# IN THE UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA

	<u>—</u> .
VICTOR M. BOOTH,	)
individually and as next friend of	)
L.B. a minor child,	)
3017 Central Avenue NE,	)
Washington, D.C. 20018;	)
washington, D.C. 20018,	)
SHAMEKA WILLIAMS,	) Case No. 21-1857
individually and as next friend of	)
K.G. and R.T., minor children;	)
3744 Foote Street NE,	) VERIFIED AMENDED
Washington, D.C. 20019;	) <b>COMPLAINT FOR</b>
	) DECLARATORY AND
SHANITA WILLIAMS,	) INJUNCTIVE RELIEF
individually and as next friend of	, )
N.W. and M.R., minor children,	)
404 13th Street SE,	)
Washington, D.C. 20003; and	)
, ,	)
JANE HELLEWELL,	, )
individually and as next friend of	)
H.B., a minor child,	)
648 Lexington Place NE,	)
Washington, D.C. 20002,	)
Plaintiffs,	)
33 /	)
VS.	)
	)
MURIEL BOWSER,	)
in her official capacity as Mayor of the	)
District of Columbia,	)
1350 Pennsylvania Avenue NW	)
Washington, D.C. 20004;	)
	)
LAQUANDRA NESBITT,	)
In her official capacity as	)
Director of the District of Columbia	)
Department of Health,	)
825 North Capitol Street SE	)
Washington, D.C. 20002; and	)
	)

LEWIS FEREBEE,	)
In his official capacity as	)
Chancellor of the District of Columbia	)
Public Schools,	)
1200 First Street NE	)
Washington, D.C. 20002,	)
	)
Defendants.	)
	_ )

#### TABLE OF CONTENTS

Page # TABLE OF AUTHORITIES ......iii ALLEGATIONS OF FACT ......4 A. B. C. The District of Columbia Adopts District-Wide Vaccine Requirements for the D. Defendants are exerting tremendous pressure on plaintiffs' children through a E. F. Defendants are exerting tremendous pressure upon Plaintiffs' children by operating walk-in vaccine clinics for children, including walk-in clinics in G. Defendants are exerting tremendous pressure upon Plaintiffs' children by imposing additional requirements on unvaccinated children in schools and Plaintiff Victor M. Booth and L.B. 24 H. T Plaintiff Shameka Williams 34 J. K. Plaintiff Jane Hellewell 40 L. M. The Minor Consent Act also violates federal law by requiring health providers to keep vaccination information secret from parents, the very N. 

O. The Constitutional Rights of Parents	63
FIRST CAUSE OF ACTION 28 U.S.C. § 2201 and 42 U.S.C. § 1983	65
Adoption and Enforcement of an Unconstitutional Statute that Deprives Parents of Federal Statutory Rights Guaranteed by the National Childhood Vaccine Injury Act of 1986, in violation of Article VI and the Fifth Amendment of the Constitution	65
SECOND CAUSE OF ACTION 28 U.S.C. § 2201, 42 U.S.C. § 1983, and 42 U.S.C. § 2000bb	67
Adoption and Enforcement of an Unconstitutional Statute In violation of the Religious Freedom Restoration Act of 1993	67
THIRD CAUSE OF ACTION 42 U.S.C. § 1983	69
Adoption and Enforcement of an Unconstitutional Statute in Violation of the First Amendment to the U.S. Constitution	69
FOURTH CAUSE OF ACTION 28 U.S.C. § 2201 and 42 U.S.C. § 1983	71
Adoption and Enforcement of an Unconstitutional Statute that Deprives Parents of Their Fundamental Right to Direct the Upbringing of their Children in Violation of the Fifth Amendment of the U.S. Constitution	71
PRAYER FOR RELIEF	73
Verification of Victor Booth	75
Verification of Shameka Williams	76
Verification of Shanita Williams	77
Verification of Jane Hellewell	78

## TABLE OF AUTHORITIES

## **Federal Cases**

Bruesewitz v. Wyeth LLC, Cantwell v. Connecticut. 310 U.S. 296 (1940)......69 Cleveland Board of Education v. LaFleur, Hazlehurst v. Sec'y of HHS, Masterpiece Cakeshop, LTD., et al. v. Colorado Civil Rights Commission et al. Parham v. J.R., Santosky v. Kramer, 455 U.S. 745 (1982)......63 Troxel v. Granville, Wisconsin v. Yoder, 406 U.S. 2 05 (1972)......63 **United States Constitution** Article VI. clause 2 .......65 Fifth Amendment 1. passim Fourteenth Amendment ......63

#### **Federal Statutes**

21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) ......54 28 U.S.C. § 1343......4 42 U.S.C. § 2000bb(a)(1)-(2) ......60 § 2000bb-2(4).......61 § 2000cc-5(7)(A) .......61

#### **State Statutes**

Code of District of Columbia § 2-578 .......8 § 38-506(2)......5 § 38-602(b)(2).......69 § 46-101 .......5 **Code of Federal Regulations District of Columbia Municipal Regulations** Title 22-B ......5 § 600.9.......51 § 600.9(a) ......5 § 600.9(d)(2)-(3) .......6 § 699.1......5 **Internet Sources** CDC, Find a COVID-19 vaccine near you, https://www.vaccines.gov......42 CDC, Find COVID-19 Vaccines, CDC's General Best Practice Guidelines for Immunization: Contraindications and Precautions, which are available at Children's Health Defense, the Defender November 1, 2021 article, entitled, 17 Pharma Henchmen Who Voted to Experiment on Your Kids — and How to Shun Them, https://childrenshealthdefense.org/defender/fda-pfizer-covid-kids-pharma/......60

