IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

VICTOR M. BOOTH, et al.,

Plaintiffs,

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

vs.

MURIEL BOWSER, et al.,

Defendants.

BRIEF OF AMICI CURIAE AMERICAN ACADEMY OF PEDIATRICS, D.C. CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, AMERICAN MEDICAL ASSOCIATION, MEDICAL SOCIETY OF THE DISTRICT OF COLUMBIA, AND SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTEREST OF AMICI CURIAE¹

The American Academy of Pediatrics ("AAP") was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. AAP's membership includes over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Among other things, AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children and adolescents to ensure access to safe and effective vaccines. AAP also collaborates with the Centers for Disease Control and Prevention ("CDC") and other professional organizations to produce the annual immunization schedules (recommended immunizations) for children from birth to age eighteen. AAP believes, and research supports, that seamless access to vaccination is important for pediatric public health.

The D.C. Chapter of the American Academy of Pediatrics ("DCAAP") is comprised of more than 450 members including pediatricians, residents, and medical students from the District's hospitals, community clinics, and school-based health centers. DCAAP promotes the optimal health and development of children and adolescents in Washington, D.C., in partnership with their families and communities, and supports the pediatricians who care for them.

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and

¹ *Amici* certify that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money intended to fund this brief, and no person other than *amici*, their members, and their counsel contributed money intended to fund this brief.

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science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including the District of Columbia.

The Medical Society of the District of Columbia ("MSDC"), with over 3,000 members, is the largest medical organization representing metropolitan Washington physicians in the District. Founded in 1817, MSDC supports and advocates for patients, physicians, the medical profession, and public health. MSDC provided medical expertise to the District of Columbia on the challenged minor consent law and supported the law before the D.C. Council.

The AMA and MSDC submit this brief on their own behalf and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

Founded in 1968, the Society for Adolescent Health and Medicine ("SAHM") is a multidisciplinary organization committed to the promotion of optimal health and well-being for all adolescents and young adults by supporting adolescent health and medicine professionals through the advancement of clinical practice, care delivery, research, advocacy, and professional development.

INTRODUCTION

Vaccination has long been a vital part of this nation's public health system. Routine childhood vaccinations not only protect minors from infectious disease, but also protect others. Parental participation in the medical decisions of minors, including vaccination, is valuable in most cases, and the vast majority of minors involve their parents in these medical decisions. But occasionally, parental involvement is impossible, impractical, or even harmful. Minors may be

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effectively independent, such as when they are married, in the military, or unaccompanied and homeless. A minor's guardian may be unable to participate in a minor's care due to work, illness, or other issues in the home. Or minors may have reason to believe a parent would punish them for their desire to receive immunization or other medical treatment. When this occurs, minors should not be denied access to potentially life-saving vaccinations.

The medical community, federal law, and every state in the nation have long recognized that minors are capable of informed consent to medical care in certain circumstances. State laws allowing minors to consent to healthcare, including vaccination, are neither uncommon nor controversial. The District's Minor Consent for Vaccination Amendment Act of 2020 ("Minor Consent Act" or "Act") recognizes the needs of the narrow group of minors who seek vaccinations without involving a guardian but who are themselves capable of consent. In doing so, the Act allows adolescents to receive immunizations in circumstances when they may otherwise not be able to obtain them at all, providing individual patients and the general public better protection from vaccine-preventable diseases. The Act is entirely consistent with medical best practices, public health, constitutional requirements, and federal law, and enjoining it would harm the public interest.

ARGUMENT

As the District explains, Plaintiffs have failed to allege non-speculative injuries or to bring a valid claim against the Minor Consent Act. *Amici* write separately to provide additional information relevant to three factors that must be considered when evaluating Plaintiffs' request for injunctive relief: the compelling government interest supporting the Act and thus the lack of likelihood of success on the merits of Plaintiffs' claims; the balance of equities; and the public interest. *See Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014). In particular, this brief addresses the strong public interest in vaccination generally and minor consent specifically; the

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widespread and well-established ability of minors to request and consent to medical treatment in various circumstances; and how the District's Minor Consent Act fits within this context.

I. Widespread Vaccination Saves Lives with Minimal Risk.

Vaccines are critical in protecting Americans from infectious diseases. Public health studies have repeatedly found that routine childhood immunization significantly reduces illness and death from vaccine-preventable disease. For example, one peer-reviewed study estimated that seven longstanding childhood vaccinations prevent roughly 33,000 deaths and 14 million cases of disease for children born in the United States each year.² For people born in the United States between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes."³

Vaccination is especially important for children and adolescents. Healthy children need vaccinations so that the larger population can maintain "herd immunity" (also called "community immunity"). That immunity is essential to preventing the spread of infectious and sometimes deadly diseases to children or adults who cannot receive vaccines for medical reasons or who are especially susceptible to contracting infectious diseases due, for example, to immunocompromise.⁴

The Centers for Disease Control and Prevention ("CDC") recommends that children from birth to age 18 receive immunizations according to publicly available schedules that are co-

² Sandra W. Roush & Trudy V. Murphy, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 J. Am. Med. Ass'n 2155, 2160 (2007), https://bit.ly/33buPMH.

³ CDC, Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013, 63 Morbidity & Mortality Wkly. Rep. 352, 352 (2014), https://bit.ly/334TAdJ.

⁴ See Paul Fine et al., "*Herd Immunity*": A Rough Guide, 52 Clinical Infectious Diseases 911 (2011), <u>https://bit.ly/3HUPpj7</u>.

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authored by *amicus* AAP (along with other professional medical organizations).⁵ The CDC Immunization Schedules form the basis of medically recommended best practices for healthcare for children, as well as federal health insurance regulations.⁶ A number of vaccinations are recommended for adolescents, including the Tetanus-diphtheria-acellular pertussis ("Tdap") booster, the meningococcal conjugate vaccine, the human papillomavirus ("HPV") vaccine, and an annual influenza vaccine.⁷

The current COVID-19 pandemic underscores the importance of vaccination. COVID-19 is a highly contagious, potentially deadly illness, and can cause long-term effects after the infection itself.⁸ COVID-19 impacts children as well as adults. According to statistics updated weekly by AAP and the Children's Hospital Association, more than 9.4 million cases of COVID-19 have been reported in children in the United States, representing 17.8% of all cases as of January 13, 2022.⁹ In the District of Columbia, more than 20% of all cases have been in people

⁵ See CDC, Immunization Schedules, Table 1. Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2021 ("Immunization Schedules"), https://bit.ly/3FPiyuG.

