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

VICTOR M. BOOTH, et al.,

Plaintiffs,

V.

Civil Action No. 21-01857 (TNM)

MURIEL BOWSER, et al.,

Defendants.

## <u>DEFENDANTS' OPPOSITION TO PLAINTIFFS'</u> <u>MOTION FOR PRELIMINARY INJUNCTION AND</u> MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

Defendants Muriel Bowser, LaQuandra Nesbitt, and Lewis Ferebee (sued in their official capacities only) (collectively, the District) oppose plaintiffs' motion for a preliminary injunction [33] and move to dismiss plaintiffs' Amended Complaint [31] (Complaint) with prejudice. *See* Dec. 17, 2021 Minute Order; Fed. R. Civ. P. 12(b)(1); LCvR 65.1(c); Fed. R. Civ. P. 12(b)(6).

Plaintiffs, parents of minor children, have invoked the religious exemption to allow their children to attend District public schools without all required immunizations "because vaccinating their children violates their sincere religious beliefs." *See* Plaintiffs' Statement of Points and Authorities in Support of Motion for Preliminary Injunction [33-1] (Pls.' Mem.) at 12.<sup>1</sup>

Plaintiffs challenge the District's Minor Consent for Vaccinations Amendment Act of 2020 (the Act), D.C. Act 23-532, 68 D.C. Reg. 4172 (Apr. 23, 2021), which permits minors, in some circumstances, to consent to receive certain vaccines. Plaintiffs allege that the law violates the National Childhood Vaccination Injury Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq.*, due process,

Page citations are to the ECF pagination.

the Free Exercise Clause, and the Religious Freedom Restoration Act.

As set forth in the accompanying memorandum of points and authorities, plaintiffs are not entitled to emergency injunctive relief, and dismissal is appropriate because plaintiffs lack standing and fail to state a claim upon which relief can be granted. Plaintiffs—despite more than two and a half months of additional time to gather evidence—have not alleged that their children received, or certainly and imminently will receive, a vaccine under the Act. They present many pages of new allegations on the "pressures" their children allegedly face, Am. Compl. at 26–33, but such allegations fail to demonstrate the need for emergency injunctive relief, much less standing.<sup>2</sup>

Indeed, plaintiffs' renewed motion for preliminary injunction was accompanied with only two "new" exhibits in support (beyond those submitted on November 15, 2021, with their Amended Complaint). But neither that evidence (nor any previously submitted) shows that plaintiffs imminently will be injured by the Act. Plaintiffs fail to meet their burden to demonstrate that their children will be imminently coerced into receiving vaccinations without their parents' knowledge or consent.

Even if they had standing, plaintiffs cannot show that the Act violates their constitutional or statutory rights because it does not impose any—let alone any unconstitutional—interference or burdens on any right, fundamental or otherwise. The Act is an eminently reasonable, narrowly tailored, *passive* public health measure that does not require plaintiffs or their children to do anything.

As a result, plaintiffs' motion for a preliminary injunction should be denied, and the

See, e.g., Plaintiffs' Exhibit Nos. 10 and 11 [31-1 at 54, 56]. But cf. Welborn v. IRS, 218 F. Supp. 3d 64, 80 (D.D.C. 2016) (When considering a motion to dismiss for lack of subject matter jurisdiction, a court cannot "rely on conclusory or hearsay statements contained in affidavits.") (quoting J.S. ex rel. N.S. v. Attica Cent. Schs., 386 F.3d 107, 110 (2d Cir. 2004)).

Amended Complaint should be dismissed with prejudice. A proposed order is attached.

Dated: January 14, 2022. Respectfully submitted,

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# DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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#### INTRODUCTION

Plaintiffs again seek a preliminary injunction to enjoin Muriel Bowser, LaQuandra Nesbitt, and Lewis Ferebee (collectively, the District) from enforcing the District's Minor Consent for Vaccinations Amendment Act of 2020 (the Act), which allows minors, in some circumstances, to obtain vaccines regardless of parental consent. Plaintiffs' motion should be denied, and the Amended Complaint should be dismissed, because plaintiffs fail to meet the requirements for injunctive relief, lack standing, and fail to identify any constitutional or statutory violation.

Plaintiffs repeat their failed arguments with added pages of allegations about the "pressures" allegedly felt by their children to get vaccinated, extended discourse about the safety and efficacy of vaccines, disagreement with measures taken to slow the pandemic, concerns about emergency use authorizations, and rhetoric that is irrelevant to their claims.

Plaintiffs filed this action seeking a preliminary injunction, but they—still—have not identified any injury to support standing, much less the imminent, irreparable injury necessary to warrant emergency relief. Their children have been attending in-person school in the District since August 2021, Am. Compl. [31] ¶ 73, but have not received a vaccine against their parents' wishes under the Act and plaintiffs have not offered any allegations to show that their children have imminent plans to obtain one via the Act in the future.<sup>3</sup> There is only continued speculation.

Even if the Court does not dispose of this matter on threshold standing grounds, plaintiffs

Plaintiffs' allegations also veer into the self-contradictory; plaintiff Booth asserts that his son "L.B.'s common sense and independent judgment is being crushed by the coercive environment created by Defendants[,]" Am. Compl. ¶ 187, but plaintiffs' challenge rests on the underlying belief that the Act unconstitutionally encourages (or enables) their children to exercise that same independent judgment. *Cf. id.* ¶ 195 (L.B.'s "mom and dad have different opinions about the vaccine so I'm in a very tight space right now."). The District respectfully suggests that the "pressure" felt by plaintiffs' children is not caused by the defendants.

have not stated a claim for relief and similarly cannot make the requisite showing for a preliminary injunction because they cannot succeed on the merits of their claims. There is no conflict between District and federal law, no violation of federal law, no compelled interference with plaintiffs' parental rights or interests, and no burden upon plaintiff parents' exercise of religious beliefs. Federal courts around the country continue to reject constitutional challenges to laws that affirmatively *mandate* vaccines—without allowing for religious exemptions—for both adults and children. *See*, *e.g.*, *Doe v. San Diego Unified Sch. Dist.*, Civil Action No. 21-1809, 2021 WL 5396136, \*3 (S.D. Cal. Nov. 28, 2021) (collecting cases); *Klaassen v. Trustees of Indiana Univ.*, Civil Action No. 21-238, 2021 WL 3073926, \*39 (N.D. Ind. July 18, 2021) (collecting cases). If such laws do not violate the Free Exercise Clause, it is hard to imagine how the *passive* District Act does.

Plaintiffs cannot show that they will suffer irreparable harm absent injunctive relief because plaintiffs have not demonstrated any injury, and the balance of the equities and public interest weigh in favor of denying injunctive relief given the District's compelling interest in protecting and promoting public health. Accordingly, plaintiffs' motion for preliminary injunction should be denied, and because plaintiffs fail to show standing to pursue any of their theories, or to state a claim, the Court should grant the District's motion to dismiss the Amended Complaint.

#### BACKGROUND

#### I. The National Childhood Vaccine Injury Act of 1986

The Supreme Court has called "the elimination of communicable diseases through vaccination ... 'one of the greatest achievements' of public health in the 20th century." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011). "But in the 1970's and 1980's vaccines became .... so effective in preventing infectious diseases that the public became much less alarmed at the threat

of those diseases, and much more concerned with the risk of injury from the vaccines themselves."

Id. The concerns about risks depressed vaccination rates. Id. at 277. And a "massive increase in vaccine-related tort litigation" led to instability in the vaccine market, and production shortages.

Id. The difficulty of obtaining compensation "threatened to depress vaccination rates even further."

Id. "This was a source of concern to public health officials, since vaccines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated." Id.

Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA) in response to these problems. *Id.* at 228. "To stabilize the market and facilitate compensation," the NCVIA "establishes a no-fault compensation program" designed to be "faster" and easier than the civil tort system and that provides "significant tort liability protections for vaccine manufacturers" who comply with all regulatory requirements. *Id.* at 228, 229; 42 U.S.C. § 300aa-22(b)(1), (c). The NCVIA also establishes federal responsibility to create "vaccine information materials" that present the benefits of vaccines and warnings of their potential dangers and directs providers to give these to "legal representatives of any child or to any other individual to whom such provider intends to administer" a vaccine. 42 U.S.C. § 300aa-26.

#### II. The Minor Consent for Vaccinations Amendment Act of 2020

The Minor Consent for Vaccinations Amendment Act of 2020 (the Act), D.C. Law 23-193, amends a District regulation permitting minors "of any age" to consent to certain medical procedures; the regulation has been in effect in some form since 1974. *See* District Regulation No. 74-22 (Aug. 30, 1974), 1974 D.C. Stat. Reg. 290–92, available at *https://tinyurl.com/4fx2rn5n*; 22-B DCMR § 600, 600.7 (same but slightly expanded). The Act was introduced on May 5, 2019, "on the heels of a measles outbreak that spread across 11 states in 2019." Council of the District of Columbia, Committee on Health, Report on Bill 23-0171, at 1, 2 (Oct. 7, 2020), available at

https://tinyurl.com/4cuty3af. According to that Committee, the Act was "needed to grant minors, who are concerned for their health and safety, protection and the right to consent to a vaccination recommended by U.S. Advisory Committee on Immunization Practices (ACIP)," and "so that the District can move towards a high enough immunization rate to achieve herd immunity—or 95% immunity—from such diseases as measles." *Id.* at 2. The Council approved the bill in November 2020, and it went into effect on March 16, 2021. *See* 68 D.C. Reg. 4172 (Apr. 23, 2021).

The Act, as codified, amends 22-B DCMR § 600, by adding a new subsection 600.9:

- 600.9 (a) A minor, 11 years of age or older, may consent to receive a vaccine if the minor is capable of meeting the informed consent standard, the vaccine is recommended by the United States Advisory Committee on Immunization Practices ("ACIP"), and will be provided in accordance with ACIP's recommended immunization schedule.
- (b) For the purposes of this subsection, a minor shall be deemed to meet 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.
- (c) The 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.

. . .

22-B DCMR § 600, 600.9.

#### III. Plaintiffs' Allegations

The four plaintiffs bring claims individually and as next friends of their minor children. Victor Booth's son L.B. is 13 years old. Am. Compl. ¶ 1. Shameka Williams's children are 13 and 4. *Id.* ¶ 2. Shanita Williams's children are 15 and 9. *Id.* ¶ 3. And Jane Hellewell's child is 15 years old. *Id.* ¶ 4. All four plaintiffs reside with their children in the District. *Id.* ¶¶ 1–4. Plaintiffs' children are enrolled at schools in the District. *Id.* All plaintiffs believe that vaccinating their children would violate their sincerely held religious beliefs, and all have asserted and obtained

religious exemptions, under D.C. Code § 38-506(1), from vaccinations otherwise required for public school attendance. *Id.* ¶ 314.