Children's Health Defense, the Defender August 14, 2020 article, entitled, Read	
the Fine Print, Part Two -Nearly 400 Adverse Reactions Listed in Vaccine	
Package Inserts, https://childrenshealthdefense.org/news/read-the-fine-print-	
part-two-nearly-400-adverse-reactions-listed-in-vaccine-package-inserts	48
Coronavirus (COVID-19) Vaccine, GOVERNMENT OF THE DISTRICT OF COLUMBIA,	
MURIEL BOWSER, MAYOR, https://coronavirus.dc.gov/vaccine	18 20
MORIEL BOWSER, MATOR, https://colonavirus.uc.gov/vaccine	10, 29
DC COVID-19 Vaccination Data, GOVERNMENT OF THE DISTRICT OF COLUMBIA,	
MURIEL BOWSER, MAYOR, https://coronavirus.dc.gov/node	18
DC.GOV, Mayor Muriel Bowser, DC Health, Immunizations,	
https://dchealth.dc.gov/page/immunizations.	19 35
nups.//denearm.de.gov/page/mmumzadons	17, 55
District of Columbia Public Schools, Vaccinations for Students,	
https://dcpsreopenstrong.com/vaccines/	19, 35
Hardy Middle School website,	
https://www.hardyms.org	35
<u></u>	
Jefferson Jones, U.S. Centers for Disease Control and Prevention, <i>Epidemiology</i>	
of COVID-19 in Children Aged 5-11 Years, available at	
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-	
3/03-COVID-Jefferson-508.pdf (accessed November 10, 2021)	55
K.G. Blumethal, L.B. Robinson, C.A. Carmago, et. al, Acute Allergic Reactions to	
mRNA COVID-19 Vaccines, 325 J. AM. MED. ASS'N 15, 1562-1565 (Mar. 8,	
2021), available at https://jamanetwork.com/journals/jama/fullarticle/2777417	
(accessed November 10, 2021)	55
(40003300 1,0,001201 10, 2021)	
KIPP DC: Public Schools, Healthy Operations,	
https://www.kippdc.org/healthy-operations/	19, 29
KIPP DC: Public Schools, Vaccine Clinic,	
https://www.kippdc.org/vaccine-clinic/	18 34 37
naps.// www.kippac.org/vaccine cinite/	10, 51, 57
Nasdaq.com, Pfizer Stock: Vaccine Maker Poised for Big 2022, Nov. 4. 2021,	
available at https://www.nasdaq.com/articles/pfizer-stock%3A-vaccine-	
<u>maker-poised-for-big-2022-2021-11-04</u> (accessed November 10, 2021)	60
Paul D Thacker, Covid-19: Researcher blows the whistle on data integrity issues	
in Pfizer's vaccine trial, THEBMJ (Nov. 2, 2021),	
https://www.bmj.com/content/375/bmj.n2635	60
<u>пирыл и и и лопу.сопи сопили этэлопу.п20ээ</u>	
Pfizer, Pfizer Reports Third-Quarter 2021 Results, Nov. 2, 2021, available at	
https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-	
REPORTS-THIRD-QUARTER-2021-RESULTS/default.aspx (accessed	
November 10, 2021)	60

Recording, November 17, 2020 meeting of the District of Columbia Council,	
available at	
http://dc.granicus.com/MediaPlayer.php?view_id=2&clip_id=5903	10
Recording, October 20, 2020 meeting of the District of Columbia Council,	
available at	
http://dc.granicus.com/MediaPlayer.php?view_id=2&clip_id=5765	9
December 2 2020 Meeting of the Committee on Health qualible of	
Recording, October 7, 2020 Meeting of the Committee on Health, available at	0
http://dc.granicus.com/MediaPlayer.php?view_id=2&clip_id=5720	8
Reports to VAERS for 12 to 17-year-olds, National Vaccine Information Center,	
Search Results, available at	
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E	
VENTS=ON&VAX=COVID19&VAXTYPES=COVID-	
19&STATE=NOTFR&WhichAge=range&LOWAGE=12&HIGHAGE=18	
(accessed November 10, 2021)	56
Deports to VAEDS of advance events among all age groups for COVID 10	
Reports to VAERS of adverse events among all age groups for COVID-19	
vaccines, National Vaccine Information Center, Search Results, available at	
https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=C	
AT&EVENTS=ON&VAX=COVID19 (accessed November 10, 2021)	56
Reports to VAERS of adverse events between Dec. 14, 2020, and Oct. 29, 2021	
National Vaccine Information Center, Search Results, available at	
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E	
VENTS=ON&VAX=COVID19&STATE=NOTFR (accessed November 10,	
2021)	56
Reports to VAERS of deaths from COVID-19 vaccines, National Vaccine	
Information Center, Search Results, available at	
https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=A	
GE&EVENTS=ON&VAX=COVID19&DIED=Yes (accessed November 10, 2021)	56
/	
Reports of VAERS of deaths in the U.S. between Dec. 14, 2020, and Oct. 29,	
2021, National Vaccine Information Center, Search Results, available at	
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E	
VENTS=ON&VAX=COVID19&DIED=Yes&STATE=NOTFR (accessed	
November 10, 2021)	56
Reports to VAERS of myocarditis and pericarditis in children in the 0-18 age	
1	
group, National Vaccine Information Center, Search Results, available at	
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E	
VENTS=ON&SYMPTOMS[]=Myocarditis+%2810028606%29&SYMPTO	
MS[]=Pericarditis+%2810034484%29&VAX=COVID19&WhichAge=range	
<u>&amp;LOWAGE=0&amp;HIGHAGE=19</u> (accessed November 10, 2021)	57