⁶ See 29 C.F.R. § 2590.715-2713 (requiring insurance providers to cover immunizations according to the Immunization Schedules); 45 C.F.R. § 147.130(1) (same).

⁷ Immunization Schedules, *supra* n.5.

⁸ CDC, COVID-19, Frequently Asked Questions, <u>https://bit.ly/3nkxjzs</u> (last visited Jan. 20, 2022); see also, e.g., Terence Stephenson et al., Long COVID—the Physical and Mental Health of Children and Non-Hospitalized Young People 3 Months after SARS-CoV-2 Infection; a National Matched Cohort Study (preprint Aug. 10, 2021), <u>https://bit.ly/3F5YfJf</u> (finding that 30.3% of 11- to 17-year-olds had three or more symptoms three months after testing positive); Claire Pomeroy, A Tsunami of Disability Is Coming as a Result of 'Long COVID,' Sci. Am. (July 6, 2021), <u>https://bit.ly/338Wxtg</u> (collecting studies).

⁹ AAP, *Children and COVID-19: State-Level Data Report* (last visited Jan. 20, 2022), <u>https://bit.ly/327rhL0</u>.

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aged 19 or younger.¹⁰ Among the 23 states reporting hospital data, as well as New York City, 32,818 children have been hospitalized due to COVID-19, including nearly 2,000 in the week ending January 13 alone.¹¹ At least 762 pediatric deaths due to COVID-19 have been reported.¹²

These numbers have skyrocketed since the introduction of the Omicron variant into the United States, with nearly one million children newly diagnosed in the week ending January 13, more than 10% of the total since the beginning of the pandemic, four times the peak of last winter's surge, and a tripling of case counts from just two weeks prior.¹³ That surge in cases has led to record levels of pediatric hospitalizations.¹⁴ Crucially, vaccination provides strong protection against severe symptoms and hospitalization. For example, children under four—for whom no vaccine is available—are now more than four times as likely to be hospitalized if they contract COVID-19 as children aged 5 to 17.¹⁵ Moreover, COVID-19 outbreaks frequently cause school closures, which, while often necessary to prevent further transmission, can harm children's mental health and emotional, social, and psychological development.¹⁶

¹³ Children and COVID-19: State-Level Data Report, supra n. 9.

¹⁴ See, e.g., Nathaniel Weixel, *CDC Reports Record Number of Child COVID-19 Hospitalizations*, The Hill (Jan. 7, 2022), <u>https://bit.ly/3n5sHNr</u>; Holly Yan & Travis Caldwell, *A Record-High Number of Kids Are Getting Hospitalized with Covid-19 as Overall Covid-19 Hospitalizations Soar Past the Delta Peak*, CNN Health (Jan. 5, 2022), <u>https://cnn.it/3q5fxSz</u>.

¹⁰ Children's Hosp. Ass'n & AAP, *Children and COVID-19: State Data Report* at App. Tbl. 3A, (Jan. 13, 2021), <u>https://bit.ly/3IczKfa</u>.

¹¹ *Id.* at App. Tbl. 2B.

¹² *Id.* at App. Tbl. 2C.

¹⁵ See, e.g., Weixel, supra n. 14.

¹⁶ See, e.g., Jorge V. Verlenden et al., Association of Children's Mode of School Instruction with Child and Parent Experiences and Well-Being During the COVID-19 Pandemic—COVID Experiences Survey, United States, October 8–November 13, 2020, 70 Morbidity & Mortality Wkly. Rep. 369 (2021), <u>https://bit.ly/3zNTXFj</u>; Meira Levinson et al., *Reopening Primary* Schools During the Pandemic, 383 New Eng. J. Med. 981 (2020), <u>https://bit.ly/3fi3g6S</u>.

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Although some anti-immunization advocates portray vaccines as "dangerous,"¹⁷ they are in fact "under constant study" to ensure that they are "extraordinarily safe."¹⁸ "A vaccine must go through detailed clinical trials before it is approved by the Food and Drug Administration (FDA) for use in children. The trials look at the vaccine's safety, side effects, and effectiveness."¹⁹ After the FDA concludes that a vaccine is "safe and effective, and its benefits are greater than any risks," it goes to another panel of outside experts, the Advisory Committee on Immunization Practices ("ACIP"), to determine whether it should be recommended for use.²⁰ And "[e]ven after a vaccine is approved and recommended for use, the safety and effectiveness of the vaccine continues to be monitored by the CDC and FDA."²¹

As a result, "[v]accines are among the most effective and safe public health interventions available to prevent serious disease and death."²² "[S]erious adverse events from vaccines are extremely rare today, and those risks are substantially smaller than the risks from vaccine-preventable diseases."²³ While Plaintiffs highlight the risk of serious injuries such as "severe

¹⁷ See, e.g., Children's Health Defense, *Vaccines*, <u>https://bit.ly/3FkUrnB</u> (last visited Jan. 20, 2022) ("[D]angerous substances abound in the vaccines that our government agencies continue to insist are safe.").

¹⁸ AAP, *Vaccine Safety: Examine the Evidence*, <u>https://bit.ly/3FdIrEp</u> (last visited Jan. 20, 2022) (collecting studies about the general safety of vaccines, including studies on safety concerns commonly raised by parents).

¹⁹ AAP, Vaccine Safety: Get the Facts, <u>https://bit.ly/3HZEgNY</u> (last visited Jan. 20, 2022).

²⁰ Id.; see also CDC, GRADE (Grading of Recommendations, Assessment, Development, and Education), <u>https://bit.ly/3Abh5xH</u> (last visited Jan. 20, 2022) (explaining ACIP's evaluation process).

²¹ Vaccine Safety: Get the Facts, supra n. 19.

²² Inst. of Med., *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*, Nat'l Acads. Press 1 (2013), <u>https://bit.ly/3K6GRYG</u>.

