, to young women and men following receipt of Merck's HPV vaccines. Plaintiffs in these cases allege, among other things, that Merck's fraud led to their injuries. Without parental knowledge of receipt of HPV vaccines, many of these families would not have known of their ability to seek compensation in the National Vaccine Injury Compensation Program and ultimately in Court.

These cases that finally have made the arduous journey to federal court are the tip of the iceberg. The Vaccine Adverse Events Reporting System (VAERS) is replete with reports of injuries following Gardasil and Gardasil 9 vaccination. Injuries include death and many serious health conditions such as brain inflammation, strokes, acute transverse myelitis, seizures and other uncontrolled body movements, blood clots, heart attacks and other cardiac conditions, autoimmune or related conditions (including Guillain Barré Syndrome, multiple sclerosis, premature ovarian failure, postural orthostatic tachycardia syndrome, rheumatoid arthritis, systemic lupus erythematosus, etc.). MedAlerts,<sup>16</sup> a VAERS search engine available through the National Vaccine Information Center,<sup>17</sup> currently (information last updated January 26, 2024) contains 75,727<sup>18</sup>

<sup>&</sup>lt;sup>16</sup> https://www.medalerts.org/index.php

<sup>17</sup> https://www.NVIC.org

<sup>&</sup>lt;sup>18</sup> https://www.medalerts.org/vaersdb/findfield.php

reports of injury, including thousands of serious and disabling injuries, and 629 deaths.<sup>19</sup> The majority of reported adverse events occurred in children under age 17.<sup>20</sup>

Gardasil 9 was licensed in 2014 and currently is the only HPV vaccine available in the United States. Clinical trials for Gardasil 9 were bootstrapped to the original formulation of Gardasil, approved in 2006. Critically, this methodology results in clinical trials bereft of true controlled clinical trial safety data because the safety of the original Gardasil was never compared to an inert saline placebo. Instead, Merck compared the vaccine to the vaccine's bioactive aluminum (a known neurotoxin) adjuvant – an ingredient specifically intended to heighten an immune system response to the vaccine.<sup>21</sup> The absence of saline placebos and other clinical trial manipulations should give you pause in allowing children to determine whether or not to get this vaccine without parental involvement in what should be a careful weighing of risks and benefits.

Our book, *HPV Vaccine on Trial*, details the many concerning questions raised by the Gardasil clinical trials and the injuries reported therein and in the marketplace. We must ask whether children can truly assess the risks of these shots. In particular, do they comprehend and will they even be warned that there is a risk that they may be rendered infertile as a result of receiving the HPV vaccine? As teens they understandably may not want to have children immediately but do they want to risk not having any children in the future? If they do not know the real risks and the minimal (if any) potential benefits of HPV vaccines, can they give informed consent? Clearly, the answer is no. In all but the most exceptional circumstances, parents should help their children make these potentially life altering decisions.

## LAWS ALLOWING MINORS TO RECEIVE VACCINES ABSENT PARENTAL KNOWLEDGE AND CONSENT VIOLATE FEDERAL LAW

Further, in addition to S. 151 raising serious concerns about providing medical treatment to children who cannot exercise informed consent, we respectfully inform you that this bill directly conflicts with the National Childhood Vaccine Injury Act of 1986. *See* 42 U.S.C. §§ 300aa-25 and 300aa-26.<sup>22</sup> Therefore, this bill is clearly unconstitutional under the Supremacy Clause of the United States Constitution. In particular, the federal law requires certain reporting and recording of information with respect to vaccinations and, of no small moment, requires that the parent (or other legal representative) of a child receive a vaccine information statement for each vaccine administered PRIOR to the child receiving the vaccine. S. 151 endeavors to cut parents out of the

<sup>&</sup>lt;sup>19</sup>https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&GROUP2=AGE&EVENTS=O N&VAX%5B%5D=HPV2&VAX%5B%5D=HPV4&VAX%5B%5D=HPV9&VAX%5B%5D=HPVX&VAXTYPE S%5B%5D=HPV

<sup>&</sup>lt;sup>20</sup>https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX%5b%5d=HPV 2&VAX%5b%5d=HPV4&VAX%5b%5d=HPV9&VAX%5b%5d=HPVX&VAXTYPES%5b%5d=HPV&SERIOU S=ON

<sup>&</sup>lt;sup>21</sup>http://wayback.archive-

it.org/7993/20170723091811/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts /UCM111287.pdf. No cohort received saline in the original clinical trial. While most "controls" received an aluminum adjuvant, Merck gave a small number of clinical trial participants a formulation containing all the components except the HPV antigens and aluminum. That formulation included risky ingredients such as polysorbate 80 and sodium borate (aka, Borax). In the Gardasil 9 trials, it appears a very small cohort may have received saline, but only after they already had received three doses of the original Gardasil, so they also were not a true placebo control group.

<sup>&</sup>lt;sup>22</sup>https://www.govinfo.gov/content/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap6A-subchapXIX-part2-subpartc-se c300aa-25.pdf

vaccination process and thus runs afoul of federal law by not providing parents with materials mandated by that law.

Children's Health Defense represented a group of parents challenging a similar law, the District of Columbia Minor Consent For Vaccination Act, in *Booth v. Bowser*, 597 F. Supp. 3d 1 (2022). In that case, CHD sought, and a Federal District Court issued, a preliminary injunction prohibiting enforcement of the law. As a result, the District of Columbia was forced to repeal its law.

Attached hereto are the order<sup>23</sup> and opinion<sup>24</sup> in *Booth v. Bowser*, illustrating how S. 151 may also be deemed unlawful. As stated by U. S. District Court Judge Trevor N. McFadden in the conclusion of his opinion in *Booth v. Bowser*: "States and the District are free to encourage individuals – including children – to get vaccines. But they cannot transgress on the Program Congress created. And they cannot trample the Constitution."

We also have enclosed a Tennessee law, the Mature Minor Doctrine Clarification Act, T. C. A. § 63-1-165, which the Tennessee governor signed into law in May 2023. Please note that this law recognizes the applicability of 42 U.S.C. § 300aa-26 of the National Childhood Vaccine Injury Act of 1986 (requiring that, prior to vaccinating a minor, the healthcare provider must provide to the minor's representative (*i.e.*, parent or guardian) a Vaccine Information Sheet), one of the sections of the federal law with which the proposed Vermont bill conflicts. The Tennessee law further supports that the Vermont bill is unconstitutional.

Children's Health Defense respectfully requests that you heed our warning that S. 151 is clearly unconstitutional and endangers the health and well-being of Vermont's children. We ask that you pull this bill.

Thank you for your time and consideration. If you have any questions, please feel free to contact us.

Sincerely,

5 Hora Mary S. Holland, Esq

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Kinn Mack Rosenberg, Esq. General Counsel Children's Health Defense kim.mackrosenberg@childrenshealthdefense.org

<sup>&</sup>lt;sup>23</sup> https://childrenshealthdefense.org/wp-content/uploads/Booth-Preliminary-Injunction-Order.pdf

<sup>&</sup>lt;sup>24</sup> https://childrenshealthdefense.org/wp-content/uploads/PI-memo-opinion-DC-minor-case.pdf

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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

Plaintiffs,

v.

Case No. 1:21-cv-01857 (TNM)

**MURIEL BOWSER**, in her official capacity as Mayor of the District of Columbia, et al.,

Defendants.

## <u>ORDER</u>

Upon consideration of Plaintiffs' motion for preliminary injunction, Defendants' motion to dismiss, the pleadings, relevant law, and related legal memoranda and arguments of counsel in opposition and support, for the reasons set forth in the accompanying Memorandum Opinion it is hereby

**ORDERED** that Plaintiffs' [33] Motion for Preliminary Injunction is GRANTED; and it is further

**ORDERED** that Defendants, their agents, employees, and successors in office are hereby enjoined from enforcing the Minor Consent for Vaccinations Amendment Act of 2020 pending further order of this Court; and it is further

**ORDERED** that Defendants' [36] Motion to Dismiss is DENIED as to Plaintiffs' First Cause of Action and Third Cause of Action. **SO ORDERED.** Under 28 U.S.C. § 1292(a)(1), this is an appealable Order as to the Court's granting of the [33] Motion for Preliminary Injunction.

Dated: March 18, 2022

TREVOR N. McFADDEN, U.S.D.J.

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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

Plaintiffs,

and

**JOSHUA A. MAZER**, *individually and on behalf of his minor child*,

Plaintiff

v.

**MURIEL BOWSER**, *in her official capacity as Mayor of the District of Columbia, et al.*,

Defendants.

Case Nos. 21-cv-01857 (TNM) and 21-cv-01782 (TNM)

#### **MEMORANDUM OPINION**

In late 2020, the D.C. Council approved a law allowing children as young as eleven to get vaccinated without parental consent or knowledge. Parents who object to childhood vaccinations filed complaints and sought preliminary injunctions in two separate cases, but they bring nearly identical claims. They argue that federal law preempts the District's law and that it violates their constitutional and statutory rights. The District opposes the imposition of preliminary injunctions and moves to dismiss. It argues that the parents lack standing, that they have not justified preliminary injunctive relief, and that they failed to state a claim.

The Court holds that all the parents have standing for their preemption claims and have shown a likelihood of success on the merits for those claims. Federal law preempts the District's

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law because the laws place contradictory duties on healthcare providers. The Court also holds that some of the parents have standing for their Free Exercise claim and that they have shown they are likely to succeed on the merits because the District's law requires providers to hide children's vaccination status from parents who invoke their religious exemption rights but not from other parents. For both the preemption and Free Exercise claims, the parents have shown that they face irreparable harm and that the balance of the equities and public interest supports granting an injunction.

Because the parents are entitled to preliminary injunctions for these two theories, the Court need not evaluate their other theories. The Court therefore will grant the motions for preliminary relief and will deny the District's motions to dismiss for all the parents as to their preemption claims and for some of the parents as to their Free Exercise claim. The Court will separately address the remaining claims.