Reports to VAERS of myocarditis and pericarditis in the 12 to 17 age group,
National Vaccine Information Center, Search Results, available at
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E
VENTS=ON&SYMPTOMS[]=Myocarditis+%2810028606%29&SYMPTO
MS[]=Pericarditis+%2810034484%29&VAX=COVID19&WhichAge=range
<u>&amp;LOWAGE=12&amp;HIGHAGE=18</u> (accessed November 10, 2021)57
Reports to VAERS of deaths in the 12 to 17 age group, National Vaccine
Information Center, Search Results, available at
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&E
VENTS=ON&VAX=COVID19&DIED=Yes&WhichAge=range&LOWAGE
<u>=12&amp;HIGHAGE=18</u> (accessed November 10, 2021)
Take the Shot, DC., Get Vaccinated, GOVERNMENT OF THE DISTRICT OF
COLUMBIA, MURIEL BOWSER, MAYOR, https://coronavirus.dc.gov/page/get-
<u>vaccinated</u>
Transcript of Oral Argument at 16:18, 28:15, 36:1, and 43:10, <i>Bruesewitz</i> , 562
U.S. 223 (No. 09-152), available at
https://www.supremecourt.gov/oral_arguments/audio/2010/09-152
USCFC Vaccine-Reported, UNITED STATES COURT OF FEDERAL CLAIMS,
https://uscfc.uscourts.gov/aggregator/sources/7
Vaccine Rules Appendix B, Rules of the United States Court of Federal Claims,
Rules 1,3, 7 and 8, available at
https://www.uscfc.uscourts.gov/sites/default/files/21.08.02%20FINAL%20Va
ccine%20Rules.pdf (accessed November 10, 2021)
Vaccines and Related Biological Products Advisory Committee Meeting October
26, 2021, FDA Briefing Document, EUA amendment for Pfizer-BioNTech
COVID-19 Vaccine for use in children 5 through 11 years of age," available
at https://www.fda.gov/media/153447/download58
Other Authorities
D.C. Mayor's Order 2021-099 signed August 10, 202114, 15
D.C. Mayor's Order 2021-109 signed September 20, 2021
The Nuremberg Code21, 22

#### PRELIMINARY STATEMENT

Plaintiffs VICTOR M. BOOTH, SHAMEKA WILLIAMS, SHANITA WILLIAMS, and JANE HELLEWELL, individually and as next friends of their respective minor children, seek a declaration under 42 U.S.C. § 1983 and 28 U.S.C. § 2201 that the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 (hereinafter "the Minor Consent Act") violates 42 U.S.C. § 300aa, et. seq., the National Childhood Vaccine Injury Act of 1986 (hereinafter "the National Vaccine Act"); violates the Constitution's Supremacy Clause and 42 U.S.C. § 1983; deprives plaintiffs of the right to freely exercise their religion in violation of the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. § 2000bb; and deprives them of the constitutional right as parents to direct the care and upbringing of their children in violation of the Due Process Clause of the Fifth Amendment and 42 U.S.C. § 1983.

The Minor Consent Act eviscerates parents' rights to make informed decisions and foolishly allows children as young as 11 to make their own consequential vaccination decisions, which can result in injury or death, as well as vaccine-induced immunity. Under this law, Defendants must conceal from parents that their children have been vaccinated, depriving them of the most rudimentary knowledge that they require to properly care for their children. Shockingly, Defendants shroud the process in secrecy by instructing insurers to conceal children's vaccination information from parents as payors. Defendants have covered all bases to deceitfully hide this vital information from parents and to obstruct their ability to serve as dutiful and effective caregivers. And for many months, Defendants have pressured Plaintiffs and their children through an intense media campaign based on fearmongering with monetary rewards to children themselves for violating their parents' rights and religious convictions. This law

exemplifies a level of hostility towards those of religious faith and non-neutrality by government that is simply intolerable under the First Amendment.

Plaintiffs seek an injunction against defendants to arrest enforcement of the Minor Consent Act based on the facts and legal conclusions below. Finally, Plaintiffs seek costs and attorneys' fees pursuant to 42 U.S.C. § 1988 and any other and further relief the Court deems proper.

In support of the causes of action presented herein, Plaintiffs state as follows:

## **PARTIES**

- 1. Plaintiff Victor M. Booth is a citizen of the United States of America who resides in the District of Columbia. Victor is the biological father of L.B., who resides with Victor in the District of Columbia. L.B. is 13 years old and is enrolled in Kipp Academy, a public charter school in the District.
- 2. Plaintiff Shameka Williams is a citizen of the United States of America who resides in the District of Columbia. Shameka is the biological mother of K.G. and R.T., who reside with Shameka in the District of Columbia. K.G. is 13 years old, and is enrolled in Rose L. Hardy Middle School, a public school in the District. R.T. is 4 years old, and will be of compulsory attendance age at the start of the 2022-2023 school year.
- 3. Plaintiff Shanita Williams is a citizen of the United States of America who resides in the District of Columbia. Shanita is the biological mother of N.W. and M.R., who reside with Shanita in the District of Columbia. N.W. is 15 years old, and is enrolled in Kipp College Preparatory, a public charter school in the District. M.R. is 9 years old, and is enrolled in Watkins Elementary School, a public school in the District.

- 4. Plaintiff Jane Hellewell is a citizen of the United States of America, who resides in the District of Columbia. Jane is the biological mother of H.B., who resides with Jane in the District of Columbia. H.B. is 15 years old and is enrolled in School Without Walls High School, a public magnet high school in the District.
- 5. Defendant Muriel Bowser is the Mayor of the District of Columbia. As the head of the District's Executive Branch, Mayor Bowser oversees the District of Columbia's Department of Health (hereinafter "D.C. Health") and appoints D.C. Health Director. Mayor Bowser is also authorized by law to govern the public schools of the District of Columbia and to appoint the Chancellor of Schools for the District of Columbia Public Schools (hereinafter "DCPS"). Mayor Bowser is sued in her official capacity only.
- 6. Defendant LaQuandra Nesbitt the Director of D.C. Health. Director Nesbitt was appointed by Mayor Bowser in 2015. As the chief executive officer of D.C. Health, Director Nesbitt directs D.C. Health and its policies under the supervision of Mayor Bowser. D.C. Health, which has a principal address of 899 North Capitol Street, NE, Washington, D.C. 20002, is an executive agency of the District. Director Nesbitt is sued in her official capacity only.
- 7. Defendant Lewis Ferebee is the Chancellor of the District of Columbia Public Schools (DCPS). Chancellor Ferebee was appointed by Mayor Bowser in 2018. As the chief executive officer of DCPS, Chancellor Ferebee directs DCPS and its policies under the supervision of Mayor Bowser, and also has the authority to promulgate rules for DCPS. Chancellor Ferebee is sued in his official capacity only.