²³ Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 Buff. L. Rev. 881,

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neurological damage and death," Pls.' Statement of P.&A. in Supp. of Their Mot. for Prelim. Inj., Doc. No. 33-1 ("Pls.' Statement"), at 10, such injuries are exceedingly rare—and, invariably, significantly less common than the rates of morbidity and mortality among unvaccinated individuals who contract the disease against which the relevant vaccine protects.²⁴

This is no less true for the COVID-19 vaccines. Not only do the vaccines reduce the risk of mortality or serious morbidity from COVID-19, vaccine recipients appear to have lower *non*-COVID-19 mortality risks than do unvaccinated people.²⁵ The one health risk that Plaintiffs emphasize, myocarditis, is a case in point. Pls.' Statement at 19-20. While studies have found a rate of 56 to 69 cases of myocarditis per million vaccine doses in boys aged 12-17,²⁶ they have found a rate of *1325* cases of myocarditis per million COVID-19 infections in children under 16, and 977 per million COVID-19 infections in people aged 16-24.²⁷ The rate of myocarditis

²⁴ See, e.g., Guillain-Barré Syndrome and Vaccines, CDC, <u>https://bit.ly/3HNxkUi</u> (last visited Jan. 20, 2022) ("[S]tudies suggest that it is more likely that a person will get GBS after getting the flu than after vaccination."); CDC, *Febrile Seizures and Childhood Vaccines*, <u>https://bit.ly/3thG6Wq</u> (last visited Jan. 20, 2022) (explaining that febrile seizures "do not cause any permanent harm and do not have any lasting effects" and "can happen with any condition that causes a fever," and that "[v]accines can also help prevent febrile seizures").

²⁵ Stanley Xu et al., *COVID-19 Vaccination and Non–COVID-19 Mortality Risk–Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021*, 70 Morbidity & Mortality Wkly. Rep. 1520 (2021), <u>https://bit.ly/3D1ZRn4</u>.

²⁶ Julia W. Gargano et al., Use of mRNA COVID-19 Vaccine after Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices—United States, June 2021, 70 Morbidity & Mortality Wkly. Rep. 977 (2021), <u>https://bit.ly/3fHTYRK</u>.

²⁷ Tegan K. Boehmer et al., Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data—United States, March 2020–January 2021, 70 Morbidity & Mortality Wkly. Rep. 1228, at Tbl. (2021), <u>https://bit.ly/3AgIJtb</u>. Note that the vaccine study reported separate statistics for males, while the infection study did not disaggregate age cohorts by sex. Because the risk of myocarditis is higher for males than females, the blended rate in the

^{938 (2015), &}lt;u>https://bit.ly/3GRLT9d</u> ("Reiss & Weithorn, *Responding to the Childhood Vaccination Crisis*") (citations omitted).

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among children under 16 who contract COVID-19 is 37 times higher than those who do not contract it, far beyond any elevation in risk associated with vaccination.²⁸

II. Minor Consent Laws Provide an Important Backstop That Protects Vulnerable Minors.

A. While parental involvement is a pediatrician's first choice, treatment without parental involvement is appropriate in some circumstances.

In most cases, parental involvement and consent to their children's healthcare is a key goal and prerequisite of pediatric practice. "[O]btaining informed permission from parents or legal guardians before medical interventions on pediatric patients [is] standard within our medical and legal culture." AAP, *Informed Consent in Decision-Making in Pediatric Practice: Technical Report*, 138 Pediatrics 2, e1 (2016) ("AAP Tech. Rep."), <u>https://bit.ly/3IjSiu8</u>. Shared, family-centered decision-making is a central tenet of pediatric care. *Id.* at e6. This practice reflects a respect for parental autonomy in the family, the fact that "parents generally are better situated than others to understand the unique needs of their children . . . and make appropriate, caring decisions regarding their children's health care," *id.* at e5, and the beneficial nature of knowledge, trust, and buy-in for the efficacy of medical treatment.

In rare circumstances, however, parental involvement is impossible or even harmful. Parents may be unable to take their children to a doctor due to work, disability, or other impairment. Homelessness or exclusion from the family may leave a minor without a parent or guardian to consent for them. Or, for a variety of reasons—often based on inaccurate beliefs about medical facts—parents may oppose medical care that is necessary to protect their child's

latter study likely *understates* how much higher the rate of myocarditis is for young males who contract COVID-19 compared to those who receive a vaccine.

²⁸ Id.

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health.²⁹ Similarly, societal or familial stigmas attached to conditions that may require medical treatment, such as psychological disorders, substance use, or the consequences of sexual activity or sexual assault, may prevent minors from seeking medical care at all if doing so requires involving their parents.³⁰ Adolescents may have reason to fear negative repercussions, from mild punishment to physical or emotional abuse, for raising the subject at all.³¹ In such circumstances, "[m]inors' own constitutional rights may compete with parental claims."³² Parental refusal of medical treatment, including vaccines, may also increase the risk of community spread of communicable diseases, including to particularly vulnerable populations such as immuno-compromised individuals, those too young to receive a vaccine, and transplant recipients.³³

³¹ See, e.g., Melissa Weddle & Patricia K. Kokotailo, *Confidentiality and Consent in Adolescent Substance Abuse: An Update*, 7 Ethics J. Am. Med. Ass'n 239, 240 (2005), <u>https://bit.ly/3F18Yj8</u>; Weithorn & Reiss, *Providing Adolescents with Independent and Confidential Access, supra* n. 30, at 817.

³² Weithorn & Reiss, *Providing Adolescents with Independent and Confidential Access, supra* n. 30, at 796-97; *see also infra* p. 17-23 (discussing minors' constitutional rights).

²⁹ See, e.g., Reiss & Weithorn, *Responding to the Childhood Vaccination Crisis*, *supra* n. 23, at 937-52 (evaluating common rationales offered for parents' refusals to vaccinate their children).

³⁰ See, e.g., AAP, Substance Use Screening and Intervention Implementation Guide at 8, https://bit.ly/3ryZxYj ("Protecting the confidentiality of information is an important consideration for determining whether adolescents will answer questions honestly and accurately, seek help, and stay engaged with their pediatricians and other health care professionals."); AAP Tech. Rep. at e9 ("The legal ability of adolescents to consent for health care needs related to sexual activity, including treatment of sexually transmitted infections (STIs) ... reflects ... the concern that adolescents will not seek care for issues that reflect sexual activity if required to involve their parents for consent"); Lois A. Weithorn & Dorit Rubinstein Reiss, Providing Adolescents with Independent and Confidential Access to Childhood Vaccines: A Proposal, 52 Conn. L. Rev. 771, 817, 825-26 (2020), https://bit.ly/3tOmeKS ("Weithorn & Reiss, Providing Adolescents with Independent and Confidential Access"); Amelia Gulliver et al., Perceived Barriers to Mental Health Help-Seeking in Young People: A Systematic Review, 10 BMC Psychiatry 113 (2010), https://bit.ly/3Agb82q.