#### I. BACKGROUND

Both the federal government and the District regulate the administration of childhood vaccines. The federal government's regulatory power stems from the National Childhood Vaccine Injury Act of 1986 (NCVIA). 42 U.S.C. §§ 300aa-1, *et seq.* Congress passed the NCVIA on the heels of "a massive increase in vaccine-related tort litigation" in the mid-1980s. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011). As a result, several vaccine manufacturers left the market even as many plaintiffs claimed that obtaining compensation for vaccine-related injuries was costly and difficult. *Id.* Vaccination rates among children began to fall, and public health officials sounded the alarm. *Id.* 

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The NCVIA contains a two-pronged solution. *First*, it grants "significant tort-liability protections [to] vaccine manufacturers." *Id.* at 229. It accomplishes this by prohibiting state law to the contrary. *See* 42 U.S.C. § 300aa-22(e).

Second, in a "quid pro quo," it created the National Vaccine Injury Compensation Program. *Bruesewitz*, 562 U.S. at 228–29. A key component of the Program is the Vaccine Injury Table, which lists covered vaccines and associated injuries. *Id.* If an injury manifests soon after administration of a vaccine, "then the vaccine is presumed to have caused the injury and the child is entitled to compensation, unless [the U.S. Department of Health and Human Services (HHS)] can prove an alternative cause of injury." *Booth* Ver. Am. Compl. (*Booth* Compl.) ¶ 306, ECF No. 31. This is called a "table injury." *Id.* But if the injury manifests later, then the petitioner must prove causation. These so-called "non-table injuries" account for more than 90% of all vaccine injury claims. *Id.* A minor cannot be a petitioner. 42 U.S.C. § 300aa-11(b)(1)(A). Instead, the minor's legal representative must petition on the minor's behalf. *Id.* 

Because of time limits set by the NCVIA, petitioners must quickly identify vaccinerelated injuries to qualify for the Program. To assist petitioners, Congress mandated that HHS produce vaccine information statements (VIS) for distribution to vaccine recipients. *Id.* § 300aa-26(a). A VIS must 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 [Program], and (4) such other relevant information as may be determined by [HHS]." *Id.* § 300aa-26(c). Every time a healthcare provider administers a vaccine listed on the Vaccine Injury Table, he must provide a VIS "to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine." *Id.* § 300aa-26(d).

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The District requires certain vaccinations for all children attending a D.C.-area school whether public, private, or parochial. *See* D.C. Code §§ 38-501, *et seq*. The District bars schools from admitting a student "unless the school has certification of immunization for that student, or unless the student is exempted pursuant to § 38-506." *Id.* § 38-502(a). Section 38-506 exempts students from the certification requirement if the "responsible person" for the student "objects in good faith and in writing . . . that the immunization would violate his or her religious beliefs." *Id.* § 38-506(1). The law also exempts students "[f]or whom the school has a written certification by a private physician . . . or the public health authorities that immunization is medically inadvisable." *Id.* § 38-506(2). Absent one of these exemptions, students certify their immunizations on part 3 of the District's Universal Health Certificate (Certificate). *See id.* § 38-602(a)(1); *see also Booth* Ex. 1, ECF No. 31-1 (copy of the Certificate).

In 2020, the District passed the Minor Consent for Vaccinations Act Amendment of 2020

(MCA). The MCA allows some children to receive a vaccine without parental consent:

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.

D.C. Law 23-193 § 2(a). The MCA states that a minor meets the informed consent standard "if the minor is able to comprehend the need for, the nature of, and any significant risks ordinarily inherent in the medical care." *Id.* § 2(b).

Several key features of the MCA are relevant here. *First*, to help minors make an informed decision, the MCA instructs the D.C. Department of Health to "produce one or more age-appropriate alternative vaccine information sheets" that explain the risks and benefits of vaccines. *Id.* § 2(c). *Second*, the MCA tells medical providers to seek reimbursement for

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vaccinations "without parental consent, directly from the insurer." *Id.* § 2(d)(1). The provider must tell the insurer that he gave the vaccine under the MCA. *Id.* Insurers may not send an Explanation of Benefits for services provided under the authority of the MCA. *Id.* § 2(d)(2). *Third*, a minor who receives a vaccine under the MCA may access his immunization records without parental consent. *Id.* § 2(e).

*Fourth*, the MCA changes the guidelines for providers filling out the Certificate. *See id.* § 3(b)(2) (codified at D.C. Code § 38-602(a)(2)). If a minor's parent has filed a religious exemption for the child and the child elects to get a vaccine anyway, a healthcare provider must leave blank part 3 of the Certificate. *Id.* Part 3 is the child's immunization record. This serves to obfuscate the child's vaccination from his parents. But the MCA does not require providers to leave blank part 3 of the Certificate for students whose parents filed a medical exemption. This part of the MCA applies *only* to students whose parents filed a religious exemption to vaccinations under § 38-506(1). For the students with a religious exemption, the provider must send the immunization record directly to the school. *Id.* The MCA directs the school to keep the record confidential. *Id.* Confidential from the religious parents, that is, because the school may share it with D.C.'s Department of Health or the school-based health center. *Id.* 

Plaintiffs in *Booth* (*Booth* Parents) are four parents who object on religious grounds to vaccinating their minor children. *See Booth* Compl. ¶¶ 1–4, 143, 211, 239, 269. Collectively, the *Booth* Parents have six children who range from 4 to 15 years old. *Id.* ¶¶ 1–4. Joshua Mazer also objects on religious grounds to vaccinating J.D., his minor child. Mazer Am. Ver. Compl. (*Mazer* Compl.) ¶ 49, ECF No. 24. J.D. is 16 years old. *Id.* ¶ 7. All Plaintiffs bring their claims under 42 U.S.C. § 1983, which grants a right of action against the District for deprivations of statutory and constitutional rights.

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The *Booth* Parents argue that (1) federal law preempts the MCA, (2) the MCA violates the Religious Freedom and Restoration Act of 1993 (RFRA), (3) the MCA conflicts with the U.S. Constitution's Free Exercise Clause, and (4) the MCA violates their fundamental right to parent. *See Booth* Compl. ¶¶ 370–410. Mazer brings similar claims and also contends that the MCA violates both his procedural due process rights and his fundamental right to make medical decisions for J.D. *See Mazer* Compl. ¶¶ 84–122.

All Plaintiffs filed motions for a preliminary injunction. The District opposes the motions and moves to dismiss both complaints. Those motions are now ripe. Because the cases involve nearly identical challenges to the same law, the Court will resolve the preliminary injunctions with a single memorandum opinion and will issue separate orders on each docket.<sup>1</sup>

The Court finds that Plaintiffs have standing and have shown that they are likely to succeed on the merits of their argument that the MCA is preempted. The *Booth* Parents are also likely to succeed on the merits of their argument that the MCA violates their Free Exercise rights. For purposes of the preliminary injunctions, the Court need not reach Plaintiffs' other arguments. *See Capitol Hill Baptist Church v. Bowser*, 496 F. Supp. 3d 284, 300 n.15 (D.D.C. 2020) ("Because the Church is likely to succeed on the merits of its RFRA claim, and considering the interest in expeditiously resolving this motion, the Court does not reach the Church's constitutional claims now."). The Court will grant the *Booth* Parents and Mazer

<sup>&</sup>lt;sup>1</sup> Courts in this district commonly follow this practice without formally consolidating the cases. *See, e.g., Hyatt v. Iancu*, 332 F. Supp. 3d 83, 88 n.1 (D.D.C. 2018) ("Although these cases were not consolidated for trial, because of their complex but nevertheless overlapping records and litigation histories, and common legal issues, the Court is issuing this single opinion concerning the merits in all three matters."); *Am. Bar Ass 'n v. FTC*, 430 F.3d 457, 466 (D.C. Cir. 2005) ("Although the district judge never formally ordered the two actions consolidated, he dealt with them together and ultimately disposed of them in a single opinion and order.").

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preliminary injunctions and will deny the District's motions to dismiss as to their preemption claims (for all Plaintiffs) and Free Exercise claim (for the *Booth* Parents only).<sup>2</sup>

#### **II. LEGAL STANDARDS**

Different standards of review govern a motion for a preliminary injunction and a motion to dismiss. "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). "A party seeking a preliminary injunction must make a clear showing that four factors, taken together, warrant relief: likely success on the merits, likely irreparable harm in the absence of preliminary relief, a balance of the equities in its favor, and accord with the public interest." *League of Women Voters of U.S. 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." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (cleaned up). "If the showing in one area is particularly strong, an injunction may issue even if the showings in other areas are rather weak." *Id.* When the government is the defendant, 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) (cleaned up).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Hurd v. Dist. of Colum.*, 864 F.3d 671, 678 (D.C. Cir. 2017) (cleaned up). A plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court accepts the

<sup>&</sup>lt;sup>2</sup> Because Plaintiffs bring claims under the Constitution and federal law, the Court has federal question jurisdiction. *See* 28 U.S.C. § 1331.

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complaint's factual allegations as true and grants the plaintiff "all inferences that can be derived from the facts alleged." *L. Xia v. Tillerson*, 865 F.3d 643, 649 (D.C. Cir. 2017) (cleaned up). The Court need not, however, credit "a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (cleaned up). The Court considers "only the facts alleged in the complaint, any documents either attached to or incorporated in the complaint[,] and matters of which [it] may take judicial notice." *Hurd*, 864 F.3d at 678 (cleaned up).

#### **III. STANDING**

The Court turns first to standing. To establish standing, Plaintiffs must allege: (1) that they have suffered an injury in fact that is both concrete and particularized and actual or imminent; (2) that the injury is fairly traceable to the District; and (3) that a favorable decision is likely to redress the identified harm. *See Sabre, Inc. v. DOT*, 429 F.3d 1113, 1117 (D.C. Cir. 2005). "[A] party who seeks a preliminary injunction must show a substantial likelihood of standing." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015).

Plaintiffs bring many claims and must show standing for each of them. *See Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008). Because the Court finds the NCVIA preempts the MCA and that the MCA violates the *Booth* Parents' Free Exercise rights, it will not assess Plaintiffs' other claims now. Thus, all Plaintiffs must show standing for their preemption claims and the *Booth* Parents must also show standing for their Free Exercise claim.