# **JURISDICTION AND VENUE**

- 8. This action is brought pursuant to 42 U.S.C. §§ 1983 and 1988, and 28 U.S.C. § 2201 *et. seq.* The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343.
- 9. Venue is proper pursuant to 28 U.S.C. § 1391, in that at all times pertinent to this action all the Defendants were residents of the District of Columbia; defendant Muriel Bowser is mayor of the District, and in that capacity oversees the District's Department of Health and public schools; the Plaintiffs reside in the District; and a substantial part of the events or omissions giving rise to the claims presented herein occurred in the District.

# **ALLEGATIONS OF FACT**

- A. Vaccine Requirements in the District of Columbia
- 10. Every parent or guardian who resides permanently or temporarily in the District during a school year, and who has custody or control of a child between the ages of five and eighteen, must have the child attend an educational institution when the public schools are in session. D.C. CODE § 38-202(a).
- 11. District law states that no students in kindergarten through twelfth grade shall be admitted to any public, private, or parochial school in the district unless they comply with immunization standards and regulations specified by the Mayor or their parents have documented a religious or medical exemption from vaccinations. D.C. CODE §§ 38-501, 38-502, and 38-503.
- 12. The Mayor is charged under District law to specify the standards of compliance and may revise the list of immunizations for students. D.C. CODE § 38-503.
- 13. The District City Council enacted in 1979 Section 38-506 of the D.C. Code, which recognizes the right of a parent to assert a religious or medical exemption on behalf of a

child.

- 14. To obtain a religious exemption for a student under the age of 18, the student's parent or guardian must object in good faith and in writing to the chief official of the school that vaccinations would violate the parent's religious beliefs. A good faith statement that a parent has sincere religious beliefs against childhood immunizations until recently has been sufficient to claim the exemption. D.C. CODE § 38-506(1).
- 15. To obtain a medical exemption for a student under the age of 18, the student's parent or guardian must provide the school with a written certification by a private physician, his or her representative, or the public health authorities that vaccinations are medically inadvisable.

  D.C. Code § 38-506(2).
- 16. The minor's parent—not the minor—is vested with the lawful authority to assert an exemption from vaccinations under D.C. CODE § 38-506.
  - B. The District of Columbia Minor Consent to Vaccinations Act of 2020
- 17. On October 20, 2020, the Council of the District of Columbia approved the District of Columbia Minor Consent to Vaccinations Act of 2020 ("the Minor Consent Act").
- 18. The Minor Consent Act amends Title 22-B of the District of Columbia Municipal Regulations to allow a minor who is eleven years of age or older to consent to receive a vaccine recommended by the Centers for Disease Control and Prevention (CDC) where the minor meets the District's informed consent standard. 22-B D.C.M.R. § 600.9(a). However, the District has failed to define its "the informed consent standard," making it hard to believe that any 11-year-old or older student is free of pressure to vaccinate against parental wishes.
- 19. "Minor" is any person under the age of eighteen. 22-B D.C.M.R. § 699.1; D.C. CODE § 46-101.

- 20. The Minor Consent Act subverts the rights and duties of parents to make informed decisions for their minor children. It both deprives them of the opportunity to make those decisions and conceals from them that their children have been asked to consent to vaccinations or have indeed been vaccinated.
- 21. In fact, it states that medical providers who administer vaccines under the Minor Consent Act shall seek reimbursement directly from the insurer without parental knowledge or consent. 22-B D.C.M.R. § 600.9(d)(1). The Minor Consent Act further provides that insurers shall not send an Explanation of Benefits (EOB) for services to parents. While minors who receive vaccines under the Minor Consent Act have access to their immunization records, parents do not. 22-B D.C.M.R. § 600.9(d)(2)-(3).
- 22. Prior to the Minor Consent Act, D.C. Code § 38-602(a) required students attending pre-kindergarten through 12th grade to furnish their school with an annual certificate of health completed and signed by a physician, unless the students' parents submitted a religious exemption under section 38-603.
- 23. The Minor Consent Act left that language unchanged, but added a second provision, now codified in D.C. Code § 38-602(a)(2). This provision states that if 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.
- 24. Part 3 of the District of Columbia's Child Health Certificate is where medical providers record the administration of nine specific vaccines (most of which are combination

vaccines): Diphtheria-Tetanus-Pertussis (under 7 years old), Diphtheria-Tetanus, Hemophilus Influenzae B (HIB), Hepatitis B (HBV), Polio, Measles-Mumps-Rubella (MMR), Varicella, Pneumococcal conjugate (PCV), and Influenza (which is not required). Part 3 also contains a blank row for recording "other" vaccines. A District of Columbia's Child Health Certificate is attached as **Exhibit 1**.

- 25. This provision mandates the creation of two health records for students whose parents claim a religious exemption. One record, accessible to parents, leaves the child's immunization record blank, even if the school has administered additional vaccinations. The "black book" second record, which is intentionally concealed from parents, records the child's actual medical history, including vaccinations.
- 26. Furthermore, D.C. Code § 38-602(a)(2) states that the school "shall keep the immunization record received from the health care provider confidential," except that it may be shared with "the Department of Health or the school-based health center," thus egregiously elevating the school's and Department of Health's rights above those of the child's parent or guardian.
- 27. The Minor Consent Act did not amend D.C. CODE § 38-506 to abolish the authority of parents to assert a religious exemption from vaccinations nor did it amend D.C. CODE § 38-603 to eliminate the religious exemption, yet it disrespects and eviscerates the religious rights of parents at every turn. On its face, the Minor Consent Act unlawfully overrides parents' rights to claim religious exemptions pursuant to D.C. CODE § 38-506(1).
- 28. On information and belief, the purpose of the Minor Consent Act is to administer vaccines for the Human Papillomavirus (HPV), meningitis, COVID-19, and others to children whose parents have asserted religious exemptions pursuant to D.C. CODE § 38-506(1), without

the parents' knowledge or consent. While the District may be acting out of good intentions, cutting parents out of their children's lives in crucial ways and depriving parents of their lawful rights is a bridge too far.

# C. The D.C. Council Enacts the Minor Consent Act

29. On October 7, 2020, the D.C. Council's Committee on Health met to consider the Minor Consent Act. The meeting is on the Council's website in accordance with the District of Columbia Open Meetings Act, D.C. Code § 2-578. As of the date of this filing, the recording for the Committee on Health is available at

http://dc.granicus.com/MediaPlayer.php?view\_id=2&clip\_id=5720.