³³ See, e.g., Varun K. Phadke et al., Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis, 315 J. Am. Med. Ass'n 1149, 1149 (2016), <u>https://bit.ly/3HXVY4w</u> (reviewing studies and concluding that "[t]he phenomenon of vaccine refusal was associated with an increased risk for measles" not only

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In recognition of these potential conflicts, pediatric practitioners "must balance the need to work collaboratively with all parents/families, respecting their culture, religion, and the importance of the family's autonomy and intimacy, with the need to protect children from serious and imminent harm." AAP Tech. Rep. at e7. As AAP has explained:

Pediatric health care providers have legal and ethical duties to provide a standard of care that meets the pediatric patient's needs and not necessarily what the parents desire or request. Parental decision-making should primarily be understood as parents' responsibility to support the interests of their child and to preserve family relationships, rather than being focused on their rights to express their own autonomous choices.

Id. at e5.

As a general rule, pediatricians provide medical care without parental consent only where state law allows a minor to "legally make decisions regarding his or her own health care." *Id.* at e9. Such situations include "specific diagnostic/care categories" that have been authorized by state law; the "mature minor" doctrine, which varies from state to state but generally allows minors who can understand the nature and consequences of the treatment offered the right to seek and consent to that treatment³⁴; and legal emancipation. *Id.* In most cases, the provider must determine whether the patient has "enough decision-making capacity, moral intelligence, and judgment to provide true informed consent." *Id.* at e13. This includes ascertaining whether the patient sufficiently understands the proposed treatment, its risks and benefits, and their own medical history to make a reasoned, informed decision about the treatment.

among "people who refuse vaccines" but among "fully vaccinated individuals"); *see generally* Immunization Action Coal., *Personal Belief Exemptions for Vaccinations Put People at Risk. Examine the Evidence for Yourself.* (Oct. 2019), <u>https://bit.ly/34JULj5</u> (collecting articles).

³⁴ See generally, e.g., Doriane Lambelet Coleman & Philip M. Rosoff, *The Legal Authority of Mature Minors to Consent to General Medical Treatment*, 131 Pediatrics 786 (2013), https://bit.ly/3GmcHhJ; Lawrence Schlam & Joseph P. Wood, *Informed Consent to the Treatment of Minors: Law and Practice*, 10 Health Matrix 141 (2000), https://bit.ly/3HUQJm5; Garry S. Sigman & Carolyn O'Connor, *Exploration for Physicians of the Mature Minor Doctrine*, 119 J. Pediatrics 520 (1991).

B. There is a substantial public interest in allowing minors capable of informed consent to request vaccination without parental approval.

Vaccination is a critically important area of medical care in which minors capable of giving informed consent should be permitted to obtain treatment without parental approval. The vaccines on the CDC Immunization Schedules are low-risk, high-efficacy preventative care that protect not only the individuals who receive them, but also the community as a whole. Yet in recent years, persistent and often intransigent resistance to vaccines has arisen in some populations, which has led many parents to refuse to allow their children to receive vaccines, no matter what their children choose and how capable they are of making their own decision. This places not only those parents' children at risk, but also other children—especially those most vulnerable, such as immunocompromised children. Vaccine hesitancy has led to outbreaks of diseases that had been completely or largely eradicated, like pertussis and measles.³⁵ As the World Health Organization has recognized, "[v]accine hesitancy—the reluctance or refusal to vaccinate despite the availability of vaccines" is a "threat[] to global health" that "threatens to reverse progress made in tackling vaccine-preventable diseases."³⁶

For example, measles—"a highly infectious, acute viral disease that can cause rash, fever, diarrhea, pneumonia, encephalitis, and death"—was eliminated from the United States as an endemic disease by 2000, thanks to the high rates of vaccination coverage produced by school vaccine requirements.³⁷ But as a result of increased vaccine hesitancy, 2019 saw "the greatest

³⁵ See, e.g., Varun K. Phadke et al., Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis, supra n. 33, at 1150, 1153; Daniel R. Feikin et al., Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization, 284 J. Am. Med. Ass'n 3145, 3145 (2000), <u>https://bit.ly/3nEemIf</u>.

³⁶ World Health Org., *Ten Threats to Global Health in 2019*, <u>https://bit.ly/3qguW2u</u>.

³⁷ Amy A. Parker et al., *Implications of a 2005 Measles Outbreak in Indiana for Sustained Elimination of Measles in the United States*, 355 New Eng. J. Med. 447, 447 (2006), https://bit.ly/33WxYjL.

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number of [measles] cases reported in the U.S. since 1992."³⁸ While such outbreaks predominantly affect vaccine-hesitant individuals or their children, they can also harm vaccinated individuals or those too young to receive the vaccine; 13% of measles cases in 2019 were among infants too young to receive the vaccine, and 11% had received one or more shots (but may not have yet received the full regimen).³⁹ Fully 10% of patients were hospitalized.⁴⁰

At the same time that declining vaccination rates jeopardize public health, the simple and medically well-understood nature of vaccines makes them particularly suitable for minor consent. As discussed above, the risks and benefits of vaccines have been extensively studied, and are relatively easy for patients to comprehend.⁴¹ Yet "misinformation and exaggerated warnings about vaccines [have] divert[ed] parents' attention away from what has been scientifically-demonstrated and [led] parents to choose the greater risk for their children: the diseases against which vaccines provide protection."⁴² As has been widely documented, "most of the beliefs that typically lead parents to refuse vaccination are without scientific foundation."⁴³

⁴⁰ *Id*.

⁴¹ *See supra* pp. 7-9.

³⁸ CDC, Measles Cases and Outbreaks (updated Jan. 3, 2022), <u>https://bit.ly/3ffkJ00</u>.

³⁹ Manisha Patel et al., *National Update on Measles Cases and Outbreaks—United States, January 1–October 1, 2019*, 68 Morbidity & Mortality Wkly. Rep. 893, 893 (2019), https://bit.ly/3rAUDtV.