Plaintiffs do not allege that their children have any plans to seek out vaccinations without their parents' knowledge or consent, or that any of their children have sought a vaccination since the Act went into effect in March 2021, or since vaccines became available in select public schools in June 2021. See generally Am. Compl. Plaintiffs do not allege that any District employee has spoken with any of their children about vaccinations, or directly offered vaccinations, or directly encouraged their children to be vaccinated. Id. Rather, plaintiffs argue that the District is exerting "tremendous pressure" on their children because their children have "access to the internet and see Defendant's media campaign" encouraging vaccination, id. ¶ 75; could theoretically obtain vaccines at clinics set up in select public schools, id. ¶¶ 79–81; are "aware" of available incentives for individuals who receive vaccination, id. ¶¶ 81–82; are "aware" that different quarantine rules apply to students who come into contact with covid patients based on vaccination status, id. ¶¶ 102–105; face peer pressure, id. ¶¶ 196, 228, 259; must wear masks in schools, even though this requirement applies regardless of vaccine status, id. ¶ 99; and are "subject to the pressure of receiving vaccines to play sports," id. ¶ 229, even though a religious exemption is available from the requirement that student athletes be vaccinated, id. ¶ 115.

Plaintiffs further allege that public statements by District officials, including D.C. Councilmembers at Council meetings and public schools' written policies, as well as District communications sent to parents, including plaintiffs, somehow increase pressure on their children to receive vaccinations. *E.g.*, *id.* at ¶¶ 30–40, 49-52, 150, 164, 166, 169–171, 203, 379.

Plaintiffs seek a declaration that the Act violates and is preempted by the NCVIA, that it violates the Religious Freedom Restoration Act (RFRA) and the Free Exercise Clause, and that it violates substantive due process. *Id.* at 83–84 (Prayer for Relief).

#### IV. Procedural History

Plaintiffs filed suit on July 12, 2021, Original Compl. [1], along with a Motion for Preliminary Injunction [2], and a memorandum in support [3], that same day. Plaintiffs then filed a corrected version of their 53-page, 227-paragraph complaint on July 13, 2021. "Errata" Original Compl. [3]. The complaint was verified and included six exhibits about vaccines. *Id.*; [1-3] to [1-8]. On July 16, 2021, the Court established a briefing schedule for plaintiffs' motion for injunctive relief and the District's motion to dismiss. Minute Order of July 16, 2021.

At the hearing on plaintiffs' motion for preliminary injunction on September 2, 2021, plaintiffs withdrew their motion, the Court granted the District's motion to dismiss without prejudice based on standing, and the Court granted plaintiffs leave to amend. On November 15, 2021, plaintiffs filed a 74-page, 410-paragraph Verified Amended Complaint [31], together with 130 pages of exhibits [31-1]. A month later, plaintiffs filed a renewed Motion for Preliminary Injunction [33], memorandum in support [33-1] (Pls.' Mem.), and two additional exhibits [33-2].

#### LEGAL STANDARD

#### I. <u>Motion to Dismiss for Lack of Subject Matter Jurisdiction</u>

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden of demonstrating that the court's jurisdiction is proper by a preponderance of the evidence. *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008). "[S]ubject matter jurisdiction is, of necessity, the first issue for an Article III court." *Loughlin v. United States*, 393 F.3d 155, 170 (D.C. Cir. 2004). "If the court determines at any time that it lacks subject-matter

jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3).

#### II. Preliminary Injunction

A preliminary injunction "is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). "The primary purpose of a preliminary injunction is to preserve the object of the controversy in its then existing condition—to preserve the status quo." *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (internal quotation marks omitted). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, *and* that an injunction is in the public interest." *Winter*, 555 U.S. at 20 (emphasis added). The last two factors merge when the government opposes an injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009). A plaintiff bears the burden of proving all four prongs of the standard before relief can be granted. *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009). *See also Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006) (movant must demonstrate "by a clear showing" that the requested emergency relief is warranted).

#### III. Motion to Dismiss for Failure to State a Claim

A case must be dismissed when a party fails to set forth "a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). The "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678

Plaintiffs argue that emergency injunctive relief may issue "where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." Pls.' Mem. at 46 (quoting D.C. Circuit case from 1995). But that is not the law—the D.C. Circuit has not "decide[d] whether the 'sliding scale' approach remains valid after *Winter*." *Archdiocese of Wash. v. Wash. Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018).

(2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Courts need not accept as true conclusory "assertions devoid of further factual enhancement," *Iqbal*, 556 U.S. at 679, and "need not ... accept inferences drawn by a plaintiff if such inferences are unsupported by the facts set out in the complaint," *Nurriddin v. Bolden*, 818 F.3d 751, 756 (D.C. Cir. 2016) (alterations adopted) (internal quotation marks omitted). Similarly, "the court is not required to accept legal conclusions as correct." *Pueschel v. Chao*, 955 F.3d 163, 166 (D.C. Cir. 2020). The Court "may consider ... the facts alleged in the complaint, any documents either attached to or incorporated in the complaint, and matters of which [the Court] may take judicial notice." *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997).

#### **ARGUMENT**

#### I. Plaintiffs' Claims Must Be Dismissed Because They Lack Standing.

To establish standing, a plaintiff must sufficiently allege three requirements: injury in fact, causation and redressability. *California v. Texas*, 141 S. Ct. 2104, 2113 (2021). "[A]n 'injury in fact' [is] an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks and citations omitted). To satisfy the imminence requirement, an injury must be "*certainly impending*"; "[a]llegations of *possible* future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (internal quotation marks omitted) (emphasis in original). To show causation, the injury must be "fairly traceable" to the defendant's action. *California*, 141 S. Ct. at 2114. "[W]here a causal relation between injury and challenged action depends upon the decision of an independent third party, ... standing is not precluded, but is ordinarily substantially more difficult to establish." *Id.* at 2117. Similarly, plaintiff bears a "rigorous burden to establish standing' for the prospective and declaratory relief"

he requests. *Proctor v. District of Columbia*, 531 F. Supp. 3d 49, 59 (D.D.C. 2021) (quoting *Swanson Grp. Mfg. LLC v. Jewell*, 790 F.3d 235, 240 (D.C. Cir. 2015)).

Here, plaintiffs again fail to show that *any* injury is certainly impending. *See Union of Concerned Scientists v. United States Dep't of Energy*, 998 F.3d 926, 929 (D.C. Cir. 2021) ("[A] threatened injury must be 'certainly impending" or there has to be a "substantial risk that the harm will occur") (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). Plaintiffs allege that they will be injured because their children could possibly elect to receive a vaccine, which, in their view, would "subvert the right and duty of parents to make informed decisions about whether their children should receive vaccinations," Am. Compl. ¶ 20; violate their "right to claim a religious exemption" from vaccinations, *id.* ¶ 382–83; and "endanger" their children because their parents have claimed a religious exemption, *id.* ¶ 394. Those alleged injuries, however, depend upon pure speculation that either their children will seek out vaccination, or be pressured to receive one in school; that a medical provider would find the children capable of providing informed consent; and that the children would in fact consent.

As described above, plaintiffs allege at length facts that they believe amount to "tremendous pressure" on their children to receive COVID vaccines. But their fears, however sincere, amount to conjecture for Article III purposes, because plaintiffs have *not* alleged that their children have expressed interest in seeking out vaccines, or that any District official has ever offered a vaccine to their children (except indirectly, as to all District residents, through websites and Twitter). To the contrary, although the Act has been in effect since March 2021 and plaintiffs' children have been attending District public schools since August 2021, *id.* ¶ 241, 271, there are no allegations that plaintiffs' children have taken any steps towards obtaining any vaccination or even had a conversation with a District employee about vaccination.

Paragraph 287 alleges that one of plaintiff Jane Hellewell's children "received the COVID-19 vaccine in direct opposition to Jane's parental judgment and rights," but it does not allege that her child employed the Act to do so; it is thus equally possible that child obtained the vaccine via some other method. Paragraph 198 alleges that one of plaintiff Victor Booth's children has said "words to the effect that" he would take a vaccine if it were "offered," but, again, there are no allegations that anyone in District public schools is walking the halls offering vaccines, or that plaintiff's child has acted on this cryptically described thought during many months of school.

At best, plaintiffs' allegations imply that District public schools will administer vaccines against their children's will, but of course the Act only authorizes vaccinations upon informed consent, see 22-B DCMR § 600.0, and District officials are entitled to a presumption that they are not violating the law. Cf. People for the Ethical Treatment of Animals v. United States Dep't of Agric. & Animal & Plant Health Inspection Serv., 918 F.3d 151, 157 (D.C. Cir. 2019) ("A presumption of regularity supports the official acts of public officers.") (quotation marks omitted). There are certainly no allegations that they have done or will do so.

Courts, including this one, routinely find that alleged injuries depending upon many-linked chains of what-ifs such as this are too speculative to support standing. *See Black Lives Matter D.C. v. Trump*, Civil Action No. 20-1469, 2021 WL 2530722, \*9 (D.D.C. June 21, 2021) (finding plaintiffs' "hypothetical chain of events ... too speculative to confer standing for injunctive relief" when injury depended on four different uncertain things happening in succession) (citing *Los Angeles v. Lyons*, 461 U.S. 95, 105–106 (1983)); *Cason v. Nat'l Football Players Assoc.*, Civil Action No. 20-01875, \_\_ F. Supp. 3d \_\_\_\_, 2021 WL 1840481, at \*7 (D.D.C. May 7, 2021) (same, noting "[t]hat is speculation atop speculation").

This is especially true when, as here, the challenged Act authorizes, but does not "mandate or direct" any action that would injure plaintiffs, and the occurrence of the feared injury further depends upon the uncertain actions of third parties. See, e.g., Clapper, 568 U.S. at 412 (plaintiffs lack standing when challenged act "at most authorizes—but does not mandate or direct" the injury-causing event) (emphasis in original); Cason, 2021 WL 1840481, at \*7 (rejecting "as overly speculative those links which are predictions of future events (especially future actions to be taken by third parties)") (quoting United Transp. Union v. I.C.C., 891 F.2d 908, 912 (D.C. Cir. 1989)); cf. California, 141 S. Ct. at 2117 (causation "substantially more difficult to establish" when occurrence of alleged injuries depends upon the actions of third parties). The Act does not require plaintiffs or their children to do anything. It authorizes healthcare providers to provide a service under certain circumstances. Plaintiffs' alleged injuries depend upon predictions about the independent behavior of their children, unknown medical professionals, and DCPS employees or officials. These predictions about the actions of third parties "are not normally susceptible of labelling as 'true' or 'false'" and should be rejected as overly speculative. United Transp., 891 F.2d at 912. They cannot support standing here. *Id*.