#### A. The *Booth* Parents possess standing.

Start with the *Booth* Parents. They must show injury is imminent. The Court looks first at how likely it is that their children will seek vaccinations without their parents' consent and then applies this separately to the injuries they assert under their preemption and Free Exercise claims.

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The *Booth* Parents allege that the District has created a "pressure-cooker environment, enticing and psychologically manipulating [their minor children] to defy their parents and take vaccinations against their parents' wills." *Booth* Compl. ¶ 72. According to them, the District is "inundated" with an "intense . . . vaccine marketing campaign" to get vaccinated against COVID-19. This campaign includes "billboards, posters, fliers, printed ads, online ads, websites with links, emails, Twitter, and other forms of mass media." *Id.* ¶¶ 76, 78. The campaign promises incentives to vaccinated individuals "such as gift cards, ear buds, and chances to win iPads, \$25,000 scholarships, and other prizes." *Id.* ¶ 81 (cleaned up). The Parents' children are aware of these incentives. *Id.* ¶ 82. All the children except the four-year-old "have access to the internet and see [the District's] media campaign." *Id.* ¶ 75. The District has created a website where children can see a list of vaccine walk-in clinics. *Id.* ¶ 86. Some clinics are in schools. *Id.* 

The *Booth* Parents say this pressure makes it likely their children will exploit the MCA to get vaccinated behind their backs. The Court considers whether this is true of just one of the Parents' children, L.B., because if one plaintiff can show standing, the Court "need not consider the standing of the other plaintiffs" who raise identical claims. *Mtn. States Legal Found. v. Glickman*, 92 F.3d 1228, 1232 (D.C. Cir. 1996). Because the Court determines that L.B. is likely to imminently get a vaccine, his father, Victor Booth, has standing.

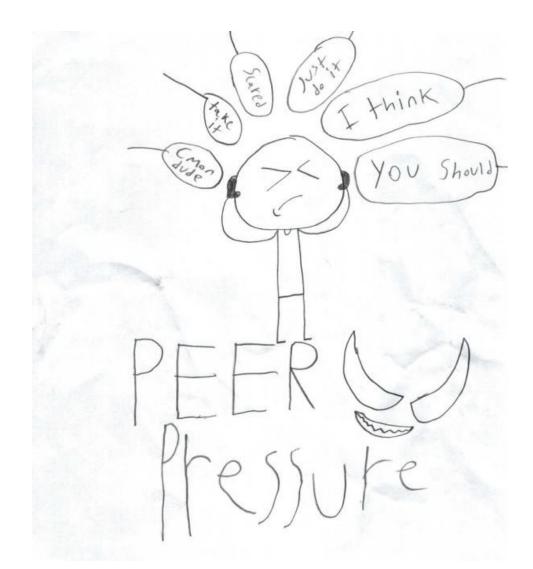
L.B. is 13 years old and attends Kipp Academy, a D.C. public charter school. *Booth* Compl. ¶ 120. Booth alleges that L.B. is "a medically fragile child" who suffers from autoimmunity, alopecia (severe hair loss), asthma, and eczema. *Id.* ¶ 122. Booth alleges that these conditions appeared following several rounds of previous vaccinations. *Id.* ¶¶ 126-29. After Booth stopped L.B.'s vaccinations, "his medical conditions improved, and his hair slowly

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began to grow back." *Id.* ¶ 136. Booth "has formed sincere religious objections to vaccinations. He is of the sincere religious belief that he should not inject a foreign substance into his son's body that may harm him." *Id.* ¶ 143. This includes both the COVID-19 vaccine and standard childhood vaccines. *Id.* ¶ 144.

Booth alleges that L.B. feels singled out for being unvaccinated against COVID-19. Because he is unvaccinated, the District once forced L.B. to quarantine for ten days after his teacher tested positive for COVID-19. *Id.* ¶ 189. Not so for his vaccinated classmates. *Id.* ¶¶ 176, 190–91. L.B. became upset and cried as a result. *Id.* ¶ 191. During the winter, Kipp Academy announced that unvaccinated children may not play sports. *Id.* ¶ 192. Baseball is vital to L.B. *Id.* He "has become increasingly angry, agitated, and upset" as a result. *Id.* ¶ 193. L.B. has told his father, "if I were offered a vaccine, I would take it." *Id.* ¶ 198. Kipp has an on-site vaccine clinic. *Id.* ¶ 91.

L.B. drew two pictures explaining his feelings. One of the drawings 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 certain places which is very annoying." *Id.* ¶ 195. The second drawing appears below:



*Booth* Ex. 11, ECF No. 31-1.

The District responds that Booth's alleged injury depends on "pure speculation" that L.B. will receive the vaccine. *Booth* Defs.' Mem. at 22, ECF No. 35.<sup>3</sup> The District claims that L.B. has not said he will try to get vaccinated or that a D.C. official has ever offered vaccines to him. *Id.* The District also notes that the MCA has been in effect since March 2021, L.B. has been in school since August 2021, and the motion for preliminary injunction was filed in December 2021. *Id.* So even if L.B. feels pressured to get the vaccine, he has been able to withstand that

<sup>&</sup>lt;sup>3</sup> All page numbers refer to the pagination generated by the Court's CM/ECF system.

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pressure thus far. More, if L.B. caved and sought out a vaccine, he would still have to persuade a healthcare provider that he met the standard for informed consent. *Id.* at 24. The District argues that because Booth's alleged injuries depend on the independent actions of third parties—both L.B. and healthcare providers—his claims are too speculative to constitute an imminent injury. *Id.* 

To be sure, Booth engages in some hypothesizing about what L.B. will do. The Supreme Court has warned that "threatened injury must be certainly impending to constitute injury in fact," and that "allegations of possible future injury" are not sufficient. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (cleaned up). But here L.B. has made it clear that he is on the cusp of getting vaccinated.

And the District does not suggest what else L.B. must do to demonstrate an imminent injury to Booth. The District says that Booth and the other Parents "have *not* alleged that their children have expressed interest in seeking out vaccines." *Booth* Defs.' Mem. at 22. But L.B. has said he would take the vaccine if offered it. *See Booth* Compl. ¶ 198. The District argues L.B.'s statement depends on the District "walking the halls offering vaccines"—something it is not doing and has no plans to do. *Booth* Defs.' Mem. at 23. Yet the District has clinics across the city, including one inside L.B.'s school. *Booth* Compl. ¶ 91. The location of the clinic, combined with the incentives offered to students who get the vaccine, is nearly indistinguishable from offering vaccines to students. Given L.B.'s statement, he could likely go to one of these clinics any day.

Now consider Booth's preemption argument. Courts have recognized a conflict between state and federal law as a concrete injury that can create standing. *See, e.g., State Farm Bank, F.S.B. v. Dist. of Colum.*, 640 F. Supp. 2d 17, 21 (D.D.C. 2009). Booth argues that because the

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MCA preempts the NCVIA, it deprives him of a VIS. *See Booth* Compl. ¶ 373–74. Still more, the MCA tries to conceal a child's vaccination status from his parents. *Id.* ¶ 374. The MCA thus "subverts the protections" of the NCVIA. *Id.* The District responds that Booth is wrong because there is no conflict between the MCA and the NCVIA. *Booth* Defs.' Mem. at 25. Without a conflict, there is no preemption. Without preemption, there is no injury. But because the Court finds a conflict between the MCA and NCVIA, *see infra* Section IV.A.1, the Court determines that there is an injury. And because the Court found that L.B. is very likely to try to get a vaccine soon, the injury is imminent.<sup>4</sup>

That leaves causation and redressability. The Court finds that the MCA causes Booth's injury because without it there is no avenue for minors to receive vaccines absent parental consent. Removing the law would revert the District to the standard age of consent of 18. *See* 22-B D.C.M.R. § 600.1. Thus, the requested relief would redress Booth's injuries. Booth has therefore shown all three elements of standing as to his preemption claim.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> The District argues that even if a parent *could* be harmed by failure to receive a VIS, that is not the case for Plaintiffs because during this litigation, Plaintiffs obtained the relevant VISs. *See Booth* Defs.' Mem. at 25. But at the motions hearing, Plaintiffs' counsel explained that the VISs change often and old VISs cannot fix the injury. *See* Hearing Tr. at 12:5–12, ECF No. 33 (*Mazer* docket). And in any event, 42 U.S.C. § 300aa-26(d) requires a healthcare provider to give a VIS to the legal representative of a child or the individual receiving the vaccine *when a provider administers a vaccine*.

<sup>&</sup>lt;sup>5</sup> The *Booth* Parents acknowledge that the NCVIA does not cover the COVID-19 vaccine. *See Booth* Pls.' Mot. at 28, ECF No. 33-1. Instead, the Federal Food, Drug, and Cosmetic Act and the Public Readiness and Preparedness Act regulate the COVID-19 vaccine. *Id.* This threatens the Parents' standing because although they contend that they object to all childhood vaccines, *see, e.g., Booth* Compl. ¶ 144, the bulk of their arguments concern COVID-19 vaccinations. If the NCVIA does not cover the COVID-19 vaccine, then the MCA's regulation of the COVID-19 vaccine cannot conflict with the NCVIA. The District does not press this argument, leaving the Court with limited briefing on this point. For now, the Court is persuaded that Booth possesses standing because he objects to all childhood vaccines. As J.D.'s story below shows, there is a risk that healthcare providers could administer childhood vaccines even if a child goes into a vaccine clinic intending to get only the COVID-19 vaccine. *See Mazer* Compl. ¶ 54. More, at

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Consider next Booth's Free Exercise claim. Booth claims that because the MCA requires providers to skip part 3 of the Certificate if a child has a religious exemption on file, the MCA exhibits "hostility to a religion or religious viewpoint." *Booth* Pls.' Mot. at 38, ECF No. 33-1 (quoting *Masterpiece Cakeshop*, *LTD v. Colo. Civ. Rights Comm'n*, 138 S. Ct. 1719, 1731 (2018)). This hostility is "inconsistent with the First Amendment's guarantee that our laws be applied in a manner that is neutral toward religion." *Id.* (quoting *Masterpiece Cakeshop*, 138 S. Ct. at 1731). This injury is imminent because L.B. may try to get a vaccine any day. The injury is traceable to the MCA because the MCA established the requirement that providers leave blank part 3 of the Certificate for minors with religious exemptions. Enjoining the MCA would therefore redress the injury.