⁴² Reiss & Weithorn, Responding to the Childhood Vaccination Crisis, supra n. 23, at 884; see generally, e.g., Jennifer Reich, Calling the Shots: Why Parents Reject Vaccines (2016); Eve Dubé et al., Vaccine Hesitancy: An Overview, 9 Hum. Vaccines & Immunotherapeutics 1763 (2013), <u>https://bit.ly/339pRjG</u>; Edward Mills et al., Systematic Review of Qualitative Studies Exploring Parental Beliefs and Attitudes Toward Childhood Vaccination Identifies Common Barriers to Vaccination, 58 J. Clinical Epidemiology 1081 (2005), <u>https://bit.ly/3FiNmns</u>; Steven P. Calandrillo, Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?, 37 U. Mich. J. L. Reform 353 (2004), <u>https://bit.ly/3tjKhkA</u>.

⁴³ Weithorn & Reiss, Providing Adolescents with Independent and Confidential Access, supra n.
30, at 788; see generally, e.g., Margaret A. Maglione et al., Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review, 134 Pediatrics 325 (2014), https://bit.ly/33qcZ8y; Francesco Nicoli & Victor Appay, Immunological Considerations

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Such misplaced concerns have skyrocketed during the COVID-19 pandemic, with conspiracy theories (such as the demonstrably false beliefs that the vaccines contain tracking microchips, rewrite recipients' DNA, or cause infertility) and related beliefs suppressing vaccination rates.⁴⁴ Anti-vaccine advocates have also promoted misinformation about the vaccines' efficacy, as exemplified by Plaintiffs' counsel's uncited assertion that "vaccinated students are . . . at equivalent risk of infection" as unvaccinated students. Pls.' Statement at 4.⁴⁵ As a result, the United States—one of the first countries in the world with widespread access to COVID-19 vaccines—lags behind most of the developed world in the rate of fully vaccinated or boosted individuals.⁴⁶

Allowing minors capable of informed consent to obtain vaccines if they so choose is an important step toward reversing these trends. The medical community broadly endorsed such measures even before the COVID-19 pandemic. For example, *amicus* AMA voted to "support state policies allowing minors' to override their parent's refusal of vaccinations" in 2019, citing "[t]he prevalence of unvaccinated pediatric patients" and "the emergence of vaccine preventable

Regarding Parental Concerns on Pediatric Immunizations, 35 Vaccine 3012 (2017), https://bit.ly/333qb3C; Frank DeStefano et al., Principal Controversies in Vaccine Safety in the United States, 69 Clinical Infectious Diseases 726 (2019), https://bit.ly/3FdJoMZ; Luke E. Taylor et al., Vaccines Are Not Associated with Autism: An Evidence Based Meta-Analysis of Case-Control and Cohort Studies, 32 Vaccine 3623 (2014), https://bit.ly/3ffFloL.

⁴⁴ See, e.g., Cathy Cassata, *Doctors Debunk 9 Popular COVID-19 Vaccine Myths and Conspiracy Theories*, Healthline (June 22, 2021), <u>https://bit.ly/3GoAE80</u>; Jemima McEvoy, *Microchips, Magnets and Shedding: Here Are 5 (Debunked) Covid Vaccine Conspiracy Theories Spreading Online*, Forbes (June 3, 2021), <u>https://bit.ly/3I0ZCLd</u>.

⁴⁵ In fact, studies uniformly demonstrate that COVID-19 vaccine regimens including a booster are effective even against the novel Omicron variant. *See, e.g.*, Sara Oliver, *Updates to the Evidence to Recommendation Framework: Pfizer-BioNTech Vaccine Booster Doses in 12–15 Year Olds*, CDC (Jan. 5, 2022), <u>https://bit.ly/3zROHA1</u> (collecting recent studies).

⁴⁶ See Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. Times (updated Jan. 20, 2022), <u>https://nyti.ms/3qiRMX3</u>.

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diseases in the United States."⁴⁷ *Amicus* Society for Adolescent Health and Medicine similarly called for "explor[ing] all available legal options for allowing minor adolescents with capacity for informed consent to give their own consent for vaccinations."⁴⁸ Several major medical journals have run articles endorsing such proposals.⁴⁹ And the specific bill at issue here was endorsed by *amici* D.C. Chapter of the American Academy of Pediatrics and the Medical Society of the District of Columbia, among others.⁵⁰

Such laws are overwhelmingly in the public interest—and, conversely, enjoining them would harm the public interest. Because medically unnecessary refusals to vaccinate place both the individual unvaccinated children and the broader public at risk, allowing mature adolescents to consent "serve[s] not only the state's police power interest in protecting public health, but also its *parens patriae* interest in promoting the health of the vaccinated children."⁵¹ It also respects "the interests of minors who wish to be vaccinated despite parental objection," including their "interests in avoiding serious illness, disability, and death."⁵²

⁵² *Id.* at 831-32.

⁴⁷ AMA, *AMA Adopts New Policies on First Day of Voting at 2019 Annual Meeting* (June 10, 2019), <u>https://bit.ly/3Fd2Jhe</u>.

⁴⁸ Abigail English et al., *Adolescent Consent for Vaccination: A Position Paper of the Society for Adolescent Health and Medicine*, 53 J. Adolescent Health 550, 550 (2013), <u>https://bit.ly/33kjqdj</u>.

⁴⁹ See, e.g., Larissa Morgan et al., COVID-19 Vaccination of Minors Without Parental Consent: Respecting Emerging Autonomy and Advancing Public Health, 175 J. Am. Med. Ass'n 995 (2021), <u>https://bit.ly/333qlYM</u>; Ross D. Silverman et al., Vaccination Over Parental Objection— Should Adolescents Be Allowed to Consent to Receiving Vaccines?, 381 New Eng. J. Med. 104, 106 (2019), <u>https://bit.ly/3I0ZFqn</u>.

⁵⁰ See Council of the D.C. Comm. on Health, Comm. Rep., "Report on Bill 23-0171, 'Minor Consent for Vaccinations Amendment Act of 2020," 35-36, 39-41 (Oct. 7, 2020), https://bit.ly/31PirBz.

⁵¹ Weithorn & Reiss, *Providing Adolescents with Independent and Confidential Access, supra* n. 30 at 830; *see also id.* at 831 ("[T]he threat to the public's health from a continuation of the current non-vaccination trends is real, as are the dangers to each individual unvaccinated child.").