- 30. At this meeting, Council Member Mary Cheh, the sponsor of the Minor Consent Act, stated that "unfortunately, we see a rising number of individuals or families across the globe, really, who are choosing not to vaccinate their children based on the widely disproven belief that vaccines may cause autism or other harmful health effects. These anti-science beliefs not only put the unvaccinated children at risk, but have led to the spread of diseases that have been all but eradicated in the past."
- 31. Council Member Cheh further stated that, "[g]iven our current, ongoing pandemic, and the incredible work being done to develop a COVID-19 vaccine, it's more important than ever, I think, that we reduce any and all barriers to these treatments, and this legislation aims to do just that, by increasing access to vaccines to minors who choose to get vaccinated, but have been unable to do so."
- 32. Within minutes of Council Member Cheh's comments, the Committee on Health unanimously approved the Minor Consent Act.

33. On October 20, 2020, the District of Columbia Council met as a Committee of the Whole to consider the Minor Consent Act. As of the date of this filing, the recording for this legislative meeting is available at

http://dc.granicus.com/MediaPlayer.php?view\_id=2&clip\_id=5765.

- 34. At that meeting, Chairman Phil Mendelson stated, "Public health can very much be in the public interest, and that is, have a compelling state interest, and we see that today with the pandemic, and the need, because of public health, to alter certain behaviors."
- 35. On October 20, 2020, Council Member Allen stated, "using vaccines are a way that we not only keep individuals safe but we keep communities safe, and we're certainly going to be having a conversation sometime next year when there's another vaccine that's going to be critically important, that's gonna see widespread distribution and we're gonna want to make sure that we're taking the right steps."
- 36. On October 20, 2020, Council Member Trayon White stated, "for me, it's not an issue of the vaccinations. It's an issue of the Council voting to circumvent the inclusion of a parent making the decision about their child. And the floor is an eleven-year-old child. I have a twelve-year-old son who can barely put together a five-page paper, or finish his homework on time, or be up late at night playing Fortnite—making decisions about his health. And so, for us to circumvent that process is very worrisome for me, and that's why I stand as relates to this legislation, as we attempt to use the law to remove parental involvement as relates to important decisions made by a minor as young as eleven years old."
- 37. On October 20, 2020, the Minor Consent Act passed First Reading by a vote of 12 in favor, 1 opposed.

- 38. On November 17, 2020, the Council considered the Minor Consent Act in a legislative meeting. As of the date of this filing, the recording for this legislative meeting is available at http://dc.granicus.com/MediaPlayer.php?view\_id=2&clip\_id=5903.
- 39. At that meeting, Council Member Vincent Gray stated, "from an abundance of caution, we selected age eleven because that is on the late-end of when children should receive the first Gardasil vaccination to prevent HPV and cervical cancer. Additionally, the first of two meningitis vaccinations are recommended at age eleven, with the goal of receiving a second booster before college, when the risk of meningitis is highest."
- 40. On November 17, 2020, Council Member Gray stated, "this amendment, which I'm moving now, requires the provider to notify the insurer that the immunization has been provided under the authority of the Minority Consent for Vaccinations Amendment Act of 2020, so the insurer will know that they should not send an explanation of benefits for the vaccination to the minor's house.... Without this amendment, the insurer would not be on notice that they needed to refrain from sending the explanation of benefits."
  - 41. The Council adopted the Amendment.
- 42. On information and belief, the purpose of the Minor Consent Act is to subvert parents' rights to religious exemptions pursuant to D.C. CODE § 38-506(1), thus driving a wedge between parents, children and their schools because of secret "black book" vaccination information intentionally withheld from parents.
- 43. On November 17, 2020, after adopting the amendment, the Council adopted the Minor Consent Act by a vote of 10 in favor, 3 opposed. The Council transmitted the Minor Consent Act to Mayor Bowser.

- 44. On December 23, 2020, the Council enacted the Minor Consent Act without the Mayor's signature, and transmitted it to the Speaker of the U.S. House of Representatives and the President of the U.S. Senate for a period of Congressional review as required by the District of Columbia Home Rule Act, D.C. Code § 1-206.02(c)
- 45. On March 19, 2021, after Congressional review, the Minor Consent Act became law.
  - D. The District of Columbia Adopts District-Wide Vaccine Requirements for the 2021-2022 School Year
- 46. On April 8, 2021, Mayor Bowser announced that starting August 30, 2021, all District schools would fully reopen for in-person learning, five days a week, for every student.
- 47. On May 10, 2021, the U.S. Food and Drug Administration (FDA) expanded the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to include children aged 12 through 15.
- 48. On May 12, 2021, the Center for Disease Control and Prevention (CDC) recommended Pfizer-BioNTech COVID-19 vaccines to children aged 12 and 15.
- 49. On May 12, 2021, at a Telephone Townhall, Assistant Superintendent of Health and Wellness Dr. Heidi Schumacher stated, "The COVID-19 vaccine is not the only vaccine that is critical for our young people. As a reminder, there are lots of routine pediatric vaccinations that are critical to protecting the health and wellbeing of our young people, and our broader community. Immunizations are indeed required for in-person attendance—these are the routine pediatric immunizations—and ensuring your child receives all age-appropriate vaccinations is one of the most important things that we can do as a community to protect our children and to protect one another. Students without documentation of the full complement of required vaccines will not be admitted to school, and we encourage families to take action now."