Plaintiffs' additional theories of injury under the NCVIA (and Supremacy Clause) are also unavailing. As an initial matter, plaintiffs' alleged injuries under the NCVIA still depend upon a finding that their children will in fact seek out and receive vaccines without their knowledge. For the reasons just discussed, such fears are also too speculative to be believed.

Second, plaintiffs' alleged injuries derive from incorrect interpretations of the NCVIA and the Act. Plaintiffs allege that the Act is preempted because it prevents medical providers from doing certain things required by NCVIA, namely, recording vaccination information in mature minors' permanent records, reporting adverse events following vaccination, and providing a

federally developed VIS to the patient or the parents. Am. Compl. ¶¶ 313–15. For the reasons discussed more fully below, *see* Section II.B.2, the Act does not prevent any of these things. The Act speaks only to what should be recorded on a form created by and used only in the District, not the patient's permanent medical record. And because the Act does not prohibit providers from recording certain information in patients' medical records, it does not, as plaintiffs allege, make it "impossible" for providers to report adverse events resulting from those vaccines. Further, while the Act requires providers to share alternative forms of the VIS with mature minor patients, that requirement does not prevent them from also sharing the federally developed VISs. Thus, plaintiffs thus face no imminent injury from these imagined violations.

Similarly, plaintiffs allege that the Act "directly contradicts" a requirement in the NCVIA that a child's parent shall have access upon request to the child's vaccine records. Am. Compl. ¶ 316. But the Act's provision on how to complete a District-specific immunization form does not affect the NCVIA's prohibition on disseminating of information "in the possession of" the District beyond the patient or her legal representative. This injury too, is imagined, not imminent.

Finally, plaintiffs allege that the Act is preempted because, by authorizing mature minors to receive vaccines without their parents' knowledge, it violates their right to receive VISs before their children are vaccinated. Am. Compl. ¶¶ 329–32. But the NCVIA provides no such right—instead, it requires that the VIS be provided to a legal guardian *or* to the patient. In any event, plaintiffs already have the information required to be provided under the NCVIA, *see* Plaintiffs' Ex. 17, [31-1] at 103 (Vaccine Information Statements), such that there is little if any likelihood that plaintiffs would suffer any harm as a result of the alleged *future* violations of the NCVIA. *See Ctr. for Law and Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1159 (D.C. Cir. 2005) (plaintiff must demonstrate "[n]ot only that the defendant's acts omitted some procedural requirement, but also

that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest"); *Coal. for Mercury-Free Drugs v. Sebelius*, 725 F. Supp. 2d 1, 13 (D.D.C. 2010) (holding that when "plaintiffs went to the clinics as informed patients," they lacked standing to challenge medical providers' provision of erroneous vaccine information, because plaintiffs themselves could not be injured by it), *aff'd* 671 F.3d 1275, 1277 (D.C. Cir. 2012).

#### II. Plaintiffs Are Not Entitled to a Preliminary Injunction.

## A. <u>Plaintiffs Cannot Show a Likelihood of Injury Sufficient to Support Standing to Obtain Emergency Relief.</u>

Even if the Court finds that plaintiffs have alleged facts sufficient to survive a motion to dismiss for lack of standing, plaintiffs' burden in support of their motion for preliminary injunction is heavier; plaintiffs cannot carry that burden, and the motion should be denied for that reason alone. "[E]ach element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof ... "Proctor, 531 F. Supp. 3d at 59 (alterations in Proctor) (quoting Lujan, 504 U.S. at 561). "[W]hen a plaintiff seeks a preliminary injunction, the plaintiff's burden to demonstrate standing 'will normally be no less than that required on a motion for summary judgment." Food & Water Watch, Inc. v. Vilsack, 79 F. Supp. 3d 174, 186 (D.D.C.) (quoting Lujan, 504 U.S. at 907 n.8), aff'd, 808 F.3d 905 (D.C. Cir. 2015). Plaintiffs must therefore carry their burden with competent evidence. Proctor, 531 F. Supp. 3d at 59. And they must at least show a "substantial likelihood" that they will be injured by the Act. Vilsack, 808 F.3d at 913. Plaintiffs fail to meet their burden.

Plaintiffs filed 130 pages of exhibits with their Amended Complaint; the evidence generally speaks to the efforts made by the District to encourage vaccination against COVID-19. The only evidence that even arguably speaks to plaintiffs' fears of imminent injury are Exhibits 10 and 11 [31-1 at 54, 56], two undated sketches by plaintiff Booth's son, L.B., of "peer pressure."

But neither evidences any imminent intent to act by L.B. or any of the other children. Nor do the two additional exhibits plaintiffs filed with their renewed Motion for Preliminary Injunction [33]. *See* Pls'. Ex. 19 [33-2 at 5] (D.C. Public Schools (DCPS) policy discussing how DCPS reports and responds to COVID-19 cases); Pls.' Ex. 20 [33-2 at 10] (FDA Briefing Document).

These exhibits fail to demonstrate plaintiffs' standing to seek emergency injunctive relief or any imminent threat of irreparable injury and fall far short of demonstrating that their injuries are *likely*, as required to succeed on a motion for emergency relief. *E.g.*, *Robinson-Reeder v. Am*. *Council on Educ.*, 626 F. Supp. 2d 11, 14 (D.D.C. 2009) (denying motion for preliminary injunction when plaintiff presented only "inadmissible hearsay and her own speculative and unsupported assertions"). A "party who fails to show a substantial likelihood of standing is not entitled to a preliminary injunction." *Vilsack*, 808 F.3d at 913 (internal quotation marks omitted).

#### B. Plaintiffs Are Not Likely To Succeed on the Merits of Any of Their Claims.

Demonstrating a likelihood of success on the merits is a free-standing requirement for a preliminary injunction, *Sherley*, 644 F.3d at 393 (quotation omitted), and "a failure to show a likelihood of success on the merits is alone sufficient to defeat a preliminary-injunction motion," *Smith v. Henderson*, 944 F. Supp. 2d 89, 96 (D.D.C. 2013). The Court need not conclude that plaintiffs will lose on the merits, only that they have not met the extraordinary burden of showing a clear entitlement to immediate relief. *Sweis v. U.S. Foreign Claims Settlement Comm'n*, 950 F. Supp. 2d 44, 48 (D.D.C. 2013). Plaintiffs must show that success is "likely." *Winter*, 555 U.S. at 20–22. Here, for the reasons discussed, plaintiffs have not met their burden because they have not demonstrated that success on the merits is possible, let alone likely.<sup>5</sup>

Plaintiffs also argue that they need not show "absolute certainty of success" on the merits to obtain injunctive relief; it is "enough" if they "raise serious legal questions[.]" Pls.' Mem. at 17 (quoting *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C.

#### 1. The Act Is Not Unconstitutional In All Its Applications.

Plaintiffs challenge the Act on its face. Am. Compl. ¶¶ 27, 394. A facial challenge asserts that the law is unconstitutional in all its applications. *In re Sealed Case*, 936 F.3d 582, 588–89 (D.C. Cir. 2019). "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). There "has been some debate" about the scope of *Salerno*, but "all agree that a facial challenge must fail where the statute has a plainly legitimate sweep." *In re Sealed Case*, 936 F.3d at 589. If the law can be constitutionally applied in some way, it has a legitimate sweep. *E.g.*, *id.* (determining criminal statute was facially valid after identifying prior prosecutions addressing conduct Congress plainly had the power to criminalize); *Jawad v. Gates*, 832 F.3d 364, 370–71 (D.C. Cir. 2016) (denying facial challenge when prior precedent affirmed constitutional application).

Here, the Act can be constitutionally applied to at least help competent minors whose only impediment to vaccination before the Act went into effect was the logistics of getting to the doctor *with* their parents to obtain desired vaccines. Now they can do it on their own. This scenario would

Cir. 1977)). Plaintiffs are incorrect. The cited case held that emergency injunctive relief may be appropriate in cases raising "serious legal questions" to "maintain the status quo" when "little if any harm will befall other interested persons or the public and when denial of the order would inflict irreparable injury on the movant." 559 F.2d at 844. Here, plaintiffs do not seek to *maintain* the status quo, but to *change* it, and to enjoin a public-health law in effect for almost 10 months. Even if the injunction sought is characterized as plaintiffs seeking only to enjoin the District from "enforcing" the Act, *see Capitol Hill Baptist Church v. District of Columbia*, 496 F.Supp.3d 284, 292 (D.D.C. 2020), plaintiffs still fail, as the Act is entirely permissive, not requiring or forbidding any actions on the part of parents or children.

not raise any of the constitutional concerns described in plaintiffs' Amended Complaint and shows that the Act has a plainly legitimate sweep. 6 Plaintiffs' facial challenge should thus be denied.

## 2. Plaintiffs Cannot Succeed on Their Supremacy Clause Claim Because There is no "Conflict" with Federal Law.

Plaintiffs allege that the Act is preempted, arguing that it "violates multiple statutory requirements" of the NCVIA. Pls.' Mem. at 18.<sup>7</sup> Specifically, plaintiffs allege that the Act violates 42 U.S.C. § 300aa-26, which requires medical practitioners to provide the minor's parents with a "vaccine information statement" (VIS) prior to vaccination. Pls.' Mem. at 21, 22. Plaintiffs also allege that the Act "blatantly violates" 42 U.S.C. § 300aa-25(a) concerning immunization records, Pls.' Mem. at 25, violates 42 U.S.C. § 300aa-25(b) ("[r]eporting adverse events") and violates 42 U.S.C. § 300aa-25(c) ("[r]elease of information"). Notwithstanding that the NCVIA's mandates apply only to healthcare providers and *not* parents or vaccine recipients, *see* Pls.' Mem. at 45 (the Act "imposes duties on" vaccine administrators), plaintiffs are incorrect on all of their theories.

This scenario is also a likely use of the Act. At a hearing on the Act before the D.C. Council's Committee on Health, a witness from the District's Department of Health testified that the District surveys families whose children are not vaccinated, and in "the majority of cases, the feedback we hear from families is that they have yet to see a medical provider because of competing priorities," or they did not realize vaccines were needed or required. Statement of Anjali Talwalkar, Report on Bill 23-0171, at 52, available at https://tinyurl.com/4cuty3af.