Booth has thus established standing as to both his preemption and MCA claims. And because Booth has shown standing, the Court "need not consider the standing of the other plaintiffs" who raise the same claims. *Mtn. States Legal Found.*, 92 F.3d at 1232.

#### **B.** Joshua Mazer has standing.

Now consider Mazer's standing. When J.D. was five years-old, she suffered a severe reaction to a vaccination that required urgent medical treatment. *Mazer* Compl. ¶ 47. Mazer "has a sincerely held religious belief contrary to vaccination for J.D. since his religion prohibits him from permitting acts that he believes would harm his child." *Id.* ¶ 49. In classic teenager fashion, despite knowing her father's opposition, J.D. wants to be vaccinated.

In the spring of 2021, J.D., who lives in Maryland, visited a doctor in the District. *Id.* ¶ 50. She told the doctor that she wanted to attend a summer camp and needed to receive a

the motions hearing, the *Booth* Parents contended the FDA is likely to soon issue final approval to COVID-19 vaccines for children. Hearing Tr. at 32:17–24. Final approval would make COVID-19 vaccines subject to the NCVIA. *See id.* 

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vaccine to attend. *Id.* ¶ 51. She revealed that her parents did not consent to her receiving the vaccine. *Id.* Although she went intending to only get one shot, the doctor encouraged her to get two others. *Id.* ¶ 54. Mazer alleges that the doctor "coached" J.D. on how to lie to her parents about the shots. *Id.* ¶ 55. J.D. was all set to get the vaccines, but when the doctor brought them out, she got nervous and left without receiving them. *Id.* Mazer says that during the visit, J.D. was not told of the vaccines' risks and did not receive a VIS. *Id.* ¶ 56. Nor did the doctor or anyone else ask her if she previously had a bad reaction to a vaccine. *Id.* 

Mazer found out about J.D.'s visit to a doctor because J.D. put the doctor's business card on a bulletin board in her room. *Id.* ¶ 61. Although Mazer has explained why he opposes her receiving a vaccine, J.D. has repeatedly told him that she needs to get various vaccines for her school's dance team performances, so that she can attend a summer camp, to secure a summer job, and to attend the college of her choice. *Id.* ¶¶ 69, 71. J.D. has posted signs above her bed about the importance of getting vaccines. *Id.* ¶ 79. Mazer states that J.D. has often communicated her intention to get the vaccine. *Id.* ¶¶ 71–76.

Mazer says that J.D. has the means to obtain a vaccination if she chooses to. There is a subway stop near her house and in front of the doctor's office she visited. *Id.* ¶ 78. She has the Uber and Lyft apps on her phone, and her older brother and friends have driven her to places in the past and are willing to do so again. *Id.* ¶ 77. J.D. has the means to pay for an immunization because she has a credit card. *Id.* And a doctor has shown a willingness to give her a vaccine. *Id.* ¶¶ 81–82.

The District counters that Mazer has not shown any certainly impending injury. *Mazer* Defs.' Opp'n. at 18–21, ECF No. 19. It argues that Mazer "does not allege that J.D. still wants to attend the summer camp, or still needs vaccination to do so, or even that the summer camp is not

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yet over. He offers no other possible motivation for J.D. to seek vaccination again." *Id.* at 19. The District also contends that now that Mazer has explained to J.D. why he does not want her to get vaccinated, she might not try again. *Id.* And finally, the District argues that the MCA only applies to so-called "mature minors" who can meet the standard of informed consent. Because it is not clear that J.D. could meet that standard, Mazer's complaint relies on too many what-ifs. *See id.* at 19–20.

None of the District's arguments withstands scrutiny. The District says that Mazer has not shown J.D. "still" wants to attend summer camp, but he alleged that very fact in his complaint. *See Mazer* Compl. ¶ 71. Counsel confirmed this at the motions hearing. Hearing Tr. at 75:23–25, ECF No. 33 (*Mazer* docket). And Mazer has offered another "possible motivation" for J.D. to seek out a vaccination. He alleged that she wanted vaccines for her dance company performances, her summer job, and to attend the college of her choice. *Mazer* Compl. ¶¶ 71–74. Despite Mazer explaining why he does not want her to get vaccinated, she "frequently" brings it up at the family dinner table and explains her desire to get one. *Id.* ¶ 80. And there is no reason to doubt that J.D. would meet the standard for informed consent—after all, she did once before. Based on all these facts, the Court finds the likelihood that J.D. will try to get at least one vaccination is imminent.

Apply this finding to Mazer's preemption claim. He alleges the same harm as the *Booth* Parents: The NCVIA provides federal rights to parents relative to vaccines, and the MCA strips them away. *Id.* ¶ 85. The harm is imminent because J.D. could try to get a vaccine at any time. The injury is traceable to the MCA because it created the mechanism by which minors can get vaccines without their parents' permission. The requested relief would redress the injury because Mazer asks the Court to enjoin the relevant part of the MCA. Mazer thus has standing

for his preemption claim.

### **IV. ANALYSIS**

Because Plaintiffs have standing, the Court now considers each element of the showing they must make to obtain a preliminary injunction.

#### A. Plaintiffs show likelihood of success on the merits.

First, Plaintiffs must show a likelihood of success on the merits. The Court bears in mind that Plaintiffs "need not establish an absolute certainty of success." *Pop. Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986). "[I]t will ordinarily be enough that the plaintiff has raised questions going to the merits so serious, substantial, difficult and doubtful, as to make them a fair ground for litigation and thus for more deliberative investigation." *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977).

#### 1. Plaintiffs are likely to succeed on their preemption claim.

Start with Plaintiffs' preemption arguments. The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Courts treat the District as a state for preemption purposes. *See CSX Transp., Inc. v. Williams*, 406 F.3d 667 (D.C. Cir. 2005) (per curiam). A federal law may preempt state law in three ways, although these categories "are not rigidly distinct." *Crosby v. Nat. 'I Foreign Trade Council*, 530 U.S. 363, 372, n.6 (2000). *First*, the federal statute may contain an express preemption provision "withdraw[ing] specified powers from the States." *Arizona v. United States*, 567 U.S. 387, 399 (2012). *Second*, field preemption applies when a federal law's "framework of regulation" is "so pervasive . . . that Congress left no room for the States to supplement it or where there is a federal interest . . . so dominant that the federal system will be assumed to preclude enforcement

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of state laws on the same subject." *Id.* (cleaned up). *Third*, conflict preemption occurs where a federal statute conflicts with state law, either because "compliance with both federal and state regulations is a physical impossibility," or because the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (cleaned up).

Express preemption is not at issue. To be sure, the NCVIA expressly prohibits states from enacting protections for vaccine manufacturers contrary to the NCVIA. *See* 42 U.S.C. 300aa-22(e). But Plaintiffs do not contend that this provision applies here. And the existence of this provision does not foreclose other types of preemption. *See, e.g., Hillman v. Maretta*, 569 U.S. 483, 498 (2013) ("[T]he existence of a separate pre-emption provision does *not* bar the ordinary working of conflict pre-emption principles.") (cleaned up).

Field preemption also is not at issue. Mazer argues only that conflict preemption applies. *See Mazer* Pl.'s Mot. at 26–28, ECF No. 4-1; *Mazer* Pl.'s Reply at 7–14, ECF No. 25. The *Booth* Parents briefly invoke field preemption when they assert that the NCVIA occupies the field of vaccine litigation and leaves "no space for . . . supplementation." *Booth* Pls.' Mot. at 27 (quoting *Sickle v. Torres Adv. Enter. Sols., LLC,* 884 F.3d 338, 347 (D.C. Cir. 2010)). But the *Booth* Parents' evidence for this assertion is that the MCA imposes duties on healthcare providers that are "contradictory" to the duties imposed by federal law. *Id.* at 28. Thus, say the *Booth* Parents, the MCA "conflicts" with the federal law. *Id.* This is an argument for conflict preemption, not field preemption.

Although Plaintiffs make several arguments about conflict preemption, two of those arguments suffice for the Court to find preemption. Plaintiffs' first argument concerns the interpretation of the phrase "of any child or to any other individual to whom such provider

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intends to administer such vaccine" in 42 U.S.C. § 300aa-26(d). The second argument concerns the meaning of the word "alternative" in the MCA.

Before reaching Plaintiffs' arguments, consider a few principles of preemption analysis. *First*, courts apply a presumption against preemption. In cases "in which Congress has legislated ... in a field which the States have traditionally occupied, ... we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (cleaned up); *see also Sickle*, 884 F.3d at 3146 (same).

*Second*, in preemption analysis, "the purpose of Congress is the ultimate touchstone." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). But although a court may look at Congress's purpose, "all preemption arguments[] must be grounded in the text and structure of the statute at issue." *Kansas v. Garcia*, 140 S. Ct. 791, 804 (2020) (cleaned up). "Congress's authoritative statement is the statutory text, not the legislative history." *Chamber of Comm. of U.S. v. Whiting*, 563 U.S. 582, 599 (2011) (cleaned up). "Invoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law; a litigant must point specifically to a constitutional text or a federal statute that does the displacing or conflicts with state law." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (lead opinion) (cleaned up).

With these principles in mind, the Court turns to Plaintiffs' arguments.