- 50. Chancellor Ferebee closed the Telephone Townhall by stating, "If you want to see our students back in school, if you believe this is important, one of the most important things that we can do together, collectively as a community, is to get as many people vaccinated as possible. And as you heard tonight, we have a tremendous opportunity in the coming days and weeks to have our twelve to fifteen-year-olds vaccinated."
- 51. On May 14, 2021, Chancellor Ferebee sent an e-mail to parents, stating that "While the COVID-19 vaccine is currently not required for students to attend school next year, we encourage all students age 12 and older and their parents and caregivers to get vaccinated. If you want to see students back in school, then it is our responsibility as a community for everyone to receive the COVID-19 vaccine when it's available to them. We are collaborating with local health officials to host vaccination clinics at our schools. More details are forthcoming" (emphasis in original).
- 52. In May 2021, the District's Office of the State Superintendent of Education released an updated Immunization Attendance Policy for schools for the 2021-2022 school year.
- 53. The Immunization Attendance Policy encourages schools to establish a School Health Team before the school year to review immunization certificate compliance periodically throughout the school year, to "identify students that are non-compliant, and to disseminate information to school families about "the critical public health need for immunizations, the consequences for immunization non-compliance (e.g., removed from school after 20-school day period), pediatric immunization schedule requirements by age, appropriate immunization forms (e.g., Universal Health Certificate), and information on where pediatric immunizations are administered in the District."

- 54. While Immunization Attendance Policy advises schools that "DC law permits medical or religious exemption from immunization if the parent, guardian, or adult student submits written documentation to the school explaining the exemption," it goes on to state that "[r]eligious exemptions are generally rare in the District and parents, guardians, or adult students must go through D.C. Health to sign the certificate to confirm they understand the health risks of not obtaining the necessary immunizations."
- 55. Three paragraphs later, the Immunization Attendance Policy also advises schools of the Minor Consent Act, stating that the Act "allows minors, 11 years of age or older, to receive a vaccine without parental consent if the minor is capable of meeting the informed consent standard, the vaccine is recommended by the U.S. Advisory Committee on Immunization Practices (ACIP), and will be provided in accordance with ACIP's recommended immunization schedule."
- 56. The Immunization Attendance Policy goes on to state, "If a minor student is utilizing a religious exemption or HPV opt-out and the student receives a vaccine under this law, the healthcare provider shall submit the immunization record directly to the minor student's school," and "the school shall keep the immunization record received from the healthcare provider confidential, except that the school may share the record with D.C. Health or the school-based health center (if applicable)," citing D.C. Code § 38-602(a)(2).
- 57. Appendix F of the Immunization Attendance Policy includes a list of "Frequently Asked Questions." One of these asks, "Is the COVID-19 Vaccine required for students to attend school in the District of Columbia?" Neither D.C. Health nor the CDC opines at this time on whether the vaccine will or should be required for students." Appendix F does not include any FAQs about the Minor Consent Act.

- 58. On or around June 1, 2021, Chancellor Ferebee stated, "the science is clear: Vaccines are the single most effective tool we have to stop the spread of the coronavirus. To help meet our commitment to fully reopen schools for every student, every day in the fall, it is our responsibility as a community to get vaccinated, including our middle school and high school students."
- 59. By August 2021, DC Health had published a list of twenty vaccine clinics that operated within the schools, including a clinic operated in Hardy Middle School.
  - 60. On August 5, 2021, DC Health opened a vaccine clinic at Kipp Academy.
- 61. On August 10, 2021, Mayor Bowser signed Mayor's Order 2021-099, which requires all employees and interns of the District's administrative agencies to attest that they are fully vaccinated against COVID-19, or that they have a religious or medical exemption.
- 62. In August 2021, DCPS announced that parents could enroll their students in a voluntary testing program to screen for COVID-19, where students would be required to hold a small vial with a funnel attached and produce a saliva sample for testing.
- 63. On August 27, 2021, DCPS changed the voluntary testing program, announcing that students would be automatically enrolled in the program as opposed to opting in. Parents could opt their children out of the program by submitting a signed form, however.
- 64. On September 20, 2021, Mayor Bowser signed Mayor's Order 2021-109, which mandated that all adults who are regularly in schools and childcare facilities in the District must receive the COVID-19 vaccine by November 1, 2021.
- 65. Mayor Bowser's order further mandated that all students who will be 12 years of age or older between September 16, 2021 and November 1, 2021 must be fully vaccinated

against COVID-19 by December 13, 2021, or they will not be allowed to train, compete, or otherwise participate in extracurricular athletics.

- 66. Mayor Bowser's order modified an earlier order, Mayor's Order 2021-099, by eliminating the testing-in-lieu-of-vaccination option for these students unless they had been granted a medical or religious exemption.
- 67. On October 4, 2021, six members of the DC Council introduced the Coronavirus Immunization of School Students and Early Childhood Workers Amendment Act of 2021 (DC B24-0423), which would amend the Immunization of School Students Act of 1979 to require the parents of any student who attends a District public, public charter, independent, private, or parochial school, and who is eligible to receive the COVID-19 vaccine, to submit proof that the student has received a full course of vaccination against COVID-19 or that the child has not received the vaccination because of a religious or medical exemption.
- 68. The bill would require all students eligible for the COVID-19 vaccine to be fully vaccinated by December 15, 2021.
- 69. On October 29, 2021, Mayor Bowser and DC Health announced plans to vaccinate children 5 to 11 years old as soon as the CDC recommended the Pfizer-BioNTech COVID-19 vaccine to that age group.
- 70. On November 2, 2021, the CDC adopted the Advisory Committee on Immunization Practices (ACIP) recommendation to administer Pfizer-BioNTech COVID-19 vaccines to children aged of 5 and 11 on an emergency use authorization basis.
- 71. The Pfizer-BioNTech COVID-19 vaccines that are being widely administered in the District are not FDA approved. Pfizer-BioNTech COVID-19 vaccines are authorized under

Emergency Use Authorizations (EUA), meaning that they only "may" be effective, not that they are effective.

- E. Defendants are exerting tremendous pressure on plaintiffs' children through a mass media marketing campaign pushing the COVID-19 vaccine
- 72. Defendants have created a pressure-cooker environment, enticing and psychologically manipulating L.B., K.G., N.W., M.R., H.B., to defy their parents and take vaccinations against their parents' wills.
- 73. L.B., K.G., N.W., M.R., and H.B., have been in school for over 2 months this school year. During this time, the District has subjected L.B., K.G., N.W., M.R., and H.B., to enormous pressure to get vaccinated.
- 74. The defendants actively and unlawfully represent experimental and unlicensed vaccines as "safe and effective," intentionally concealing the real risks of these non-FDA approved vaccines.
- 75. L.B., K.G., N.W., M.R., and H.B., have access to the internet and see Defendants' media campaign.
- 76. The DC area is inundated with an intense marketing campaign to convince DC residents, including Plaintiffs' minor children, to receive vaccinations with slogans such as "Take the Shot, D.C."
- 77. D.C. Health and Mayor Bowser publish and coordinate a large portion of the intense marketing campaign to pressure D.C. residents, including Plaintiffs' minor children, to receive vaccinations and specifically to take the COVID-19 vaccine.
- 78. The D.C. vaccine marketing campaign includes billboards, posters, fliers, printed ads, online ads, websites with links, emails, Twitter and other forms of mass media.