Plaintiffs allege, generally, that the Act violates the NCVIA because it deprives them of their rights under that law "to have prior knowledge and consent before vaccines are administered to minor children[.]" Am. Compl. at 83; see also id. ¶ 374. Plaintiffs' theory of procedural injury under the NCVIA fails because it relies on a misreading of the plain language of federal law, as demonstrated. To the extent plaintiffs argue that federal law mandates parental consent prior to the administration of vaccines they are incorrect as a matter of law. See, e.g., Centers for Disease Control and Prevention (CDC), Vaccines for Children Program vs. CDC COVID-19 Vaccination Program (https://www.cdc.gov/vaccines/covid-19/vfc-vs-covid19-vax-programs.html) (Dec. 3, 2021) ("The federal government does not have specific requirements for medical consent for vaccination. Providers should adhere to the medical consent laws of their state/jurisdiction ....").

Typically, there are three ways by which federal law will preempt State or local law: (1) in the text of federal legislation; (2) when Congress intends that the federal government occupy the "field" exclusively; or (3) where State or local law actually conflicts with federal law. *Mich. Canners & Freezers Ass'n, Inc. v. Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 469 (1984). "[T]he purpose of Congress is the ultimate touchstone." *Organic Consumers Ass'n*, 285 F. Supp. 3d at 104 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

Preemption can be either express or implied. Sickle v. Torres Advanced Enterprise Sol'ns, LLC, 884 F.3d 338, 346 (D.C. Cir. 2018) (citing Geier v. American Honda Motor Co., 529 U.S. 861, 884 (2000)). Express preemption occurs when federal law contains "an express preemption provision" displacing state or local law. Id. (quoting Arizona v. United States, 567 U.S. 387, 399 (2012)). Implied preemption occurs via "the substantive nature and reach of the federal regulatory scheme[.]" Id. (citing Crosby v. National Foreign Trade Council, 530 U.S. 363, 388 (2000)). Field and conflict preemption are forms of implied preemption. Id. (citing Oneok, Inc. v. Learjet, Inc., 135 S. Ct. 1591, 1595 (2015)).

There is a strong presumption *against* preemption, which "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act ...." *Arizona* v. *Inter Tribal Council of Arizona, Inc.*, 570 U.S. 1, 13 (2013) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The historic police powers of the States and the District encompass the authority to protect the health and safety of their citizens. *See*, *e.g.*, *Medtronic*, *Inc.*, 518 U.S. at 475; *Barnes v. Glen Theatre*, 501 U.S. 560, 569 (1991); *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 25 (1905).

Plaintiffs invoke the NCVIA. The NCVIA "establishes a no-fault compensation program" in lieu of State civil tort systems to compensate persons injured by certain vaccines for claims

against the manufacturers. *Bruesewitz*, 562 U.S. at 228. In exchange for this streamlined system, the NCVIA provided "significant tort-liability protections for vaccine manufacturers." *Bruesewitz*, 562 U.S. at 239; 42 U.S.C. § 300aa-22(b)(1), (c). It expressly preempts state law imposing liability on manufacturers for certain actions, *see id.* at (e)("Preemption") and provides that State law otherwise applies to vaccine-related civil damages actions, *id.* at (a) ("General Rule"). *See also* 42 U.S.C. § 300aa-11 (prohibiting the filing of certain actions seeking more than \$1,000 or unspecified damages in State or federal court without prior use of stream-lined system). There is no explicit preemption provision in the NCVIA implicating the District's Act and plaintiffs have not cited any. To the contrary, the Act expressly addresses preemption, and speaks only to certain prohibitions on liability for manufacturers. 42 U.S.C. § 300aa-22(e). Thus, plaintiffs can only succeed if they can demonstrate implied preemption. They cannot.

To succeed on their conflict preemption theory, plaintiffs must show that the operation of the NCVIA and District law "clash in a way that makes 'compliance with both [local] and federal law ... impossible,' or [that District law] 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sickle*, 884 F.3d at 347 (citations omitted). Here, plaintiffs cannot meet their burden because there is no conflict.

Plaintiffs argue that the Act conflicts with the NCVIA's requirement that all parents be given a VIS before any minor receives a vaccine. Pls.' Mem. at 21 (citing 42 U.S.C. § 300aa-26); Am. Compl. ¶¶ 328–29 (same). This interpretation is incorrect for at least three reasons. First, the plain language of that provision says that healthcare providers who administer the referenced vaccines "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]." 42 U.S.C. § 300aa-26(d)(2) (emphasis added). Thus, if a mature minor may receive a vaccine under the Act (or any similar

State law), then he or she qualifies as "any other individual to whom" a healthcare provider intends to administer a vaccine, *id.*, and a provider may easily comply with both laws. There is no conflict here. See CDC, Vaccines for Children Program vs. CDC COVID-19 Vaccination Program, cited above at n.9 ("Providers must give the appropriate Vaccine Information Statement to the patient (or parent or legal representative) prior to every dose of specific vaccines covered under the National Vaccine Childhood Injury Act.") (emphasis added); CDC, VIS Frequently Asked Questions, available at https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html (Dec. 20, 2021).

The full quotation from the expert agency's interpretation makes this clear and affirms that State law should be consulted as to who is a "child" for purposes of the NCVIA:

Q: How do we determine when a VIS must be given to a "legal representative" rather than to the patient? For example, if an 18-year old is considered a child, would it be illegal to give a VIS to him or her directly, as opposed to a parent or guardian?

A: The National Childhood Vaccine Injury Act does not define a "child" for purposes of the Act. "Legal representative" is defined as "a parent or an individual who qualifies as a legal guardian under State law." A reasonable interpretation is that State law, and specifically the State's medical consent law, should be deferred to for purposes of defining who is a minor. For example, if an 18 year old can consent to immunization under a State's law, that 18 year old is the person who should be provided a copy of the VIS.

Id.

Thus, whether an 18-year-old is considered a child for vaccination purposes must be determined according to the relevant State's medical consent law. Said another way, "if [a child]

For the same reasons, plaintiffs fail to state a claim that the Act violates the NCVIA. *See* Am. Compl. at 75 (arguing that the Act deprives plaintiffs of "federal statutory rights guaranteed by" the NCVIA). In addition, the portions of the NCVIA plaintiffs cite impose a duty on *medical providers* to supply certain information, not the District. Even assuming—for purposes of this briefing only—that the NCVIA creates a federal right enforceable through 42 U.S.C. § 1983, it is hard to see how any law passed by the District could directly violate this provision of the NCVIA.

can consent to immunization under a State's law, that [child] is the person who should be provided a copy of the VIS." *Id*. Because mature minors can consent to immunization in some circumstances in the District under the Act, they are the ones to whom the VIS should be provided.

If, as the District contends, the text of the NCVIA is clear, that text controls; if it is not, the Court should defer to the reasonable interpretation of the CDC. *E.g.*, *Safari Club Int'l v. Zinke*, 878 F.3d 316, 326 (D.C. Cir. 2017) (citations omitted).

Second, plaintiffs' interpretation of the NCVIA's information requirements is incorrect because it suggests that Congress acted silently to preempt and abrogate many State laws, well before the NCVIA was enacted, that permitted minors to consent to medical treatment without their parents' knowledge or assistance. *See*, *e.g.*, Ex. A [16-2], "State Legislation Relating to Treatment of Minors (as of September 1971)," attached as appendix to Harriet F. Pilpel, "Minors' Rights to Medical Care," 36 *Alb. L. Rev.* 462 (1972), showing laws permitting minors to consent to various medical treatments existing in 49 States; District Reg. No. 74-22 (Aug. 30, 1974). But obliteration of State law cannot be implied; Congress's intent must be "unmistakably clear." *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989).

Third, plaintiffs argue that because the Act requires healthcare providers to produce age-appropriate "alternative vaccine information sheets," Pls.' Mem. at 22, it conflicts with the NCVIA, because "an alternative is not a supplement." *Id.* Plaintiffs provide no competent support for this interpretation, because it defies common sense. Merely because a law mandates an additional source of information cannot mean—without more—that the law then implicitly rejects

any other information. While the use of the word "alternative" here may have been imprecise, it cannot carry the weight plaintiffs place on it—it does not conflict with federal requirements.

Plaintiffs also argue that the Act violates 42 U.S.C. § 300aa-25(a)–(c), which requires healthcare providers who administer Vaccine Injury Table vaccines to record, report, and release certain information about vaccine administration. Pls.' Mem. at 24–27; Am. Compl. ¶¶ 317–23. Under those provisions, medical providers must "record, or ensure that there is recorded" that vaccine information "in [the patient's] medical record (or in a permanent office log or file to which a legal representative shall have access upon request)[.]" 42 U.S.C. § 300aa-25(a). Additionally, health care providers and vaccine manufacturers must report adverse vaccine events to the Secretary. *Id.* § 300aa-25(b). Moreover, the NCVIA prohibits the provision of information within the District's possession "which may identify an individual . . . to any person except" the "person who received the vaccine," or "the legal representative of such person." *Id.* § 300aa-25(c).

Plaintiffs assert that the Act violates these provisions of federal law because D.C. Code § 38-602(a)(2) states that

[I]f a vaccine under the Minor Consent Act is administered to a student whose parents have filed either a religious exemption or an exemption from the Human Papillomavirus (HPV) vaccine, 'the healthcare provider shall leave blank Part 3 of the immunization record, and submit the immunization record directly to the minor student's school,' thus hiding essential information from the child's parents.

Am. Compl. ¶ 23.

The Act further instructs that "[t]he school shall keep the immunization record received from the health care provider confidential; except, that the school may share the record with the Department of Health or the school-based health center." Id. ¶ 26.

To the extent plaintiffs complain of some hypothetical, future deprivation of VISs prepared by the federal government, that argument fails at the outset because plaintiffs have shown that they already have (and have easy access to) all relevant VISs. *See* Plaintiffs' Ex. 17, [31-1] at 103–21.

Plaintiffs continue to confuse the record referenced here, which is particular to D.C. schools, with patients' general medical records. The recordkeeping mandates of the two laws refer to different systems entirely and do not overlap, much less conflict. The Act requires healthcare providers to "leave blank" only a specific portion of a student's *District* school health record. The reference to "part 3 of the immunization record" means that the document referred to is the DC Health Universal Health Certificate, required of all students who attend schools or daycare in the District. D.C. Code § 38-502; 5A DCMR § 130.4; 5E DCMR § 5300.2.<sup>10</sup> The Act does not implicate permanent medical records and does not mandate or direct providers to ignore federal law. Plaintiffs are therefore incorrect to contend that the Act "undermine[s]" federal law. Pls.' Mem. at 27. The Act does no such thing; it simply directs healthcare providers to leave blank one section of a District-only form used exclusively by District schools and daycare providers. As much as plaintiff might disagree with this upshot as a public policy matter, the local and federal requirements can and do comfortably coexist.