The meaning of the phrase "of any child or to any other individual to whom such provider intends to administer such vaccine." Plaintiffs argue that the MCA places duties on healthcare providers that contradict duties imposed by the NCVIA. They maintain that because the MCA cuts parents out of the vaccination process, a parent will never receive the VIS. See

*Mazer* Compl. ¶¶ 42–44; *Booth* Compl. ¶¶ 325–35. They contend that this conflicts with 42 U.S.C. § 300aa-26(d), which requires healthcare providers to give a VIS to parents:

[E]ach health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the [VIS], supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

The District responds by zeroing in on the phrase "to any other individual to whom such provider intends to administer such vaccine." In the District's telling, "if a mature minor may receive a vaccine" under the MCA, "then he or she qualifies as 'any other individual to whom' a healthcare provider intends to administer a vaccine" and thus "a provider may easily comply with both laws." *Mazer* Defs.' Opp'n. at 27; *see also Booth* Defs.' Mem. at 31–32 (same).

But the District's interpretation has several problems. *First*, Congress's reference to "the legal representatives of any child" and then to "any other individual" conveys that when the person receiving the vaccination is a child, the VIS must be given to the legal representative. 42 U.S.C. § 300aa-26(d). If Congress did not mean for the legal representative to receive a VIS when his child receives a vaccine, then the phrase "the legal representatives of any child" would be superfluous. All Congress would have needed to say is that a healthcare provider should give a VIS "to any individual to whom such provider intends to administer such vaccine." But it did not do that. And courts shun statutory interpretations that result in surplusage. *See Torres v. Lynch*, 578 U.S. 452, 463 n.8 (2016) ("[O]ur ordinary assumption [is] that Congress, when drafting a statute, gives each provision independent meaning."); *see also* Antonin Scalia and Bryan J. Garner, *Reading Law: The Interpretation of Legal Texts* 176–78 (2012) ("Because legal drafters should not include words that have no effect, courts avoid a reading that renders some

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words altogether redundant . . . [W]ords with no meaning—language with no substantive effect—should be regarded as the exception rather than the rule.").

*Second*, the District's interpretation renders the word "other" meaningless. The most natural reading is that, by placing the word "other" before "individual," Congress intended to exclude "any child." The ordinary meaning of the word "other" makes this clear. *See Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 47 (1989) ("We have often stated that in the absence of a statutory definition we start with the assumption that the legislative purpose is expressed by the ordinary meaning of the words used."); OED Online, *Other* def. A.5 (defining "other" as "[s]eparate or distinct from that or those already specified or implied; different; (hence) further, additional");<sup>6</sup> Am. Her. Dict., *Other* def. 1.a (defining "other" as "[b]eing the remaining one of two or more").<sup>7</sup> Thus, "any other individual" cannot include "any child" because the use of the word "other" means that "individual" is "separate or distinct from" or "additional" to "child." The District's conclusion makes sense only if one reads "other" out of the statute. Because courts avoid interpretations that result in surplusage, Plaintiffs have the better statutory reading.

If "any other individual" excludes "child," then the question naturally arises: Who is a child? Congress provided no definition in the NCVIA. The District contends that the Court should define "child" based on state law. *See Mazer* Defs.' Opp'n at 28 ("A reasonable interpretation is that State law, and specifically the State's medical consent law, should be

<sup>&</sup>lt;sup>6</sup> *Available at* https://www.oed.com/view/Entry/133219?isAdvanced=false&result=1&rskey=HI3GrA& (last visited March 10, 2022).

<sup>&</sup>lt;sup>7</sup> *Available at* https://www.ahdictionary.com/word/search.html?q=other (last visited March 10, 2022).

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deferred to for purposes of defining who is a minor.") (quoting CDC, *VIS Frequently Asked Questions*<sup>8</sup>); *Booth* Defs.' Mem. at 32 (same). Because the MCA says that an informed minor as young as 11 can receive the vaccine, the District says such a person is not a "child" for purposes of the NCVIA. Thus, if a healthcare provider gives the VIS to the minor at the time of the vaccination, there is no conflict between the NCVIA and the MCA.

This interpretation has some appeal and presents a closer call than the District's first statutory interpretation argument. The Supreme Court has held that where a federal statute leaves a term undefined and the term references a familial relationship, a court should look to state law. *See Seaboard Air Line Ry. v. Kenney*, 240 U.S. 489 (1916) ("[W]ho are next of kin is determined by the legislation of the various states to whose authority that subject is normally committed, [so] it would seem to be clear that the absence of a definition in the act of Congress plainly indicates the purpose of Congress to leave the determination of that question to the state law."); *see also De Sylva v. Ballentine*, 351 U.S. 570, 580 (1956) ("[T]here is no federal law of domestic relations, which is primarily a matter of state concern."). And the Centers for Disease Control and Prevention have arguably endorsed the District's approach. *See* CDC, *VIS Frequently Asked Questions*.<sup>9</sup>

<sup>&</sup>lt;sup>8</sup> Available at https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html (last visited March 10, 2022).

<sup>&</sup>lt;sup>9</sup> The District contends the Court should grant *Chevron* deference to the CDC's answers to frequently asked questions (FAQ). *See Booth* Defs.' Reply at 13 n.4, ECF No. 42. But *Chevron* deference does not apply to informal interpretations like this one. *See Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."). More, the CDC's FAQ give 18 as an example of the age of consent for vaccinations, a very different proposition than the District's 11-year-old line. *See* CDC, *VIS Frequently Asked Questions, available at* https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html (last visited March 10, 2022).

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But this interpretation also has problems. *First,* it conflicts with other Supreme Court guidance to start "with the general assumption that in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law." *Holyfield*, 490 U.S. at 43. There is no "plain indication" that Congress intended to make the NCVIA dependent on state law—in fact, quite the contrary. Congress knew how to define an NCVIA term with reference to state law because it did so for "legal representative." *See* 42 U.S.C. § 300aa-33(2) (defining "legal representative" to mean "a parent or an individual who qualifies as a legal guardian under State law"). This suggests Congress did not want to define "child" with reference to state law. *See* Scalia and Garner, *supra*, at 107 (explaining the "Negative-Implication Canon . . . The expression of one thing implies the exclusion of others").

Second, the District's interpretation would impair the uniform application of the NCVIA. Jerome v. United States, 318 U.S. 101, 104 (1943) ("[T]he application of federal legislation is nationwide and . . . at times [a] federal program would be impaired if state law were to control."); see also Holyfield, 490 U.S. at 43 (instructing courts to assess whether Congress intended a federal law to have "uniform nationwide application").

Recall that Congress passed the NCVIA to "stabilize the vaccine market." *Bruesewitz*, 562 U.S. at 228. Before the NCVIA, lawsuits under state law were driving vaccine manufacturers from the market. *Id.* at 227. At the same time, parents suing vaccine manufacturers had trouble obtaining compensation. *Id.* Many parents decided it was better not to vaccinate their children at all. *Id.* So, in a "quid pro quo," Congress provided for "[f]ast, informal adjudication . . . made possible by the Act's Vaccine Injury Table" while also conferring "significant tort-liability protections" on vaccine manufacturers. *Id.* at 228–29. Thus,

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Congress preempted the patchwork of state remedies with a uniform federal system. Defining "child" using fifty different state definitions would erode the stability the NCVIA provides to the vaccine market. Using an ordinary understanding of "child" advances that goal. This problem is highlighted by J.D., who cannot get vaccinated in her home state of Maryland without parental consent but can now slip into the District and be considered a "mature minor."

*Third*, the District's interpretation conflicts with the statute's structure and purpose. Two crucial exchanges of information lie at the heart of the NCVIA. The first is the exchange of information from parent to doctor. Healthcare providers recommend against vaccinations if individuals reacted poorly to past immunizations. *See Booth* Compl. ¶ 332. A VIS describes the risks of certain vaccines and explains when they are contraindicated. *See* 42 U.S.C. § 300aa-26, *et seq.*; *Booth* Compl. ¶ 332. But as J.D.'s story shows, a child—even a "mature" one—is unlikely to know or remember the reactions she had to vaccines as an infant. By removing the parent from the vaccine decision, the MCA undercuts a key purpose of the VIS and a safety check before the vaccination. J.D.'s doctor is likely to authorize a vaccination without having an accurate understanding of her risk profile.

The second exchange of information flows from the doctor to the child's parent. The VIS not only warns the parent of what complications to look out for, but it also tells him how to file a complaint with the Program. *See Booth* Compl. ¶¶ 330–35. Recall that the NCVIA allows only parents and legal guardians to make claims for vaccine injuries under the Program. *See* 42 U.S.C. § 300aa-11(b)(1) (stating that the only people who can petition for compensation from the Program are persons who have sustained vaccine-related injuries or "the legal representative of such person if such person is a minor").<sup>10</sup> If the parent of a vaccinated child does not receive a

<sup>&</sup>lt;sup>10</sup> Although the VIS must be given to the legal representative of a *child*, see 42 U.S.C. § 300aa-

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VIS, how is the parent supposed to know to file a claim in the Program—a claim that only the parent can file?

Compounding this challenge, the MCA encourages children to deceive their parents. Once a child has gone behind her parents' backs to get a vaccine, what is she supposed to do if she has a negative reaction? Some children might tell their parents; others very well might be afraid and try to hide their actions. Besides the obvious medical risk such a situation entails, this throws a wrench in the NCIVA's goal of "[f]ast, informal adjudication" of vaccine injuries. *Bruesewitz*, 562 U.S. at 228. This fast adjudication depends on rapid identification of injuries. For example, the Vaccine Injury Table says that for "Vaccines containing tetanus toxoid," anaphylaxis could occur in less than four hours. *See* Health Res. and Svcs. Admin., *Vaccine Injury Table*.<sup>11</sup> A shoulder injury related to vaccine administration could manifest within 48 hours. *Id.* A parent who did not know his child had been vaccinated would not know to be on the lookout for adverse reactions. Nor would he have any reason to suspect that an adverse reaction, if he noticed one, was because of the vaccine. More, for a child to receive compensation under the Program, her legal guardian must file a claim within three years. 42

<sup>26(</sup>d), a *minor* cannot file a claim under the Program, *see id.* § 300aa-11(b)(1). At the motions hearing, the parties disputed who counts as a minor under the NCVIA (which does not define the term). *See* Hearing Tr. 17:3–18:23 (Plaintiffs contending "minor" means 18); 44:25–45:16 (District arguing "minor" should be interpreted based on the MCA). Neither party could provide a definitive answer, nor could either party explain why the NCVIA uses the term "child" in one section and "minor" in another. In any event, a minor cannot file a claim. Presumably, this is true even of "mature" minors. At summary judgment, the District might be able to show that "minor" means someone under age 18. For now, though, the District's general minor health consent regulation guides the Court. This regulation says that "[a]ny person who is eighteen (18) years of age or older may consent to the provision of health services for himself or herself." *See* 22-B D.C.M.R. § 600.1.