- 79. Defendants have set up walk-in clinics for COVID-19 vaccines throughout the D.C. area.
- 80. Defendants' websites contain easy-to-follow instructions on how to locate vaccine walk-in clinics, including walk-in clinics at District schools.
- 81. Any child, including L.B., K.G., N.W., H.B., can search the internet and very easily find walk-in vaccine clinics throughout D.C. and specifically in D.C. schools.
- 1. Mayor Browser's undue pressure on children to receive vaccinations includes "incentives," such as gift cards, free ear buds and chances to win I-pads, \$25,000 scholarships and other prizes. Incentives for adults to have their children vaccinated include larger prizes such as chances to win \$10,000 of free groceries and new cars.
- 82. L.B., K.G., N.W., H.B., are well aware that they may receive Mayor Browser's "incentives" if they get vaccinated.
- 83. On an almost daily basis through use of Twitter, Mayor Bowser encourages the children of D.C. to get vaccinated.
- 84. Mayor Bowser's webpage, available at <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a>, contains regularly updated information for "Walk Up Vaccination sites." The website contains references to "Government of District of Columbia, Muriel Bowser Mayor", "Get Vaccinated", "Take the Shot D.C." and "Walk Up Vaccination Sites." The website is regularly updated with dates, times and places of walk-up vaccination sites, including in schools. The website refers to "Walk-up locations for any one 12 and older." The advertised locations are frequently updated with sites that include such places as public libraries and children's schools. A printout of the website, taken from <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a> November 13, 2021, is attached hereto as <a href="mailto:Exhibit 2">Exhibit 2</a>.

- 85. Defendants' websites advertise \$51 gift cards as well as other prizes and giveaways. The websites contain catchy slogans, such as "Don't Wait. Vaccinate!" Government-sponsored twitter sites "#TAKETHE SHOTDC "and "#DCHOPE" are advertised. Free transportation is advertised. The vaccines advertised include "Pfizer age 12+" and "Children 5 to 11 years old are now eligible to get vaccinated."
  - F. Defendants are exerting tremendous pressure upon Plaintiffs' children by operating walk-in vaccine clinics for children, including walk-in clinics in schools
- 86. Another website operated by Defendants, available at <a href="https://coronavirus.dc.gov/vaccine">https://coronavirus.dc.gov/vaccine</a>, advertises permanent and temporary vaccine walk-in clinics throughout the D.C. area. The list of vaccine walk-in clinics includes schools. Mayor Bowser runs the website, a printout of the website, taken on November 13, 2021, is attached hereto as <a href="https://coronavirus.dc.gov/node">Exhibit 3</a> and is available at <a href="https://coronavirus.dc.gov/node">https://coronavirus.dc.gov/node</a>.
- 87. Kipp public schools also maintain a website entitled Kipp DC PUBLIC SCHOOLS Quick Resources for Families, available at <a href="https://www.kippdc.org/vaccine-clinic/">https://www.kippdc.org/vaccine-clinic/</a>, a printout of which is attached hereto as Exhibit 4. It provides easy access to vaccine clinics.
- 88. Under the tab "Clinics for age 12+," Kipp's vaccine clinic website states "You can get your vaccine by going to one of <u>DC's free walk-up clinics</u> or make an appointment at <u>free vaccine location</u> near you. We ask Kipp families share proof of full vaccination (2 shots) with our COVID Response Team by either uploading the card via the email they've received or by emailing covid@kippdc.org."
- 89. "DC's free walk-up clinics" is a hyperlink to <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a>.

- 90. "<u>Free vaccine location</u>" is a hyperlink to <a href="https://www.vaccines.gov/search/">https://www.vaccines.gov/search/</a>. A printout of that website, taken on November 13, 2021, is attached hereto as **Exhibit 5**.
  - 91. In August 2021, DC Health opened vaccine clinics at Kipp school campuses.
- 92. The Kipp school maintains a website that anyone can access and reserve a time slot for a student to receive vaccinations.
- 93. While encouraging and providing information for vaccines, the website for Rose Hardy Middle School contains a link to <a href="https://dcpsreopenstrong.com/vaccines/">https://dcpsreopenstrong.com/vaccines/</a>. A printout of the website is attached hereto as **Exhibit 6**.
  - 94. Defendants operate the website <a href="https://dchealth.dc.gov/page/immunizations">https://dchealth.dc.gov/page/immunizations</a>.
- 95. Upon information and belief, Defendants operate other websites. Defendants' websites, Twitter accounts and other forms of media are updated on an almost daily basis to encourage children to be vaccinated and to aid in obtaining the administration of vaccinations.
  - G. Defendants are exerting tremendous pressure upon Plaintiffs' children by imposing additional requirements on unvaccinated children in schools and barring children from participating in sports
- 96. Defendants have implemented a "robust, 10-layered mitigation health and safety framework" which includes subcategories of "FACE MASKS REQUIRED, REGULAR COVID TESTING, DAILY COVID CHECK, TEMPERATURE SCREENING, QUARANTINE PROTOCOLS, HVAC & AIR PURIFICATION IMPROVEMENTS, ENHANCED CLEANING, SOCIAL DISTANCING AS MUCH AS POSSIBLE, ADDITIONAL NURSING & OTHER STAFF, COVID VACCINES." The health and safety framework is published on the website <a href="https://www.kippdc.org/healthy-operations/">https://www.kippdc.org/healthy-operations/</a>, a printout of which is attached hereto as Exhibit 7.