Plaintiffs similarly argue that because the Act requires the healthcare provider to "submit the immunization record directly to the minor student's school" and because "[t]he school shall keep this immunization record confidential," D.C. Code § 38-602(a)(2), the Act violates the provision in 42 U.S.C. § 300aa-25(a) that directs that a healthcare provider, with respect to each vaccine administered, "shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request)[.]" See Am. Compl. ¶¶ 322, 375. Not so. To reiterate: the challenged District

A copy of the current DC Health Universal Health Certificate was attached to prior briefing as Exhibit B [16-3] (and as Plaintiffs' Exhibit 1 [31-1 at 5]) and is available online at https://dchealth.dc.gov/sites/default/files/dc/sites/doh/service\_content/attachments/DOH%20Universal%20Health%20Certificate\_2019\_0.pdf (Dec. 20, 2021). Part 3 of the Certificate is entitled "Immunization Information." *Id*.

provision applies only to District *school* immunization records, while § 300aa-25(a) applies to "permanent medical record[s]." The cited documents are different, even if the duties are imposed on the same persons (health care providers), so there is no conflict at all, much less the "clear conflict" argued. Am. Compl. ¶ 322.<sup>11</sup>

Plaintiffs are likewise mistaken to argue that the Act conflicts with 42 U.S.C. § 300aa-25(c). Pls.' Mem. at 27. The NCVIA protects an individual's vaccine-related information "which is in the possession of the Federal Government and State and local governments" from disclosure, except to "(A) the person who received the vaccine, or (B) the legal representative of such person." 42 U.S.C. § 300aa-25(c)(1). The Act's provision on how to complete the District-specific immunization form does not affect the federal prohibition on disseminating of information "in the possession of" the District beyond the patient or her legal representative.

Finally, in one throwaway paragraph, plaintiffs argue that Congress, through the NCVIA, has regulated so pervasively in this area that "field preemption" applies. Pls.' Mem. at 27. But no court has ever found that the NCVIA preempts all state laws in the field of vaccine (or childhood-vaccine) regulation. *Cf. Abbott v. American Cyanamid Co.*, 844 F.2d 1108, 1116 (4th Cir. 1988) (Wilkins, J., concurring) ("[The NCVIA] unmistakably demonstrates that Congress intended to preempt state law in only limited areas of this field."); *cf., Murphy v. National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018) ("Field preemption occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation."")

Additionally, plaintiffs argue that the Act violates 42 U.S.C. § 300aa-25(b), which requires the reporting of information concerning vaccine "adverse events," because if the healthcare provider complies with the Act "and leaves the immunization record 'blank', then it is impossible to comply with subsection (b)[.]" Am. Compl. ¶ 322; Pls.' Mem. at 26. As shown above, however, the Act's directive with respect to a *District-only* school immunization form has no bearing on the medical provider's ability to report an adverse event to federal authorities.

(quoting *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 140 (1986)). Indeed, plaintiffs' argument borders on the specious. It would mean state and local regulation is "foreclose[d] altogether" in this area. *Sickle*, 884 F.3d at 347. But the inclusion of narrow, express preemption provisions in the NCVIA itself indicates field preemption does not apply here. *See*, *e.g.*, *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 167 (1989) ("The case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of interest and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.") (internal quotations omitted); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 547 (1992) ("[A]n express pre-emption provision tends to contradict any inference that Congress intended to occupy a field ... .") (Scalia, J., concurring in part and dissenting in part).

Moreover, other federal healthcare law expressly acknowledges and incorporates the "mature minor" doctrine found in most State law. Regulations under HIPAA, Pub. L. No. 104-191, 110 Stat. 1936, acknowledge State authority to grant minors the ability to consent to certain medical care without parental notification; the specific regulation grants those minors privacy rights and generally defers to state law. 45 CFR § 164.502(g)(3) (discussing when a minor "has the authority to act as an individual, with respect to protected health information pertaining to a health care service" including when "[t]he minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting in loco parentis, and the minor, a court, or another person authorized by law consents to such health care service"); *id.* (defining "personal representative" as used in HIPAA to be the relevant decisionmaker "under applicable law," including State law); *see also Standards for Privacy of Individually Identifiable Health Information*, U.S. Dep't of Health & Human Servs., 67 Fed. Reg. 53182, 53201 (Aug. 14, 2002)

("[T]he addition of paragraphs (g)(3)(ii)(A) and (B) of § 164.502, clarify that State and other applicable law governs when such law explicitly requires, permits, or prohibits disclosure of protected health information to a parent."). Congress plainly intends to share the field.

In sum, plaintiffs cite no case—and the District is aware of none—holding that the NCVIA preempts in any way the kind of Act challenged here. Plaintiffs' claim of preemption fails.

3. Plaintiffs Cannot Succeed on Their Substantive Due Process Claims Because the Act Does Not Deprive Them of a Liberty Interest or Fundamental Right; Alternatively, It Is Narrowly Tailored To Serve a Compelling State Interest, and Survives Rational Basis Review.

Fifth Amendment due process protects substantive liberty interests. *E.g.*, *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997). Fundamental liberty interests—those "deeply rooted in this Nation's history and tradition"—may not be infringed upon, "unless the infringement is narrowly tailored to serve a compelling state interest." *Id.* at 721 (internal quotation marks omitted). Infringements upon liberty interests that are not fundamental are subject only to rational basis review. *Id.* at 767 n.9; *see also*, *e.g.*, *Robinson v. District of Columbia*, 234 F. Supp. 3d 14, 25 (D.D.C. 2017) (citing *Gordon v. Holder*, 721 F.3d 638, 656 (D.C. Cir. 2013)). Due process claims require a "careful description" of the asserted interest. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 702 (D.C. Cir. 2007) (*en banc*). The Supreme Court, moreover, "has cautioned against expanding substantive rights protected by the Due Process Clause." *Id*.

#### a. The Act Does Not Infringe On Any Liberty or Right.

Plaintiffs allege that they have a fundamental right, as "fit parents to be informed of and to consent to the immunizations of their minor children in non-emergency situations[.]" Pls.' Mem. at 39. *See also id.* (noting "the right to refuse unwanted medical procedures") (quoting *Doe v.* 

*Zucker*, 496 F. Supp. 3d 744, 756 (N.D.N.Y. 2020)). <sup>12</sup> Although the Supreme Court generally recognizes "the fundamental right of parents to make decisions concerning the care, custody, and control of their children[,]" *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (*plurality op.*), the right or interest described in *Troxel* does *not* encompass the plenary right plaintiffs assert. <sup>13</sup>

Plaintiffs allege that the Act allows the District to "intervene[] and substitute[] its decision making for that of the parents." Am. Compl. ¶ 329. Plaintiffs are incorrect. The Act simply acknowledges the longstanding ability of mature minors to determine for themselves whether or not to seek certain medical care, so long as they can demonstrate that they can give informed consent. See, e.g., Kozup v. Georgetown Univ., 851 F.2d 437, 439 (D.C. Cir. 1988) (explaining that under District common law "[i]n the case of a minor patient, the relevant consent is that of the parents," but that "this doctrine is subject to certain exceptions ... when parental consent is not necessary," including when "the patient is a 'mature minor.") (quoting Bonner v. Moran, 126 F.2d 121, 122 (D.C. Cir. 1941)). Indeed, the Supreme Court has held that States have a compelling interest in "safeguarding the physical and psychological well-being of a minor." Globe Newspaper Co. v. Superior Court for Norfolk County, 457 U.S. 596, 607–608 (1982).

Zucker does not help plaintiffs. There, parents of minor children sought to enjoin "burdensome" regulations outlining the process to obtain medical exemptions to immunization requirements. 496 F. Supp. 3d at 749. The court denied the motion for preliminary injunction, finding the challenged regulations "do not force parents to consent to vaccination of their children." *Id.* at 756. So too here, as the Act does not force anyone to do anything.

It may be true generally, as plaintiffs assert, that "there is a presumption that fit parents act in the best interests of their children." Pls.' Mem. at 40 (quoting *Troxel*, 530 U.S. at 68). But the rest of plaintiffs' syllogism (that the Act "makes no attempt to rebut" that presumption) is a nonstarter. The Act is not contrary to this presumption—it simply focuses on the capacity and fitness of the minors to provide informed consent.

Plaintiffs' implied unconditional right to control their children's medical care was long ago squarely rejected by the Supreme Court. Planned Parenthood of Central Miss. v. Danforth, 428 U.S. 52, 74 (1976) (holding State "may not impose a blanket provision ... requiring the consent of a parent or person in loco parentis" for minors before specified medical treatment); cf. Prince, 321 U.S. at 166-67 ("Neither rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth's well being, the state as parens patriae may restrict the parent's control ... ."). "Minors, as well as adults, are protected by the Constitution and possess constitutional rights." Danforth, 428 U.S. at 74. History and tradition, moreover, confirm a constitutional right to bodily integrity, see Ingraham v. Wright, 430 U.S. 651, 673 (1977), as well as the right of mature minors to consent to medical care, see, e.g., Bonner, 126 F.2d at 122. Indeed, the District, like many States, has laws authorizing minors to consent to various medical procedures and care, including for mental health, substance abuse treatment, contraceptive services, and prenatal care. 22-B DCMR § 600, 600.7 ("A minor of any age may consent to health services which he or she requests for the prevention, diagnosis, or treatment of the following medical situations ..."); 14 Restatement of the Law—Children and the Law, § 19.01 Consent to Treatment by Mature Minor (Am. L. Inst. 2019). "[M]any of these statutes have been in place for 3 or 4 decades." Abigail English, et al., "Legal Basis for Consent for Health Care and Vaccination for Adolescents," 121 **Pediatrics** S85 (2008)(hereafter English al.(https://pediatrics.aappublications.org/content/pediatrics/121/Supplement 1/S85.full-text.pdf) (Dec. 3, 2021); Ex. A [17-2] (table of State laws from 1971). And the common-law mature minor doctrine is even more longstanding. See Bakker v. Welsh, 108 N.W. 94, 96 (Mich. 1906).

Plaintiffs provide no principled basis for why the particular medical procedure at issue here—administration of a vaccine—but not these others, would fail constitutional scrutiny.

Courts have found deprivations of the liberty interest of parents in the care and upbringing of their children only in cases where the government "compelled interference in the parent-child relationship." Anspach v. City of Philadelphia, 503 F.3d 256, 262 (3d Cir. 2007); accord Russ v. Watts, 414 F.3d 783, 788 (7th Cir. 2005). As the Third Circuit explained, any infringement on a protected liberty interest in this context typically arises where the state "either requir[es] or prohibit[s] some activity." Anspach, 503 F.3d at 263; see, e.g., M.L.B. v. S.L.J., 519 U.S. 102 (1996) (Mississippi statute prohibited indigent mother's right to appeal judgment terminating her parental rights without prepayment of court costs); Miller v. Mitchell, 598 F.3d 139, 144 (3rd Cir. 2010) (district attorney threatened prosecution unless daughters attended "education and counseling" to "gain an understanding of what it means to be a girl in today's society"); Gruenke v. Seip, 225 F.3d 290, 303–304 (3d Cir. 2000) (high school coach forced minor student to take a pregnancy test); De Nolasco v. United States Immigration & Customs Enforcement, 319 F. Supp. 3d 491, 500 (D.D.C. 2018) (government separated immigrants from their young children); Goings v. Court Servs. and Offender Supervision Agency, 786 F. Supp. 2d 48, 79 (D.D.C. 2011) (probation conditions prohibited all contact with defendant's own minor children).