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The case for such an allowance is at least as strong as it is in the other areas where minor consent is common or even ubiquitous. See infra Part II.C. The risk from the vaccines on the CDC Immunization Schedules is exceedingly low, as they "have many health benefits and few side effects."53 Most of the infectious diseases against which vaccines protect are highly contagious, such that vaccines provide a substantial public health benefit even beyond the individual child. Allowing consent by informed minors ensures that the health and schooling of that minor and other minors are not jeopardized by a parent's inability to bring them to a doctor due to work commitments, illness, disability, or other impairment, and allows for homeless adolescents to access medical care. And the implacable nature of anti-vaccine attitudes in some households "may deter [children] from broaching the topic at all" with their parents, as they "may reasonably fear . . . negative repercussions from an expression of interest in being vaccinated, ranging from tension and conflict in the parent-child relationship, parental actions to prevent the minor from taking steps to become vaccinated, punitive consequences for the minor or, in extreme cases, abuse directed at the minor."⁵⁴ There are thus substantial reasons that allowing minor consent is in the public interest, far outweighing any putative interest individual parents may claim in preventing their children from accessing such medical care.

C. Federal law recognizes the availability of minor consent, and all states allow minors to consent to healthcare in certain circumstances.

A fundamental error permeating Plaintiffs' brief is the presumption that the general principle of parental involvement and consent is inviolable unless the parent is declared unfit. This is incorrect.

⁵³ Nat'l Acad. of Sci. Eng'g & Med., Vaccines Are Safe (Dec. 21, 2018), <u>https://bit.ly/3ffl4ji</u>; see generally CDC, Safety Information by Vaccine (last updated July 16, 2020), <u>https://bit.ly/33pOeJR</u>; CDC, Safety of COVID-19 Vaccines (Dec. 29, 2021), <u>https://bit.ly/3r7fuFa</u>.

⁵⁴ Weithorn & Reiss, *Providing Adolescents with Independent and Confidential Access, supra* n. 30, at 834-35.

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The Supreme Court has long recognized that neither parental nor religious rights "include liberty to expose the community or the child to communicable disease or the latter to ill health or death." *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944). "Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves." *Id.* at 170. The Court has applied this principle in a variety of healthcare settings.⁵⁵ More generally, children are "possessed of fundamental rights which the state must respect," *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 511 (1969), just as adults are. *See In re Gault*, 387 U.S. 1, 13 (1967) ("[N]either the Fourteenth Amendment nor the Bill of Rights is for adults alone.").

Consistent with that understanding, the federal government has long acknowledged and facilitated minor consent laws, taking steps to ensure that minors' confidentiality is appropriately protected and that federal law not interfere with state law. The implementing regulations for the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936 (1996), provide that minors "ha[ve] the authority to act as an individual" with regard to their protected health information where state law allows them to consent to medical care on their own. 45 C.F.R. § 164.502(g)(3)(i). Those regulations also prohibit providers from disclosing protected health information to a parent or guardian where "prohibited by an applicable provision of State or other law." *Id.* § 164.502(g)(3)(ii)(B). Where state law is silent, the regulations leave it to "licensed health care professional[s], in the exercise of professional judgment," to determine whether to disclose health information to a parent when a minor independently consents to medical care. *Id.* § 164.502(g)(3)(ii)(C).

⁵⁵ See, e.g., Parham v. J.R., 442 U.S. 584, 604 (1979) ("parents cannot always have absolute and unreviewable discretion to decide whether to have a child institutionalized" for mental health treatment); *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 74-75 (1976) (state may not impose a blanket requirement of parental consent on minor decisions regarding pregnancy).

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While the precise laws vary, all 50 states (in addition to the District of Columbia) have enacted laws that permit minors to consent to health care under certain circumstances.⁵⁶ The laws can be divided into two overlapping categories: those based on the status of the minor and those based on the type of care.⁵⁷ Some of these laws grant minors who are effectively independent from their parents or guardians (such as minors who are married, have joined the military, or are unaccompanied homeless youth) full autonomy over all of their healthcare decisions.⁵⁸ Other states have adopted the "mature minor" doctrine discussed above.⁵⁹ Many state laws authorize all minors to access one or more specified types of treatment.⁶⁰ Of special relevance here, the forms of treatment covered by these laws tend to be in areas of medicine where the chance of familial conflict could deter an adolescent from seeking medical care. For example, "[a]t least 34 states have enacted statutes that allow minors to consent for some outpatient mental health services."⁶¹ "As of 2020, all jurisdictions have laws that explicitly allow a minor of a particular age (as defined by each state) to give informed consent to receive STD diagnosis and treatment services."⁶² At least 44 states permit minors to consent to alcohol or drug abuse treatment, with 13 states confining consent to certain age groups and at least 31

⁵⁶ See Abigail English et al., Center for Adolescent Health & the Law, State Minor Consent Laws: A Summary at 2 (3d ed., 2010); AAP Tech. Rep. at e9; Weithorn & Reiss, Providing Adolescents with Independent and Confidential Access, supra n. 30, at 808-29.

⁵⁷ State Minor Consent Laws, supra n. 56, at 2.

⁵⁸ See, e.g., Ala. Code §§ 22-8-4, 22-8-7; Ariz. Rev. Stat. § 44-1-132.

⁵⁹ See supra p. 11 & n. 34; see, e.g., Ark. Code Ann. § 20-9-602(7); Idaho Code § 39-4503.

⁶⁰ State Minor Consent Laws, supra n. 56, at 2.

 $^{^{61}}$ *Id* at 6.

⁶² CDC, State Laws That Enable a Minor to Provide Informed Consent to Receive HIV and STD Services (Jan. 8, 2021), <u>https://bit.ly/31S75g8</u>.

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authorizing minors of any age.⁶³ At least 37 states permit minors to consent to prenatal services, as does the District of Columbia.⁶⁴ And at least 47 states and the District of Columbia allow minors to consent to contraceptive services in some circumstances.⁶⁵

Minor consent to immunization, while less commonly the subject of single-purpose state laws, is no less well established. At least as early as 1928, state courts recognized that minors "of sufficient intelligence to understand and appreciate the consequences of the vaccine" could provide their consent to be vaccinated.⁶⁶ Vaccines have been recognized as being one of the many types of services that minors can consent to under the "mature minor" doctrine,⁶⁷ and vaccines against STDs fall within many states' authorization for STD treatment.⁶⁸ At least 14 states—Alabama, Arkansas, Georgia, Hawaii, Idaho, Illinois, Michigan, Minnesota, North Carolina, Oregon, Rhode Island, South Carolina, Tennessee, and Washington—have minor consent laws that specifically address immunization, authorize certain minors to consent to "any" medical care, or have expressly reaffirmed in the past year that their laws permit minors to selfconsent to vaccination in some circumstances.⁶⁹ And where state law is ambiguous, some cities

⁶³ Richard C. Boldt, *Adolescent Decision Making: Legal Issues with Respect to Treatment for Substance Misuse and Mental Illness*, 15 J. Health Care L. & Pol'y 75, 90-92 (2012), https://bit.ly/3nHPdvW.