<sup>&</sup>lt;sup>11</sup> *Available at* https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf (last visited March 9, 2022).

U.S.C. § 300aa-16(a)(2). The NCVIA does not allow a minor to file a claim and makes no provision for tolling of the statute of limitations until the age of majority. *See id.*; *id.* § 300aa-11(b)(1)(A).

True, the VIS is not the only way a parent could learn that his child got vaccinated. Nor is a VIS the only way to learn about the Program. The internet, word-of-mouth, and—of course—lawyers could all be sources of information. But the Court's task when engaged in statutory interpretation is to try to make sense not only of the statutory provision at issue, but of the entire statute. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."). "[T]here can be no justification for needlessly rendering provisions in conflict if they can be interpreted harmoniously." Scalia and Garner, *supra*, at 180. Taken as a whole, the NCVIA shows Congress did not intend for minors to take control of their own vaccination decisions. The District's interpretation of "child" cuts parents out of the vaccination process and so deviates from Congress's intent.

\* \* \*

To be sure, this interpretive exercise is a close call. Both sides advance persuasive arguments. But even if the Court is wrong that the ordinary meaning of "child" applies instead of state law, the District has a final problem.<sup>12</sup> A court may not use state law to define a term in a federal law in a way that beggars belief. *See De Sylva*, 351 U.S. at 581 (holding that defining a

<sup>&</sup>lt;sup>12</sup> Plaintiffs do not point to a federal common law definition of "child." Nor is that surprising given that domestic relations are "primarily a matter of state concern. *De Sylva*, 351 U.S. at 580. But at the motions hearing, the District pointed to the implementing regulations for the Public Readiness and Preparedness Act, which regulates COVID-19 vaccines. *See* Hearing Tr. 64:5–17. The regulations define child as an individual "18 years of age or younger." 42 C.F.R. § 110.3(e)(1)(i).

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term in a federal law based on state law "does not mean that a State would be entitled to use the word . . . in a way entirely strange to those familiar with its ordinary usage"). Even the District admitted there are limits to how a state can define "child." *See* Hearing Tr. at 43:14–44:8. And the Court doubts most parents consider their eleven-year-olds anything but children. *See, e.g., Booth* Compl. ¶ 36 (D.C. Council Member stating at a meeting to consider the MCA: "I have a twelve-year-old son who can barely put together a five-page paper, or finish his homework on time, or be up late at night playing Fortnite—making decisions about his health. And so, for us to circumvent that process is very worrisome to me[.]"). Perhaps states have some latitude to define "child" under the NCVIA, but the MCA stretches beyond the bounds of reason.

Plaintiffs viably interpret the word "child." The District does not. The Court therefore accepts Plaintiffs' interpretation.

*The meaning of the word "alternative.*" Plaintiffs argue that the MCA also conflicts with the NCVIA's requirement to provide a VIS. *See Booth* Pls.' Mot. at 21–24; *Mazer* Pl.'s Reply at 12–13. Recall that the NCVIA requires healthcare providers to give the VIS to a child's legal representative or the person whom the provider is vaccinating. *See* 42 U.S.C. § 300aa-26(d). The VIS is a specific document produced by HHS for each vaccine on the Vaccine Injury Table. *See id.* § 300aa-26(a). In contrast, the MCA says that the D.C. Department of Health "shall produce one or more age-appropriate *alternative* vaccine information sheets, which shall be made available before vaccination of minors to support providers for use in the informed consent process." MCA § 2(c) (emphasis added). Plaintiffs argue that the MCA improperly seeks to replace the VIS with an "age-appropriate alternative" VIS.

The District responds that "[m]erely because a law mandates an additional source of information cannot mean—without more—that the law implicitly rejects any other information."

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*Booth* Defs.' Mem. at 33–34. The District acknowledges that "the use of the word 'alternative' here may have been imprecise." *Id.* at 34. But it contends that a mere imprecision "cannot carry the weight plaintiffs place on it—it does not conflict with federal requirements." *Id.* 

True, finding preemption based on one word is a tall order. But the District chose the word—not Plaintiffs or the Court. And contrary to the District's contention, an "alternative" age-appropriate VIS is not "an additional source of information." *Id.* It is an exclusive source. "Alternative" has an unambiguous meaning. OED Online, *Alternative* def. A.4 (defining "alternative" as "[o]f two things: such that one or the other may be chosen, the choice of either typically involving the rejection of the other.")<sup>13</sup>; Am. Her. Dict., *Alternative* def 1.b (defining "alternative" as "[b]eing one of two mutually exclusive choices or courses of action")<sup>14</sup>. The natural way to read the statute is that healthcare providers in the District are to provide the age-appropriate VIS instead of the federal VIS—not along with it.

"We have held that state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–18 (2011) (cleaned up). Such is the case here. The District could have offered evidence that healthcare providers in the District provide minors with both the VIS and the District-created, age-appropriate VIS. And perhaps it will at summary judgment. But it did not at this stage. Indeed, the only evidence the Court has before it now points in the other direction. *See Mazer* Compl. ¶ 56 (stating J.D. did not receive a VIS). Thus, the Court finds Plaintiffs' reading of the Act is the better one.

<sup>&</sup>lt;sup>13</sup> Available at https://www.oed.com/view/Entry/5803?redirectedFrom=alternative& (last visited March 9, 2022).

<sup>&</sup>lt;sup>14</sup> Available at https://www.ahdictionary.com/word/search.html?q=alternative (last visited March 9, 2022).

\* \* \*

Two final arguments by the District—applicable to both preemption arguments discussed above—bear brief mention. *First*, the District argues that when Congress enacted the NCVIA, many states had laws that allowed minors to consent to medical treatment without parental knowledge or assistance. Surely, says the District, Congress did not mean to preempt all these laws—at least not without explicitly saying so. *See Booth* Defs.' Mem. at 33; *Mazer* Defs.' Opp'n at 28–29. But the District does not contend that any of these state laws allowed minors to consent to *vaccines*. As the District's own regulations show, states set different ages of consent for different medical procedures. *See* 22-B D.C.M.R. §§ 600, *et seq*. (establishing, for example, 17 as the age to consent to blood donation, but "any age" to consent to treatment for substance abuse).<sup>15</sup>

Second, the District argues "other federal healthcare law expressly acknowledges and incorporates the 'mature minor' doctrine found in most State law." *Booth* Defs.' Mem. at 37; *see also Mazer* Defs.' Opp'n at 29 (same). The District contends this proves "Congress plainly intends to share the field" of vaccine regulation. *Booth* Defs.' Mem. at 38. But the District's only example is Health Insurance Portability and Accountability Act *regulations* that reference the mature minor doctrine. *See Booth* Defs.' Mem. at 37; *Mazer* Defs.' Opp'n at 29 (same).

<sup>&</sup>lt;sup>15</sup> An amici curiae brief submitted by organizations including the American Academy of Pediatrics and the American Medical Association claims 14 states "have minor consent laws that specifically address immunization, authorize certain minors to consent to 'any' medical care, or have expressly reaffirmed in the past year that their laws permit minors to self-consent to vaccination." Br. of Amici Curiae American Academy of Pediatrics, *et al*, at 28, ECF No. 38. Fair enough. But the Court's holding does not rule out the possibility that some vaccine-specific minor consent laws could coexist with the NCVIA. In any event, neither the District nor amici discuss how these laws treat the VIS and religious exemptions—factors crucial to the Court's analysis of the MCA.

Regulations do not convey congressional intent.

For all these reasons, the Court finds that Plaintiffs will likely succeed on the merits of their claim that the NCVIA preempts the MCA.

# 2. The Booth Parents are likely to succeed on their Free Exercise claim.

Turn next to the *Booth* Parents' Free Exercise claim.<sup>16</sup> The First Amendment states that "Congress shall make no law respecting an establishment of religion or prohibiting the free exercise thereof." U.S. Const. amend. I. But although the Constitution protects religious exercise, it does not say how a court should analyze a claim that the government is infringing on free exercise. And the parties disagree about which standards should apply.

Plaintiffs argue that the Court should examine whether the MCA is neutral and generally applicable. *See Booth* Pls.' Mot. at 38. Under this familiar standard, laws that burden an individual's ability to practice his religion are subject to strict scrutiny unless they are neutral and generally applicable. *See Church of the Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 531 (1993). A law lacks neutrality when "the object of [the] law is to infringe upon or restrict practices because of their religious motivation." *Id.* at 533. A law "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way." *Fulton v. City of Phila.*, 141 S. Ct. 1868, 1877 (2021). A court should look particularly closely at whether the law selectively targets religion. *See Lukumi*,

<sup>&</sup>lt;sup>16</sup> Mazer only asks that the Court enjoin the District from implementing and enforcing § 2 of the MCA. *See Mazer* Mot. for Prelim. Inj., ECF No. 4 at 1. Section 2 of the MCA adds § 600.9 to the D.C. Municipal Regulations to permit children 11 and older to consent to receive a vaccine without their parents' knowledge. *See id.* Mazer does not ask the Court to enjoin § 3 of the MCA, which tells healthcare providers to leave blank part 3 of the Certificate for children with a religious exemption. *See id.* Section 3 is the subject of the Court's Free Exercise analysis. Thus, the Court examines likelihood of success on the merits of the Free Exercise claim only for the *Booth* Parents.

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508 U.S. at 542 ("All laws are selective to some extent, but categories of selection are of paramount concern when a law has the incidental effect of burdening religious practice.").