Anspach is particularly instructive. There, a pregnant 16-year-old girl visited a city health center independently and sought out and received (and then took) the "morning after" pill. 503 F.3d at 259–60. Subsequently she and her parents sued, alleging a violation of substantive due process on the basis that the center's "policies were aimed at preventing parents from learning of their minor daughter's possible pregnancies." *Id.* at 261. The Third Circuit rejected that stance where the minor was not "in any way compelled, constrained, or coerced into [her] course of action," and there existed "no prohibition against the [parents] participating in [the minor child's] decision[]." *Id.* at 266–67; *see also id.* at 264 ("[N]o one prevented [the minor] from calling her

"manipulative, coercive, or restraining conduct by the State." *Id.* at 266. <sup>15</sup> The court noted that the "real problem" at the heart of the plaintiff-parents' claim, based on their lack of knowledge about their child's medical decision, was "not that the state actors *interfered* with" the plaintiff's rights as parents, but that "the state actors did not assist" them in "affirmatively *foster[ing]* the parent/child relationship"—a right that the Due Process Clause does not confer. *Id.* at 266–67.

The same analysis should apply here because the challenged Act is entirely permissive <sup>16</sup> and does not compel, coerce, or prohibit any action by parents or children. It merely authorizes a "mature minor" to receive certain vaccines without parental consent. The Act contains no "form of constraint or compulsion"; there is no "requirement [by the State] that the [children] of plaintiffs avail [themselves] of the services offered ... and no prohibition against the plaintiffs' participating in decisions of their minor [children] ... . The plaintiffs remain free to exercise their traditional care, custody and control over their unemancipated children." *Anspach*, 503 F.3d at 267 (quoting *Doe v. Irwin*, 615 F.2d 1162, 1168 (6th Cir. 1980)). Thus, there is no infringement. *Id*.

The *Anspach* Court also reasoned that the plaintiffs' claims, if successful "would undermine the minor's right to privacy and exceed the scope of familial liberty interest ...." *Id.* at 262; *see also id.* at 268 ("The Constitution does not protect parental sensibilities, nor guarantee that a child will follow their parents' moral directives.").

<sup>16</sup> "[A]ll fifty states and the District of Columbia have laws requiring students to receive certain vaccines before they may attend school." Klaassen, 2021 WL 3073926 at \*19 (citing Nat'l Conf. of State Legislatures, States with Religious and Philosophical Exemptions from School Immunization Requirements (updated Nov. 22, https://www.ncsl.org/research/health/school-immunization-exemptionstate-laws.aspx) (Dec. 20, 2021). See also CDC, Vaccination Laws (same) (available https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html) (Dec. 20, 2021). Here, in contrast, the Act does not *mandate* any behavior by parents or children.

The Court should be "hesitant to extend the Due Process Clause to cover official actions that were not deliberately directed at the parent-child relationship, in disregard of the Supreme Court's admonition in *Daniels*." *McCurdy*, 352 F.3d at 829; *see also Anspach*, 503 F.3d at 262 ("Courts have recognized the parental liberty interest only where the behavior of the state actor compelled interference in the parent-child relationship."). "The majority of the other Circuits that have addressed the issue have 'expressly declined to find a violation of the familial liberty interest where the state action at issue was not aimed specifically at interfering with the relationship." *Love v. Riverhead Central Sch. Dist.*, 823 F. Supp. 2d 193, 200 (E.D.N.Y. 2011) (quoting *Russ v. Watts*, 414 F.3d 783, 787–88 (7th Cir. 2005) (citing cases)). Courts deny claims where, as here, any effect an Act may have on the parent-child relationship is incidental. *See Ghadami v. D.H.S.*, Civil Action No. 19-00397, 2020 WL 1308376 at \*11 (D.D.C. Mar. 19, 2020) (citing *al-Aulaqi v. Obama*, 727 F. Supp. 2d 1, 26 (D.D.C. 2010)) (rejecting due process challenge, reasoning "there is no constitutional protected liberty interest where the government's interference is indirect").

Plaintiffs also assert a fundamental right "to be informed of and to consent to the immunizations of their minor children in non-emergency situations[.]" That argument also fails. As the Third Circuit has explained, "parental notification has been permitted in limited circumstances in the context of abortion" but "has never been affirmatively required." *Anspach*, 503 F.3d at 271. Indeed, nothing in federal law or District law requires medical information to be provided to the parents of minors beyond the NCVIA which, as explained, directs that a VIS be provided either to the legal guardian of a minor or to the mature minor herself. HIPAA protections ensuring the confidentiality of patient records extend to mature minors vis-à-vis their parents. And the common law tradition of parental involvement in a child's medical decision-making has long been subject to an exception for mature minors. *See* above at 24–27. Plaintiffs argue that the

provisions of the Act requiring the vaccine provider to deal directly with the insurer may prevent them from learning of their child's vaccination, but that result is no different from the HIPAA confidentiality enjoyed by mature minors in receiving any of the other health services in 22-B DCMR § 600.7 and does not itself render the Act constitutionally infirm.

b. The Act Is Narrowly Tailored To Support a Compelling Governmental Interest And Therefore Also Survives Rational Basis Review.

Even assuming the Act infringes upon a fundamental right, plaintiffs are not likely to succeed on their claims because the Act is narrowly tailored to serve a compelling governmental interest. *See Glucksberg*, 521 U.S. at 721.

Plaintiffs argue that the Act "does not further any compelling interest that would justify overriding the decision of fit parents to decline childhood vaccines." Am. Compl. ¶ 405. But the District has a compelling interest in stemming the spread of deadly communicable diseases. *E.g., Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest ...."); *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App'x 348, 353 (4th Cir. 2011) (finding "the state's wish to prevent the spread of communicable diseases clearly constitutes a compelling interest" and upholding vaccination requirement to attend school); *McCormick v. Stalder*, 105 F.3d 1059, 1061 (5th Cir. 1997) (state's interest in preventing spread of highly contagious and deadly disease is compelling).

And this interest was, in fact, the stated purpose of the D.C. Council in passing the Act. *See* Report on Bill 23-0171 at 2. The legislation that became the Act "was introduced on the heels of a measles outbreak that spread across 11 states in 2019." *Id.* The Act was "needed to grant minors, who are concerned for their health and safety, protection and the right to consent to a vaccination recommended by U.S. Advisory Committee on Immunization Practices (ACIP)," and

"so that the District can move towards a high enough immunization rate to achieve herd immunity—or 95% immunity—from such diseases as measles." *Id.* "Non-immunized children are proven to pose a great risk to those they interact with on a daily basis, and with each vulnerable person they come into contact with, whether it be other children in school or family members, that risk grows exponentially." *Id.*; *see also*, *e.g.*, *Bruesewitz*, 562 U.S. at 227 ("[V]accines are effective in preventing outbreaks of disease only if a large percentage of the population is vaccinated.") (citing R. Merrill, *Introduction to Epidemiology* 65–68 (2010)); W.G. van Panhusi, *et al.*, "Contagious diseases in the United States from 1888 to the present." 369 *N. Engl. J. Med.* 21252–22158 (2013) (estimating that between 1924 and 2012, more than 100 million cases of serious diseases were prevented by childhood vaccines).

As the legislative history shows, the Act was not intended to "overrid[e] parents' decisions to decline childhood vaccines based on sincere religious beliefs." Am. Compl. ¶ 384. It is aimed at minors who want to receive vaccines and who are capable of providing informed consent themselves. It applies to any of those individuals, regardless of their parents' fitness or beliefs. It enables competent minors, who could not previously obtain such vaccines because of their parents' objections or simply because of logistical difficulties, to protect their bodies from deadly disease, and, in so doing, reduce the incidence and spread of deadly disease in the community.

Plaintiffs also maintain that the Act is not narrowly tailored because it "overrid[e]s the decisions of "fit parent[s]." *Id.* ¶ 406; Pls.' Mem. at 39–40. They provide no reasoned basis, however, for how a fitness determination would operate as a reasonable method for the District to achieve the stated goals of the Act with a lesser burden on constitutionally protected activity. *See* Report on Bill 23-0171 at 2.

The critical inquiry with respect to narrow tailoring is the class of persons to whom the law applies, and in that respect the Act is narrowly tailored to promote the District's interest by providing criteria that the minor must meet to be considered capable of providing such consent. 22-B DCMR § 600.9(b). The Act only applies to those minors who are "able to comprehend the need for, the nature of, and any significant risks ordinarily inherent in the medical care." *Id.* It excludes those minors who are incapable of appreciating the need for, or any risk posed by, administration of a vaccine. The Act's requirement incorporates the "mature minor" doctrine that, as discussed, has long been recognized in the common law as an exception to any parental consent required for medical procedures. *E.g.*, *Kozup*, 851 F.2d at 439 (citing D.C. case from 1941).

In sum, the Act is narrowly tailored to balance the District's compelling interest in preventing communicable disease, the interests of competent minors in protecting their own bodies from such disease, and the interests of parents in making those decisions for minors who are not capable of weighing the risks and benefits themselves. For all of these reasons, the Act also survives rational basis review as a reasonable public health measure rationally related to the District's interests. *See Gordon*, 721 F.3d at 656 (explaining that plaintiff must demonstrate "there is no rational relationship between [the Act] and some legitimate governmental purpose") *Id.*; *cf. Jacobson*, 197 U.S. at 31 (holding Court should intervene only "if a statute purporting to have been enacted to protect the public health ... has no real or substantial relation to those objects ....").

## 4. Plaintiffs Cannot Succeed on Their RFRA Claim Because Enforcement of the Act Is Not a Substantial Burden on Plaintiffs' Religious Conduct.

Plaintiffs argue that the Act violates RFRA because it substantially burdens their exercise of religion. Pls.' Mem. at 30–33. Plaintiffs' assertion is meritless. The District has not pressured or compelled plaintiffs to violate their religious beliefs or engage in any activity at all, much less

activity that their religion forbids. Thus, without showing a substantial burden on plaintiffs' religious conduct, plaintiffs cannot succeed on their RFRA claim.