⁶⁴ Guttmacher Inst., *Minors' Access to Prenatal Care* (July. 1, 2021), <u>https://bit.ly/3r8HsjQ</u>.

⁶⁵ Guttmacher Inst., *Minors' Access to Contraceptive Services* (July 1, 2021), <u>https://bit.ly/3ffVYRc</u>.

⁶⁶ Gulf & S.I.R. Co. v. Sullivan, 119 So. 501, 502 (Miss. 1928).

⁶⁷ See, e.g., Baird v. Att'y Gen., 360 N.E.2d 288, 295-97 (Mass. 1977).

⁶⁸ See State Laws That Enable a Minor, supra n. 62 (listing states that allow minors to consent to STD prevention).

⁶⁹ Alabama: Ala. Code § 22-8-4 ("[a]ny minor who is 14 years of age or older, or has graduated from high school, or is married, or having been married is divorced or is pregnant may give effective consent to any legally authorized" healthcare); *see also* Eric Graves, *Alabama law says kids 14 and older don't need parent permission to get COVID vaccine*, WAFF48 (May 17, 2021), <u>https://bit.ly/3nj5Yxj</u>.

Arkansas: Ark. Code § 20-9-602(7) (mature minors may consent to medical treatment); *see also* Ark. Ctr. for Health Improvement, *Can Minors Get the COVID-19 Vaccine Without Parental Consent* (May 6, 2021), <u>https://bit.ly/3nhBufj</u>.

Georgia: Ga. Code Ann. § 15-11-727(b)(7) (emancipated minors may authorize own "preventive health care").

Hawaii: Haw. Rev. Stat. §§ 577D-1, 577D-2 (some minors may consent to "primary medical care" including "immunizations").

Idaho: Idaho Code § 39-4503 ("Any person, . . . who comprehends the need for, the nature of and the significant risks ordinarily inherent in any contemplated hospital, medical, dental, surgical or other health care, treatment or procedure is competent to consent thereto on his or her own behalf."); *see also* Idaho Dep't of Health & Welfare, *COVID-19 Briefing: Updates on COVID-19 in Idaho* (Apr. 9, 2021), <u>https://bit.ly/3nhNz4f</u>.

Illinois: Ill. Admin. Code tit. 77, § 693.130 ("A minor 12 years of age or older who may have come into contact with any STI may give consent to . . . vaccination against . . . an STI.").

Michigan: Mich. Comp. Laws Ann. § 722.4 (some minors may consent to own "preventive health care").

Minnesota: Minn. Stat. Ann. § 144.3441 (minors may consent to Hepatitis B vaccination).

North Carolina: N.C. Gen. Stat. § 90-21.5(a)(i) (allowing "[a]ny minor" to consent to medical health services for the prevention of "diseases reportable under [N.C. Gen. Stat.] 130A-135," which includes communicable diseases); *see also* Jessica Winters, *North Carolina law states that kids 12-17 can get Pfizer vaccine without parental consent*, WFMY 2 (May 13, 2021), <u>https://bit.ly/3103GyM</u> (quoting North Carolina Department of Public Safety spokesperson as saying "State law does not require [parental consent for vaccines], children can do that on their own.").

Oregon: See Or. Rev. Stat. § 109.640(2) (minors 15 or older may consent to medical treatment); Kate Brown, *Minor Consent Statement*, Or. Health Auth. (May 25, 2021), <u>https://bit.ly/3GA2YVf</u> ("[M]inors age 15 and older have the legal authority to consent to medical treatment, including vaccinations.").

Rhode Island: *See* R.I. Gen. Laws Ann. § 23-4.6-1 (allowing "[a]ny person of the age of sixteen (16) or over or married" to consent to routine healthcare); R.I. Dep't of Health, *COVID-19 Vaccine FAQs*, <u>https://bit.ly/3fdbhKv</u> (last visited Jan 20, 2022) ("A person age 16 or 17 in Rhode Island can sign a vaccination consent form on their own and they do not need to be accompanied by a parent or guardian to receive a vaccine.").

South Carolina: S.C. Code Ann. § 63-5-340 ("Any minor who has reached the age of sixteen years may consent to any health services"); *id.* § 63-5-350 ("Health services of any kind may be rendered to minors of any age without the consent of a parent or legal guardian when, in the judgment of a person authorized by law to render a particular health service, such services are deemed necessary"); *see also* Emily Correll, *Teens Ages 16 and 17 Don't Need Parents Consent to Get Vaccinated in South Carolina*, WLTX (Mar. 31, 2021), https://bit.ly/3qinDan.

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have similarly authorized minors to consent to immunization; Philadelphia, for example, allows people 11 or older to authorize their own immunization, as long as they are capable of providing informed consent, just as the District does here.⁷⁰

In sum, every state recognizes that minor self-consent is a crucial exception to the general rule of parental decision-making. While there is no dispute that parental involvement is preferable when it does not interfere with the minor's access to health care, the universal existence of such exceptions is incompatible with Plaintiffs' claim that the right of a parent to control the healthcare decisions of a minor is absolute.

III. The District's Minor Consent Act Is Medically Appropriate and in the Public Interest, and Furthers the District's Compelling Interest.

As shown above, the District and other governments have a compelling interest in providing minors who are unable to get parental consent with access to immunization, and enjoining it would harm the public interest. Plaintiffs' attempt to distinguish the Minor Consent Act from previous steps to increase childhood vaccination rates are unavailing, as the District explains. *See* Defs.' Mem. of P&A in Opp. to Pls.' Mot. for Prelim. Inj. & in Supp. of Defs.' Mot. to Dismiss Pls.' Am. Compl. ("Defs.' Mem."), Doc. No. 35. In particular, two of Plaintiffs' arguments against the District's and public's interests in the Minor Consent Act are incorrect as a matter of medical practice and medical ethics law. Both the Act's "informed consent" standard

Tennessee: Tenn. Dep't of Health, *Mature Minor Doctrine*, <u>https://bit.ly/3qfaGOG</u> (last visited Jan. 20, 2022) (Tennessee has a "rebuttable presumption" that minors 14 and older have capacity to consent to medical care, including vaccinations).