The District pushes back. It argues that the Court should engage in a two-step analysis. It says that the Court should examine whether Plaintiffs have made a "threshold showing" that "a law or regulation imposes a substantial, as opposed to an inconsequential, burden on the litigant's religious practice before the Free Exercise Clause is implicated." *Booth* Defs.' Mem. at 51 (cleaned up). Only if the Court finds that Plaintiffs have met this standard should it examine whether the MCA is neutral and generally applicable. *See id*.

The District invokes the wrong standard. The case it points to, *Levitan v. Ashcroft*, 281 F.3d 1313 (D.C. Cir. 2002), does say a plaintiff must make a "threshold showing" that "a law or regulation imposes a substantial, as opposed to inconsequential, burden on the litigant's religious practice." *Levitan*, 281 F.3d at 1320. But *Levitan* involved a neutral and generally applicable law: A ban on federal prisoners consuming alcohol. *Id.* at 1315–16. A religious prisoner who wanted to use wine in religious services objected. *Id.* Crucially, the religious prisoner did not allege that the prison treated another category of prisoners more favorably. *See id.* 

Not so here. The *Booth* Parents argue the MCA burdens them because it orders healthcare providers to leave blank part 3 of the Certificate for all children with a religious exemption on file. *See Booth* Pls.' Mot. at 38. More, they allege the MCA "is clearly hostile to religion, because whether the vaccination record is left 'blank' is based solely on the existence of the parents' religious exemption." *Booth* Pls.' Reply at 37, ECF No. 39; *see also id.* at 34 ("[P]arents with medical exemptions are treated differently: their decisions are not 'singled out,' nor are they 'targeted' like parents who claim a religious exemption[.]").

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When a plaintiff argues a law is not neutral and generally applicable, he needs to show a burden, but not a *substantial* one. *See Tenafly Eruv Ass'n, Inc. v. Borough of Tenafly*, 309 F.3d 144, 170 (3d Cir. 2002) ("Under [*Employment Div. v. Smith*, 494 U.S. 872 (1990)] and *Lukumi*... there is no substantial burden requirement when government discriminates against religious conduct."); *Hartmann v. Stone*, 68 F.3d 973, 979 n.4 (6th Cir. 1995) (citing *Lukumi* to apply strict scrutiny while finding that plaintiffs "need not demonstrate a substantial burden on the practice of their religion"); *Brown v. Borough of Mahaffey*, 35 F.3d 846, 849 (3d Cir. 1994) ("The rare cases which address acts or laws which target religious activity have never limited liability to instances where a substantial burden was proved by the plaintiff.") (cleaned up).

More, recent Supreme Court decisions have applied strict scrutiny to non-neutral and generally applicable laws without asking whether these laws impose *substantial* burdens. *See Fulton*, 141 S. Ct. 1868. at 1876–77; *see also Lukumi*, 508 U.S. at 531–46; *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) (per curiam) (finding that a law restricting religious gatherings for public health reasons was not neutral or generally applicable and was subject to strict scrutiny despite no finding of a substantial burden); *Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (per curiam) ("[G]overnment regulations are not neutral and generally applicable, and therefore trigger strict scrutiny under the Free Exercise Clause, *whenever they treat any comparable secular activity more favorably than religious exercise*.") (emphasis added).

The Court thus proceeds to evaluate whether the law is neutral and generally applicable. Start with neutrality. Supreme Court precedent distinguishes between facial and substantive neutrality. "A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." *Lukumi*, 508 U.S. at 533 (1993). A court

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may find a facially neutral law non-neutral in application if the law covertly targets religious beliefs. *See id.* at 534. Because the MCA "refers to a religious practice" and thus is not facially neutral, the Court need not ask whether the law covertly targets religion. *Id.* at 533; *see* MCA § 3(b)(2) (mentioning religious exemptions by name).<sup>17</sup>

Nor is the law generally applicable. Recall that D.C. Code § 38-506 provides for exemptions from childhood vaccinations for religious *and* medical reasons. But the MCA's directive to leave blank part 3 of the Certificate only applies to parents who have filed *religious* exemptions for their children. So if a child whose parent filed a religious exemption goes behind his parents' back and gets a vaccine, the healthcare provider will leave blank part 3 of the Certificate and will submit the immunization record directly to the school. *See* MCA § 3(b)(2). The MCA orders the school to keep that immunization record confidential. *Id.* But if a child whose parent filed a *medical* exemption gets a vaccine, the MCA does not instruct the healthcare provider to leave blank part 3 of the Certificate. Nor does the MCA direct the school to keep the immunization record confidential. This puts religious parents at an informational disadvantage as compared to non-religious parents.

The District does not explain why the MCA instructs healthcare providers to leave part 3 of the Certificate blank for parents with a religious exemption but not for parents with a medical one. Instead, it asserts that "[m]edical exemptions are based on the *provider's* determination that a vaccine is not medically recommended, and, therefore, providers would not be in the position of administering a vaccine under the Act." *Booth* Defs.' Reply at 23 n.8, ECF No. 42. The

<sup>&</sup>lt;sup>17</sup> Contrary to the District's contention, Plaintiffs need not prove that the MCA "evinces hostility similar to *Masterpiece* [*Cakeshop*]." *Booth* Defs.' Mem. at 53. Even absent proof of animus, the Supreme Court said in *Smith* that a law will not qualify as neutral if a religious exercise is the "object" of a law and is not just "incidental[ly]" affected by it. *Smith*, 494 U.S. at 878. Because the MCA specifically calls out religious exemptions, religious exercise is its "object." *Id*.

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District's meaning is not entirely clear, but it appears to be saying that the Act does not affect medical exemptions. That, however, is exactly the problem. *See Lukumi*, 508 U.S. at 542. ("All laws are selective to some extent, but categories of selection are of paramount concern when a law has the incidental effect of burdening religious practice."). The MCA burdens religious practice by withholding from religious parents information available to secular parents who file a medical exemption for their children. Thus, the law is not generally applicable.

The District has one more argument. It contends that it is not required to provide *any* religious exemptions. *See Booth* Defs.' Mem. at 52. The District cites *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944), for the proposition that a plaintiff "cannot claim freedom from compulsory vaccination for [his] child more than for himself on religious grounds." So, says the District, it should not be penalized for providing a qualified religious exemption when it was never required to provide one to begin with.

But the law at issue in *Prince* is different from the District's law. There was no allegation in *Prince*, as there is here, that the law targeted religious parents.<sup>18</sup> When the government makes "a value judgment that secular (i.e., medical) motivations" for special treatment are "important enough to overcome" its interest in uniformly applying a policy "but that religious motivations are not," this "raises concern." *See Frat. 'l Ord. of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359, 366 (3d Cir. 1999) (Alito, J.). The singling out of religion triggers strict scrutiny. *Lukumi*, 508 U.S. at 531; *see also Frat. 'l Ord. of Police*, 170 F.3d at 366 ("[W]hen the government makes a value judgment in favor of secular motivations,

<sup>&</sup>lt;sup>18</sup> The District cites two other cases for the proposition that the Constitution does not require religious exemptions to vaccination mandates: *Phillips v. City of New York*, 775 F.3d 538 (2d Cir. 2015), and *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App'x 348 (4th Cir. 2011). *See Booth* Defs.' Mem. at 52–53. But neither case involved a governmental authority targeting religious parents. Thus, like *Prince*, these cases do not help the District.

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but not religious motivations, the government's actions must survive heightened scrutiny."). When strict scrutiny applies, the government must show its burden on religion is "justified by a compelling governmental interest and [is] narrowly tailored to advance that interest." *Lukumi*, 508 U.S. at 531–32. The MCA does not survive this test.

The District claims it needed the MCA "so that the District can move towards a high enough immunization rate to achieve herd immunity—or 95% immunity—from diseases such as measles." *Booth* Defs.' Mem. at 17 (quoting the Council of the District of Columbia, Comm. on Health, Report on Bill 23-0171, at 1, 2 (Oct. 7, 2020)). Preventing the spread of communicable disease is a compelling governmental interest. *See Cuomo*, 141 S. Ct. at 67. But the District undermines that compelling interest by treating medical and religious exemptions differently with no explanation for why it does so. *See Fulton*, 141 S. Ct. at 1877 ("A law also lacks general applicability if it prohibits religious conduct while permitting secular conduct that *undermines the government's asserted interests in a similar way.*") (emphasis added).

For the same reason, even assuming the District has shown a compelling interest, the MCA is not narrowly tailored. Recall that D.C. Code § 38-506(2) allows an exemption for anyone able to obtain a "written certification by a private physician" that a vaccination is "medically inadvisable." *Id.* What does "medically inadvisable" mean? The D.C. Code does not define the phrase. Nor does the District interpret it. The ambiguity leaves one guessing whether something as simple as the risk of a rash or shoulder pain could be enough to exempt an individual from vaccination. *See Booth* Compl. ¶ 307 (listing rashes and shoulder pain as injuries for which the Program has paid out compensation). And it leaves the Court with no option at this stage of the litigation except to conclude that the MCA is not narrowly tailored to achieve the District's interest. *See Frat'l Ord. of Police*, 170 F.3d at 367 ("We are at a loss to

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understand why religious exemptions threaten important city interests but medical exemptions do not."); *see also Lukumi*, 508 U.S. at 546 (holding that a law that is too broad or too narrow is not narrowly tailored).

In coming to this conclusion, the Court does not rule out that the District could make the necessary showing to satisfy strict scrutiny at summary judgment. But at this stage, the District has not made that showing. Because the *Booth* Parents have credibly alleged that the MCA targets religious parents and the District has not shown that the MCA is narrowly tailored to meet a compelling interest, they are likely to succeed on their Free Exercise claim.<sup>19</sup>

# **B.** Plaintiffs are likely to suffer irreparable injury absent injunctive relief.

The Court next considers whether Plaintiffs have shown that they will suffer irreparable injury absent injunctive relief. *See League of Women Voters*, 838 F.3d at 6. The *Booth* Parents easily satisfy this burden because "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Cuomo*, 141 S. Ct. at 67 (cleaned up). The conclusion that they are likely to succeed on the merits of their Free Exercise claim thus also suffices to show that they will be irreparably harmed without injunctive relief.