RFRA provides that the government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless it can demonstrate the application of the burden: "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(a), (b). To demonstrate a substantial burden on their religious exercise, plaintiffs must show that the District "put[] 'substantial pressure on an adherent to modify [their] behavior and to violate [their] beliefs." *Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008) (quoting *Thomas v. Review Bd.*, 450 U.S. 707, 718 (1981)). "RFRA decisions turn on an element of compulsion," *Archdiocese of Wash. v. Wash. Metro. Area Transit Auth.*, 281 F. Supp. 3d 88, 114 (D.D.C. 2017), *aff'd*, 897 F.3d 314 (D.C. Cir. 2018), but the element of compulsion required to establish a substantial burden under RFRA is not present here.

The Act does not compel plaintiffs to do anything that conflicts with their religious beliefs; the Act merely creates the potential for a mature minor child to participate in an activity that her parent may find religiously objectionable. *See* Background. This distinction is crucial under the law and fatal to plaintiffs' RFRA claim. To find that a State substantially burdens a parent's religious exercise, courts have determined that the State must be "either requiring or prohibiting some activity." *Irwin*, 615 F.2d at 1168 (collecting cases); *see*, *e.g.*, *Yoder* 406 U.S. at 218 (finding a substantial burden when a compulsory education law compelled the Amish to "perform acts undeniably at odds with fundamental tenets of their religious beliefs"). On the other hand, courts have found that merely allowing a child to participate in an activity the parent finds religiously objectionable does not constitute a substantial burden under RFRA. *See Irwin*, 615 F.2d at 1168

(finding no substantial burden when the state established a voluntary birth control clinic where minors could obtain services without parental notification or consent); *Anspach*, 503 F.3d at 274 (finding no substantial burden where the city allowed minors to receive emergency contraception without parental permission). This case squarely falls into the second category. "Religious exercise necessarily involves an action or practice," and government activity that conflicts with an individual's religious beliefs but does not require him to modify behavior does not constitute a substantial burden under RFRA. *Kaemmerling*, 553 F.3d at 679. Here, plaintiffs argue that they "have sincere religious beliefs against vaccinating their minor children." Pls.' Mem. at 31. But the Act does not require them to vaccinate their minor children. *See* Background. Thus, plaintiffs have failed to identify any religious exercise that would have to be modified to conform with the Act, and the Act's creation of a *voluntary* mechanism for minors to obtain vaccines in limited circumstances does not substantially burden plaintiffs' religious exercise.

Plaintiffs contend that that District is "exerting 'substantial pressure' on both parents and children to 'modify [their] behavior and violate [their] beliefs." Pls.' Mem. at 32 (quoting *Kaemmerling*, 553 F.3d. at 678). The only instances of "pressure" plaintiffs identify are some communications encouraging vaccination. Pls.' Mem. at 3–4. But even taking plaintiffs' allegations as true, a government's promotion of vaccines and attempts to persuade members of the community to voluntarily take vaccines do not constitute a substantial burden under RFRA. *See Nikolao v. Lyon*, 875 F.3d 310, 315–16 (6th Cir. 2017) (finding a parent failed to state a free exercise claim when county health department employees attempted to dissuade her from obtaining a religious exemption for vaccinating her children because she was not "coerced ... into doing or not doing anything"). On this point, plaintiffs attempt to distinguish *B.W.C. v. Williams*, 990 F.3d 614 (8th Cir. 2021), Pls.' Mem. at 32, but the case is apt. In *B.W.C.*, the court found no

violation of parents' religious exercise rights when they were required to sign a form (to obtain a religious exemption from school-required vaccinations) with information "strongly encouraging" childhood vaccinations, but the government did not "force their children to get immunized." 990 F.3d at 620–21. Here, the facts are similar. Plaintiffs have failed to identify any way in which the Act's *permission* of vaccines and the District's alleged "pressure" require them to modify their behavior or violate their religious beliefs. And thus, plaintiffs fail to identify a substantial burden to their religious exercise.

At bottom, plaintiffs argue that it is impermissible for the government to merely facilitate children's participation in activities that would contradict their parents' beliefs if the children participated. See Pls.' Mem. at 31. This argument fails. "[T]he law distinguishes between direct participation and remote facilitation, treating the former as compelling and the latter as negligible." Real Alternatives, Inc. v. Sec'y Dep't of Health & Hum. Servs., 867 F.3d 338, 361 (3d Cir. 2017). Indeed, under plaintiffs' broad reading of the definition of "substantial burden," it would follow that parents could require the government to satisfy strict scrutiny to justify its facilitation of any number of childhood activities that could conflict with the parents' religious beliefs, such as allowing children to choose the food they order on a school lunch line or what books they check out from a library or where they are permitted to drive with a valid license. See Lyng v. Nw. Indian Cemetery Protective Ass'n, 485 U.S. 439, 450-51 (1988) (finding that the right to religious exercise "does not and cannot imply that incidental effects of government programs, which may make it more difficult to practice certain religions but which have no tendency to coerce individuals into acting contrary to their religious beliefs, require government to bring forward a compelling justification for its otherwise lawful actions"). A state's "authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience." *Yoder*, 321 U.S. at 166.

Notably, in spite of plaintiffs' suggestion to the contrary, the sincerity of plaintiffs' religious belief against vaccinating their minor children is not in dispute. See Pls.' Mem. at 31. But plaintiffs' characterization that the potential for their child to receive a vaccine against their wishes is a "substantial burden," see Pl.'s Mem. at 31, is a "legal conclusion, cast as a factual allegation," which does not provide "facts sufficient to state a substantial burden," Kaemmerling, 553 F.3d at 679. In other words, "the existence of [a] belief, and even the sincere desire to act in accordance with it, is not enough to sustain a [RFRA] claim." Archdiocese of Wash., 281 F. Supp. 3d at 114. Indeed, "to make religious motivation the critical focus is ... to read out of RFRA the condition that only substantial burdens on the exercise of religion trigger the compelling interest requirement." Id. at 114. Instead, the substantial burden inquiry should focus on whether the regulation at issue "force[d] [plaintiffs] to engage in conduct that their religion forbids or ... prevents them from engaging in conduct their religion requires." Henderson v. Kennedy, 253 F.3d 12, 16 (D.C. Cir. 2001). In using this approach, the D.C. Circuit has cautioned against "expanding [the] RFRA's coverage beyond what Congress intended ... [by] reduc[ing RFRA claims] into questions of fact, proven by the credibility of the claimant." Mahoney v. Doe, 642 F.3d 1112, 1121 (D.C. Cir. 2011). Here, the Court may acknowledge the earnestness of plaintiffs' belief that "plaintiffs have sincere religious beliefs against vaccinating their minor children," Pls.' Mem. at 28, but that is not sufficient, alone, to state a substantial burden under RFRA.

Even if plaintiffs had shown the Act imposes a substantial burden on their exercise of religion, the Act furthers a compelling government interest with the least restrictive means, as discussed above, satisfying the RFRA exception. *See* Section II.B.3; 42 U.S.C. § 2000bb-1(b).

# 5. Plaintiffs Cannot Succeed on Their Free Exercise Claim Because Enforcement of the Act Is Not a Substantial Burden on Plaintiffs' Religious Conduct, And the Act Is Neutral and Generally Applicable.

Plaintiffs contend that the Act violates the Free Exercise Clause by "targeting and endangering children whose parents have claims a lawful religious exemption" from the requirement that students receive certain vaccinations before attending school in the District. Pls.' Opp'n at 37. That is incorrect. The District has not violated plaintiffs' free exercise rights because:

(1) the Act does not substantially burden plaintiffs' religious practice; and (2) the Act is neutral and generally applicable. As a result, plaintiffs cannot succeed on their free exercise claim.

First, plaintiffs must make a "threshold showing" that "a law or regulation imposes a substantial, as opposed to inconsequential, burden on the litigant's religious practice" before the Free Exercise Clause is implicated. *Levitan v. Ashcroft*, 281 F.3d 1313, 1320 (D.C. Cir. 2002). In that evaluation, courts must find that "[t]he litigant's beliefs [are] sincere and the practices at issue [are] of a religious nature," and that the law "burden[s] a central tenet or important practice of the litigant's religion." *Id.* For the reasons described above, *see* Section II.B.4, plaintiffs cannot show that the Act substantially burdens their religious practice. This alone defeats the claim.

Second, even if the Court found a substantial burden, plaintiffs' free exercise claim could not succeed because the Act is neutral and generally applicable. The First Amendment "does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)." *Archdiocese of Wash.*, 281 F. Supp. 3d at 112 (quoting *Emp't Div. Dep't of Human Res. of Oreg. v. Smith*, 494 U.S. 872, 879 (1990), and citing *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 531–32 (1993)). A law is neutral "if the object of a law is [not] to infringe upon or restrict practices because of their religious motivation." *Lukumi Babalu*, 508 U.S. at 533. *Id.* at 543.

Here, plaintiffs argue that the Act is not neutral and generally applicable because the Act provides instructions specific to the school immunization paperwork for minor students utilizing religious exemptions to attend District schools. Pls.' Mem. at 37–38. But plaintiffs do not identify any evidence of an intent to harm their religious exercise. *Cf. Lukumi Babalu*, 508 U.S. at 534 (finding that "suppression of the central element of the Santeria worship service was the object of the ordinances" when "the only conduct subject to ordinances ... is the religious exercise of Santeria church members."); *Tenafly Eruv Ass'n, Inc. v. Borough of Tenafly*, 309 F.3d 144, 167–68 (3d Cir. 2002) (finding that a city's ordinance that prohibited affixing materials to utility poles was not neutral when the city removed religious but not non-religious items).

The fact that paperwork exists for a religious exemption indicates that a unique benefit was conferred to District students with certain religious beliefs (*i.e.*, the choice not to receive vaccinations), and that the Act provided instructions specific to that unique paperwork alone does not suggest that the law is not neutral or generally applicable. *See United States v. Lee*, 455 U.S. 252, 261 (1982) (finding the requirement to pay social security tax generally applicable and not a Free Exercise Clause violation despite existence of categorical exemptions on religious grounds to self-employed individuals); *Priests for Life v. U.S. Dep't of Health & Human Servs.*, 7 F. Supp. 3d 88, 105 (D.D.C. 2013), *aff'd* 772 F.3d 229 ("As ... other courts ... have found, carving out an exemption for defined religious entities does not make a law nonneutral ... .") (internal quotation marks omitted), *vacated on alternative grounds, Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

Moreover, it is well-established that the Free Exercise Clause does not require States to provide *any* form of religious exemptions to student vaccine requirements. *See, e.g.*, *Prince*, 321 U.S. at 166–67 ("The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."); *Phillips v.* 

City of New York, 775 F.3d 538, 543 (2d Cir. 2015) ("New York could constitutionally require that all children be vaccinated in order to attend public school."); Workman v. Mingo Cty. Bd. of Educ., 419 F. App'x 348, 353–54 (4th Cir. 2011) ("In sum, following the reasoning of Jacobson and Prince, we conclude that the West Virginia statute requiring vaccinations as a condition of admission to school does not unconstitutionally infringe [the plaintiff's] right to free exercise."). Plaintiffs seem to acknowledge the existence of this body of case law related to the government "conditioning a benefit—such as in-person school attendance—on the receipt of vaccinations." Pls.' Mem. at 32. And, here, plaintiffs' free exercise claim is based "[s]pecifically" on "the Amendment to D.C. Code § 38-602(b)(2)[, which] states: 'if a minor is utilizing a religious exemption for vaccinations ... the health care provider shall leave blank part 3 of the immunization record." Pls.' Mem. at 28. Thus, plaintiffs argue that the District's modification of the paperwork used for religious exemptions would trigger a violation of the Free Exercise Clause but the District's elimination of the exemption would not. This does not make sense.