Washington: Univ. of Wash., *Providing Health Care to Minors under Washington Law*, <u>https://bit.ly/3Gjsv4L</u> (last visited Jan. 20, 2022) (minors may consent to immunizations if they meet state "mature minor" definition).

⁷⁰ Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents § 4(b), City of Phila. Dep't of Public Health (consolidated July 19, 2019; first issued July 26, 2007), <u>https://bit.ly/3GjsKwH</u>.

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and its confidentiality provisions are entirely consistent with medical best practices, the law governing medical privacy, and the National Vaccine Act.

A. The "informed consent" standard in the District's Minor Consent Act is medically appropriate and in the public interest.

The District's Minor Consent Act recognizes the severe health consequences of declining vaccination rates, *see supra* Part II.B, while respecting the need to work collaboratively with families and the limits to a minor's capacity to consent, *see supra* Part II.A. Moreover, the Act is consistent with the specific healthcare practices recommended by *amici*.

The Minor Consent Act presumes that a parent or guardian will be involved and that minor consent is an exception that may only be invoked if certain conditions are met. *See* D.C. Mun. Regs. tit. 22-B, § 600.9. Consistent with best practices, it permits a minor to consent only if the minor is "capable of meeting the informed consent standard," defined as a minor "able to comprehend the need for, the nature of, and any significant risks ordinarily inherent in the medical care." *Id.* § 600.9(a)–(b); *see also* AAP Tech. Rep. at e9. This puts the responsibility on the healthcare provider to ascertain whether the patient has enough decision-making capacity to provide true informed consent. *See* AAP Tech. Rep. at e9. Minors who are unable to answer basic questions about their own medical history would be unlikely to meet this standard.⁷¹ The Act also requires healthcare providers to give a requesting minor "age-appropriate vaccine information sheets." D.C. Mun. Regs. tit. 22-B, § 600.9(c). This is in additional assurance that the minor will have all necessary resources to understand the nature and risks of a vaccination, and gives the provider additional opportunity to dialogue with the patient to confirm whether there is informed consent.

⁷¹ *Cf.* AAP Tech. Rep. at e9 (noting that ability to consent requires, *inter alia*, "capacity to understand and appreciate an intervention's . . . risks," which necessarily requires an awareness of relevant medical history).

B. The confidentiality provisions of the Minor Consent Act are medically appropriate and in the public interest.

D.C.'s Minor Consent Act states that providers administering immunizations to minors under the law shall seek reimbursement directly from the relevant insurer without parental consent, and that the insurer will not send an Explanation of Benefits. D.C. Mun. Regs. tit. 22-B, § 600.9(d)(2). It also directs providers to leave part three of the D.C. Universal Health Certificate blank and to submit immunization records directly to schools. D.C. Code Ann. § 38-602(a)(2). Otherwise, it says nothing at all about what providers may or may not say to parents of minors who independently request vaccination.

Consistent with HIPAA regulations and medical best practice, this appropriately leaves to physicians' judgment the case-dependent decision in each individual doctor-patient-parent relationship of how to balance the adolescent's interest in confidentiality and the parent's interest in disclosure. See 45 C.F.R. § 164.502(g)(3)(ii)(B). As discussed above, medical confidentiality is often crucial to ensuring that minors seek appropriate medical treatment. See supra pp. 9-11 & n. 30. What information should be disclosed to a parent varies from case to case and is an appropriate subject for discussion with the patient and the considered judgment of the provider. In some situations, a provider's goal should be "to have [the] patient agree to involve his or her parents," and to "work out a strategy together [with the patient] for how to disclose the information." AAP, Substance Use Screening, supra n. 30, at 8. In others, a pediatrician may determine that the parent must be informed to safeguard the minor's health, even over the minor's objection. See id. In still others, a provider may conclude that an adolescent's health will best be served by keeping information or treatment plans confidential from parents, because doing so ensures that the adolescent "will answer questions honestly and accurately, seek help, and stay engaged with their pediatricians and other health care professionals." Id. In every case,

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this is a fact-dependent decision that calls for physicians to exercise their judgment, not a decision that should be dictated by law—and the District has appropriately treated it as such.

All that the confidentiality provisions of the Minor Consent Act do is ensure that the fact of vaccination will not be inadvertently available to parents through documents intended for other purposes—i.e., medical billing and school administration. Providers may tell parents or not, as they conclude is appropriate, but they and the patient need not worry that their decision regarding confidentiality will be undermined by technical documentation.

Plaintiffs claims that it is "impossible" for a provider to comply with both the Minor Consent Act and the National Vaccine Act's requirements that providers report adverse events and record certain information in the patient's "permanent medical record." Pls.' Statement. at 14-16. This is incorrect. The D.C. Universal Health Certificate is not a patient's permanent medical record; it is a certificate provided to D.C. schools and childcare facilities so the school or facility will be aware of their students' health concerns and can ensure that students are not exposed unnecessarily to infectious diseases, and so the Department of Health may address tuberculosis or lead exposure threats.⁷² The Minor Consent Act does not suggest in any way that providers should deviate from their typical (and statutorily required, *see* 42 U.S.C. § 300aa-25(a)-(b)) practices in recording the administration of vaccinations in patients' actual medical records and reporting any adverse events.

Finally, the law is entirely silent as to how providers should comply with the federal requirement for providing a Vaccine Information Statement ("VIS"), except to require the Department of Health to produce age-appropriate alternative VISs that can be used in the informed consent process. 22-B DCMR § 600.9(c). Nothing in the Act prohibits doctors from

⁷² See D.C. Health, D.C. Health Universal Certificate (2019), <u>https://bit.ly/3FjHcTZ</u>.

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providing the federally required VIS to the patient or the patient's legal representatives. As Defendants explain, Plaintiffs are mistaken to assert that Section 300aa-26(d) is not satisfied by providing a VIS to the patient alone. *See* Defs.' Mem. at 18-20. But even if Plaintiffs were right, both D.C. law and federal law allow doctors to (1) provide a VIS to an individual parent prior to the immunization of that parent's child, or (2) send VISs to the parents of all of the doctor's patients, preemptively satisfying the statute in case any patient should request vaccination. There is thus no conflict between the Minor Consent Act and the federal statute—or the public interest.

CONCLUSION

For these reasons and those expressed in Defendants' brief, the Court should grant the motion to dismiss and deny the motion for a preliminary injunction.

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Respectfully submitted,

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