More, both the *Booth* Parents and Mazer have shown they are likely to suffer irreparable injury absent injunctive relief for their preemption claims. They must show "(1) that the harm is certain and great, actual and not theoretical, and so imminent that there is a clear and present

<sup>&</sup>lt;sup>19</sup> The District argues that the *Booth* Parents only challenge the MCA on its face and therefore must show that there is "no set of circumstances . . . under which [the MCA] would be valid." *Booth* Defs.' Mem. at 28 (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). But they also made an as-applied challenge. *See Booth* Compl. ¶ 207. More, there is no reading of the MCA that does not discriminate against religious parents. And the Supreme Court has granted facial challenges where the law is facially discriminatory to religion without applying the "no set of circumstances" test. *See, e.g., Lukumi*, 508 U.S. at 532, 547 (voiding the entire law without applying the "no set of circumstances" test because "the protections of the Free Exercise Clause pertain if the law at issue discriminates against some or all religious beliefs").

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need for equitable relief to prevent irreparable harm; and (2) that the harm is beyond remediation." *Capitol Hill Baptist*, 496 F. Supp. 3d at 301 (cleaned up). Plaintiffs have met the first requirement because they have shown that L.B. and J.D. are likely to get a vaccine any day. And they meet the second requirement because administration of a vaccine is "beyond remediation"—it cannot be undone. *Id*.

# C. The balance of the equities and the public interest support granting the preliminary injunction.

Finally: Have Plaintiffs shown that the balance of the equities and the public interest supports the Court granting relief? These factors merge when, as here, the government is the party opposing the injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

The balance of the equities and the public interest favor granting relief. The public has an interest in upholding the integrity of Congress's laws and honoring the free exercise of religion. Of course, the public also has an interest in controlling the spread of disease. But by its own admission, "religious exemptions are generally rare in the District." *Booth* Compl. ¶ 54 (quoting the District's Immunization Attendance Policy).

And although the District relies heavily on the COVID-19 pandemic to justify its need for the MCA, the pandemic was not its impetus. *See Booth* Defs.' Mem. at 16 ("The [MCA] was introduced on May 5, 2019, on the heels of a measles outbreak[.]"). More, COVID-19 infections in the District are trending downward. *See* Johns Hopkins Univ. School of Med., Coronavirus Res. Ctr., *District of Columbia*.<sup>20</sup> Nearly 93% of the District is fully vaccinated—a higher share

 <sup>&</sup>lt;sup>20</sup> Available at https://coronavirus.jhu.edu/region/us/district-of-columbia (last visited March 17, 2022).

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of the population than any state. *See* Johns Hopkins Univ. School of Med., Coronavirus Res. Ctr., *Understanding Vaccination Progress*.<sup>21</sup>

Enjoining the MCA will not prevent children from being vaccinated. Nor will it prevent the District from continuing to advertise the importance of vaccines, incentivizing vaccinations, and setting up vaccine clinics in schools. The only impact will be that children will be unable to decide to get vaccinations without their parents' consent. If the District believes this will greatly endanger children's health and welfare, it can present that evidence at summary judgment.

# V. CONCLUSION

Vaccines are "one of the greatest achievements" of public health in the 20th century. *Bruesewitz*, 562 U.S. at 226. So Congress decided to step in to protect vaccine manufacturers with the NCVIA. States and the District are free to encourage individuals—including children to get vaccines. But they cannot transgress on the Program Congress created. And they cannot trample on the Constitution.

Plaintiffs have shown that the NCVIA likely preempts the MCA and the *Booth* Parents have shown that the MCA likely violates their Free Exercise rights. The Court will grant Plaintiffs' motions for preliminary injunctive relief and will deny the Districts' motions to dismiss as to the preemption claims (for all Plaintiffs) and the Free Exercise claim (for the *Booth* Parents). Separate orders will issue.

Dated: March 18, 2022

TREVOR N. McFADDEN, U.S.D.J.

<sup>&</sup>lt;sup>21</sup> Available at https://coronavirus.jhu.edu/vaccines/us-states (last visited March 17, 2022).

KeyCite Yellow Flag - Negative Treatment Proposed Legislation

West's Tennessee Code Annotated Title 63. Professions of the Healing Arts (Refs & Annos) Chapter 1. Division of Health Related Boards (Refs & Annos) Part 1. General Provisions

### T. C. A. § 63-1-165

### § 63-1-165. Mature Minor Doctrine Clarification Act

Effective: May 17, 2023 Currentness

(a) The general assembly finds and declares the following:

(1) The National Childhood Vaccine Injury Act of 1986 (42 U.S.C. § 300aa-26) requires, prior to the administration of a vaccine listed in the vaccine injury table to a minor, that healthcare providers provide the vaccine information statement from the centers for disease control and prevention to the legal representatives of the minor;

(2) The Tennessee supreme court's decision in *Cardwell v. Bechtol*, 724 S.W.2d 739 (1987), found that the **mature minor** exception, guided by the "Rule of Sevens," is part of Tennessee common law, but only in the context of tort law and jury considerations, and not the general rule requiring parental consent for the medical treatment of **minors**;

(3) The *Cardwell* court stated, "Adoption of the **mature minor** exception to the common law rule is by no means a general license to treat **minors** without parental consent and its application is dependent on the facts of each case. It must be seen in the context of the tort in question.";

(4) Despite its holding in the case, the *Cardwell* court declined to alter the general rule, which is "requiring parental consent for the medical treatment of **minors**";

(5) In its opinion in the case of *Parham v. J.R.*, 442 U.S. 584 (1979), the United States supreme court wrote, "Simply because the decision of a parent is not agreeable to a child, or because it involves risks, does not automatically transfer the power to make that decision from the parents to some agency or officer of the state. The same characterizations can be made for a tonsillectomy, appendectomy, or other medical procedure. Most children, even in adolescence, simply are not able to make sound judgments concerning many decisions, including their need for medical care or treatment. Parents can and must make those judgments."; and

(6) In the case of *Troxel v. Granville*, 530 U.S. 57 (2000), Justice O'Connor wrote for the United States supreme court, "The Fourteenth Amendment's Due Process Clause has a substantive component that 'provides heightened protection against

government interference with certain fundamental rights and liberty interests,' *Washington v. Glucksberg*, 521 U.S. 702, 720, including parents' fundamental right to make decisions concerning the care, custody, and control of their children''.

(b) As used in this section:

(1) "Department" means the department of health;

(2) "Healthcare provider" means a healthcare professional, healthcare establishment, or healthcare facility licensed, registered, certified, or permitted pursuant to this title or title 68 or regulated under the authority of either the department of health or an agency, board, council, or committee attached to the department of health, and that is authorized to administer vaccinations in this state;

(3) "**Minor**":

(A) Means an individual who has not attained eighteen (18) years of age; and

(B) Does not include an individual who:

(i) Is emancipated pursuant to title 29, chapter 31;

(ii) Is in need of emergency treatment pursuant to § 63-6-222;

(iii) Is or was previously a member of the armed forces of the United States, or a member of a reserve or national guard unit; or

(iv) Is the parent of a **minor** child and has full custody of that **minor** child;

(4) "Vaccination" means the act of introducing a vaccine into the body; and

(5) "Vaccine" means a substance intended for use in humans to stimulate the body's immune response against an infectious disease or pathogen.

(c)(1) A healthcare provider shall not provide a vaccination to a **minor** unless the healthcare provider first receives informed consent from a parent or legal guardian of the **minor**. The healthcare provider shall document receipt of, and include in the **minor's** medical record proof of, such prior parental or guardian informed consent.

(2) An employee or agent of this state shall not provide, request, or facilitate the vaccination of a **minor** child who is in the custody of this state, except:

(A) Upon written request to, and court order from, the appropriate court;

(B) If a parent or legal guardian of the minor has provided prior written informed consent to the vaccination; or

(C) If the parental rights of each of the **minor's** parents or legal guardians have been terminated by a court, and all opportunities for appeal have been exhausted.

(3) A violation of this section is an unlawful practice and is grounds for the offending healthcare provider's licensing authority to suspend, revoke, or refuse to renew the healthcare provider's license or take other disciplinary action allowed by law.

(4) If the licensing authority of a healthcare provider receives information of a violation or potential violation of this section by the healthcare provider, then the licensing authority shall conduct an immediate investigation and take appropriate disciplinary action.

(d) To the extent this section conflicts with another law, this section controls.

**Credits** 2023 Pub.Acts, c. 477, § 2, eff. May 17, 2023.

### **Editors' Notes**

Relevant Additional Resources Additional Resources listed below contain your search terms.

### HISTORICAL AND STATUTORY NOTES

2023 Pub.Acts, c. 477, §§ 1, 4, and 5, provide:

"SECTION 1. This act is known and may be cited as the 'Mature Minor Doctrine Clarification Act.'"

"SECTION 4. If a provision of this **act** or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the **act** that can be given effect without the invalid provision or application, and to that end, the provisions of this **act** are severable.

"SECTION 5. The department of health is authorized to promulgate rules to effectuate this **act**. The rules must be promulgated in accordance with the Uniform Administrative Procedures **Act**, compiled in Tennessee Code Annotated, Title 4, Chapter 5."

#### Former Section:

Former § 63-1-165, related to "Ultrasound sonography in nonclinical 3D/4D ultrasound boutique setting--age and certification requirements", derived from 2018 Pub.Acts, c. 1054, § 1, was repealed by 2019 Pub.Acts, c. 222, § 1, eff. April 30, 2019.

### T. C. A. § 63-1-165, TN ST § 63-1-165

Current with laws from the 2023 Regular Sess. and 1st Extraordinary Sess. of the 113th Tennessee General Assembly. Pursuant to §§ 1-1-110, 1-1-111, and 1-2-114, the Tennessee Code Commission certifies the final, official version of the Tennessee Code and, until then, may make editorial changes to the statutes. References to the updates made by the most recent legislative session should be to the Public Chapter and not to the T.C.A. until final revisions have been made to the text, numbering, and hierarchical headings on Westlaw to conform to the official text. Unless legislatively provided, section name lines are prepared by the publisher.

**End of Document** 

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