Plaintiffs rely on *Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Com'n*, 138 S. Ct. 1719 (2018) to argue that the District's enforcement of the Act shows "hostility" that shows that the "Act is not neutral toward religion[.]" Pls.' Mem. at 38. But plaintiffs have not alleged any treatment (of them or their children) that would evince hostility similar to *Masterpiece*. In that case, the Supreme Court examined a state commission's treatment of a religious individual, and found that the commission "disparaged [the baker's] religion by describing it as despicable," "characterizing [the baker's religion] as ... something insubstantial and even insincere," and failing to distinguish its treatment of the baker's case and "the cases of other bakers who objected to a requested cake on the basis of conscience." *Masterpiece Cakeshop, Ltd.*, 138 S. Ct. at 1730. Here, plaintiffs have alleged no such evidence of hostility toward religion. Instead, plaintiffs merely

allege that the Act's modification of paperwork related to the religious exemption is "clearly hostile" to religion, Pls.' Mem. at 38, without explaining *how*. Again, plaintiffs' claims of hostility fall flat when considering that the religious exemption is a benefit given—though the District has no obligation to do so—to individuals *based on their religious beliefs*.

In sum, because the Act does not impose a burden on plaintiffs' religious conduct and the Act is neutral and generally applicable, there is no violation of the Free Exercise Clause. *See Adair v. England*, 183 F. Supp. 2d 31, 53 (D.D.C. 2002) (finding that neutral and generally applicable laws "need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice"). But even if the Court found that the District did not satisfy those requirements, the District has a compelling government interest in applying the Act and does so using narrowly tailored means. *See* Section II(B)(3); *Lukumi Babalu*, 508 U.S. at 546 ("A law burdening religious practice that is not neutral or not of general application must ... be narrowly tailored in pursuit of [a compelling government interest].").

## C. <u>Plaintiffs Will Not Suffer Irreparable Harm Absent Relief Because They Have</u> Not Shown They Are Likely To Suffer Any Injury.

"Plaintiffs seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). Although the factors relevant to a preliminary injunction "interrelate on a sliding scale ... the movant must, at a minimum, demonstrate that irreparable injury is *likely* in the absence of an injunction." *Bill Barrett Corp. v. U.S. Dep't of Interior*, 601 F. Supp. 2d 331, 334–35 (D.D.C. 2009) (internal quotation marks and citations omitted) (emphasis in original). "[P]roving irreparable injury is a considerable burden, requiring proof that the movant's injury is certain, great and actual—not theoretical—and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm." *Power Mobility Coal. v. Leavitt*, 404 F. Supp. 2d 190, 204 (D.D.C. 2005) (internal citations and

quotation marks omitted); Chaplaincy of Full Gospel Churches, 454 F.3d at 297 (same); Manzanita Band of Kumeyaay Nation v. Wolf, 496 F. Supp. 3d 257, 260 (D.D.C. 2020) (same). If a party fails to make a sufficient showing, a court may deny a motion for preliminary relief without considering the other factors. CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 747 (D.C. Cir. 1995).

Here, plaintiffs have not made a sufficient showing of an imminent injury to satisfy the irreparable harm prong. Though plaintiffs note that the "loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury,'" see Pls.' Mem. at 41 (quoting Mills v. District of Columbia, 571 F.3d 1304, 1312 (D.C. Cir. 2009)), the mere "possibility" of a constitutional harm is not sufficient to satisfy plaintiffs' burden of showing that irreparable harm would occur absent a preliminary injunction, Winter, 555 U.S. at 21. Plaintiffs have not met this burden; as discussed above, plaintiffs have not shown that they are likely to succeed on any of their claims. See Section II.B. Indeed, plaintiffs fail to identify any harm that results from the Act, let alone a harm that is likely to occur. As also discussed above, plaintiffs only allege that it is possible for their children to receive a vaccination against their wishes; plaintiffs do not state that such an occurrence is imminent or even likely to occur. See Section I.

Courts regularly deny claims for emergency relief when a party fails to provide evidence that the alleged harm will materialize. *See*, *e.g.*, *Bin Lep v. Trump*, Civil Action No. 20-3344, 2020 WL 7340059, \*12 (D.D.C. Dec. 14, 2020) (motion for preliminary injunction denied when plaintiff had "no concrete proof" that the harm alleged would occur)); *Reinhard v. Johnson*, 209 F. Supp. 3d 207, 220 (D.D.C. 2016) (finding that "claim [of irreparable harm] is speculative and not supported by any facts"); *Pan Am Flight 73 Liaison Grp. v. Davé*, 711 F. Supp. 2d 13, 32 (D.D.C. 2010) ("Irreparable harm ... cannot rest on mere possibilities.").

Moreover, as plaintiffs acknowledge, the Act became effective over ten months ago. Pls.' Mem. at 35. Plaintiffs' delay in seeking "emergency" relief weighs against the grant of an injunction. See, e.g., Salazar v. District of Columbia, 671 F.3d 1258, 1266 (D.C. Cir. 2012) (citing Quince Orchard Valley Citizens Ass'n v. Hodel, 872 F.2d 75, 80 (4th Cir. 1989) (a "period of delay" may "indicate an absence of the kind of irreparable harm required to support a preliminary injunction")); Public Citizen Research Group v. Acosta, 363 F. Supp. 3d 1, 22 (D.D.C. 2018) ("[P]laintiffs waited over three months ... to seek preliminary relief. Such delay, though perhaps not dispositive, strongly discredits Plaintiffs' claim that they are suffering irreparable harm[.]").

Thus, because plaintiffs fail to identify any imminent, irreparable harm that results from the Act, they have not carried their "considerable burden" to show irreparable harm.

# D. The Balance of the Equities and the Public Interest Weigh in Favor of the District.

Even if a movant demonstrates a likelihood of success and irreparable injury, the Court still must balance the equities between the parties and consider the public interest. *Open Tech. Fund v. Pack*, 470 F. Supp. 3d 8, 31 (D.D.C. 2020). Those two factors "merge when the Government is the opposing party." *Nken*, 556 U.S. at 435.

Plaintiffs argue that they will be harmed by the Act because it "violates the statutory and constitutional rights of parents." Pls.' Mem. at 47. But for the reasons described, there are no such rights at stake here. Plaintiffs identify no other harm that will befall them absent an injunction, nor could they. The Act has no bearing on their rights and they have failed to identify any injury.

In contrast, the District has a compelling interest in maintaining the Act. *See* Section II(B)(3). As discussed above, the Council passed the Act in response to observing outbreaks of preventable diseases in other jurisdictions to ensure that the District could meet the high threshold for herd immunity (95% of the community immunized) to prevent such an outbreak in the District.

See Background. By enacting the Act, the District exercised its "right to protect itself against ... disease[s] which threate[n] the safety of its members." *Jacobson*, 197 U.S. at 27. Courts should hesitate to engage in "second-guessing" to prevent elected representatives from taking the appropriate steps to protect the public health; "an 'unelected federal judiciary,' ... lacks the background, competence, and expertise to assess public health and is not accountable to the people." *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1614 (2020) (Roberts, C.J., concurring); *see also Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) ("[S]tate and federal legislatures [enjoy] wide discretion to pass legislation in areas where there is medical and scientific uncertainty.") (citing *Jacobson*, 197 U.S. at 30–31); *Zucht v. King*, 260 U.S. 174, 176 (1922) ("[A] municipality may vest in its officials broad discretion in matters affecting the application and enforcement of a health law"). "[A court] may presume, absent a showing to the contrary, that [a government] acts in the public interest." *Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492, 501 (1988) (quoting *Hallie v. Eau Claire*, 471 U.S. 34, 45 (1985)). Here, the public interest and balance of the equities weigh heavily in favor of the District.

### III. The District Is Entitled to Dismissal on All Claims Under Rule 12(b)(6).

Even if plaintiffs have standing, plaintiffs' claims are meritless and they are not entitled to any relief. Plaintiffs not only fail to satisfy the standard for obtaining a preliminary injunction, they also fail to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). Even if the Court accepts as true plaintiffs' factual allegations, plaintiffs have not pled sufficient facts to "allow[] the court to draw [a] reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). Here, as discussed, plaintiffs fail to provide any plausible allegations that could support their claims under the Supremacy

Clause, Due Process Clause, RFRA, and the Free Exercise Clause. Thus, plaintiffs fail to state a claim for relief, and the District is entitled to dismissal on all claims in the Complaint. 17

#### **CONCLUSION**

For the foregoing reasons, the Court should deny plaintiffs' motion for preliminary injunction and grant the District's motion to dismiss plaintiffs' Complaint with prejudice. 18

Dated: January 14, 2022. Respectfully submitted,

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2018) (internal quotation marks omitted). Plaintiffs' redundant claims should be dismissed.

If the Court finds plaintiffs have standing and have stated a claim, it should nonetheless dismiss plaintiffs' Section 1983 claims against the individual defendants because an "officialcapacity suit is, in all respects other than name, to be treated as a suit against the [municipal] entity." Kentucky v. Graham, 473 U.S. 159, 166 (1985). Plaintiffs bring only official-capacity claims against the individual defendants. "D.C. Courts routinely dismiss claims against individuals named in their official capacity as redundant and an inefficient use of judicial resources." Proctor v. District of Columbia, Civil Action No. 18-00701, 2018 WL 6181739, at \*5 (D.D.C. Nov. 27,

<sup>18</sup> The Act does not contain severability language. Thus, to the extent the Court finds any particular provision of the Act problematic, it should sever only that portion of the Act and leave the rest. See, e.g., Barr v. American Ass'n of Political Consultants, Inc., 140 S. Ct. 2335, 2350 (July 6, 2020) (When there is no express severability language in legislation, "[t]he Court presumes that an unconstitutional provision in a law is severable from the remainder of the law or statute.").

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