- 97. On information and belief, the 10-layered mitigation health and safety framework fosters an environment of fear and compliance.
- 98. A new program in the D.C. schools will transition from saliva tests "to a shallow nasal swab test for students." The stated goal of nasal swab testing is "testing 100% of students every week."
- 99. The public schools are subject to a mask mandate: "All adults and students, regardless of vaccination status, will be required to wear masks while in our school buildings and on school grounds. Masks may be removed during lunch periods and nap times."
- 100. The type of cloth and surgical masks required to be worn by L.B., K.G., N.W., M.R., H.B., are not FDA-approved to prevent viral transmission.
- 101. The prolonged use of the type of masks that L.B., K.G., N.W., M.R., H.B., and other students are required to wear has psychological impacts upon the children.
- 102. According to Defendants' contact tracing policy, if an unvaccinated person comes within six feet of a person who tests positive for COVID-19, then the unvaccinated person must isolate at home for 10 days.
- 103. However, if a vaccinated person comes within six feet of a person who tests positive for COVID-19, the vaccinated person does not have to isolate at home for 10 days.
- 104. Due to vaccination status, L.B., K.G., N.W., M.R., H.B., are subjected to additional pressure in the form of threatened isolation due to contact tracing.
- 105. Plaintiffs' schools conduct random COVID-19 tests. Because of their vaccination status, there is a high probability that L.B., K.G., N.W., M.R., H.B., will be excluded from school for multiple ten-day periods in the future. L.B., K.G., N.W., H.B., are well aware that if

they receive vaccinations, they will not be excluded from school for ten-day periods each time they come in contact with someone who later tests positive for the Covid-19 virus.

- 106. Defendants have announced that children who have not been fully vaccinated by December 1, 2021 may not play sports.
  - 107. L.B., K.G., N.W., M.R., H.B. want to play sports.
- 108. Being denied the opportunity to play sports because they are not fully vaccinated is another form of pressure on L.B., K.G., N.W., H.B., to defy their parents and receive vaccinations.
- 109. School is a controlled environment. The pressure in the controlled environment to receive vaccinations is increased by Defendants' intense media campaign, official pressure, officially fostered peer pressure, monetary incentives, masks, saliva testing, nasal swabs and contact tracing with a ten-day isolation penalty for the unvaccinated.
- 110. The D.C. Minor Consent Act and the readily available vaccine clinics provide an extremely tempting release from the pressure on L.B., K.G., N.W., and H.B. to receive vaccinations against their parents' sincere religious beliefs.
- 111. The COVID-19 vaccine pushed on the children of the District of Columbia is not FDA-approved. It is Emergency Use Authorization only. COVID-19 vaccines are by definition experimental medical products.
- 112. Following World War II, the war crimes tribunal at Nuremberg laid down 10 principles regarding experiments on human subjects in a code now accepted worldwide. The Nuremberg Code is attached hereto and incorporated by reference as **Exhibit 8**.
  - 113. The first principle of the Nuremberg code states:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so

situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

- 114. The conditions under which Plaintiffs' children are being pressured and coerced into taking non-FDA approved, experimental COVID-19 vaccines directly violates the Nuremberg Code: The children cannot exercise free power of choice; they do not have appropriate legal capacity to consent; they are subject to duress, overreaching, and other ulterior forms of constraint and coercion; and they do not have sufficient knowledge and comprehension to make enlightened decisions. In short, the Minor Consent Act puts children in harm's way and violates the core principle of medical ethics.
- 115. On or about November 2021, the Office of the State Superintendent of Education, a D.C. government office under the control of Mayor Muriel Bowser, issued a document entitled "School Year 2021-22, Student Athletes: COVID-19 Vaccination Religious Exemption Certificate," a copy of which is attached hereto as **Exhibit 9**. The new religious exemption form contains additional requirements for student athletes. The form requires the parent to "provide a personal written statement on why you are seeking a religious exemption for the above named student, the religious principles that guide your objection to immunization, and whether you are opposed to all immunizations, and if not, the religious basis on which you object to the COVID-19 immunization. You may attach additional documentation, if necessary, and you may provide the name and contact information for a religious/spiritual leader who can corroborate your beliefs."
- 116. The new Vaccination Religious Exemption Certificate further states, "this religious exemption request shall be reviewed by the school leader or designee. After review, if

the school leader or designee is unable to make a determination because of inadequate information about the nature of the sincerely held religious belief, they may request additional information from the requestor before approval or denial." The next section of the form states: "School leader or designee shall select from the following. This religious exemption request is (select one). \_\_\_\_\_\_ Approved on the ground of sincerely held religious belief and no undue burden to accommodate the exemption. \_\_\_\_\_ Denied (select all that apply): \_\_\_\_\_ No sincerely held religious belief \_\_\_\_\_ Undue burden to accommodate the exemption"

- 117. The Vaccine Exemption Certificate, which is really a vaccine exemption request form, contains additional conditions that must be initialed by the parent. The first states, "I request that the above-named student be exempt from the COVID-19 vaccine based on my sincerely held religious beliefs. I understand that if an outbreak of COVID-19 should occur, an exempt student may be excluded from school and school activities by the school administrative head for a period of time as determined by the DC Department of Health based on a case-by-case analysis of public health risk."
- 118. The third box the parent is required to initial states, "I understand that student athletes with an approved religious exemption must: (1) wear a mask in athletic events (even if the current indoor masking order is rescinded or superseded); (2) be tested weekly for COVID-19: and (3) provide the school a negative COVID-19 test result on a weekly basis in order to report to their school based extracurricular activity." All of these requirements add to the pressure on Plaintiffs' children to defy their parents religious exemptions.

# H. Plaintiff Victor M. Booth and L.B.

- 119. Plaintiff Victor M. Booth resides with his minor child, L.B., in the District of Columbia.
- 120. L.B. is thirteen years old and is enrolled in Kipp Academy, a public charter school located in D.C.
- 121. L.B. is a good student who enjoys school. He wants to attend school to be with his friends.
- 122. L.B. is also a medically fragile child. He suffers from autoimmunity, and as a result, L.B. suffers from alopecia (severe hair loss), asthma and eczema.
- 123. At times, L.B. exhibits behavioral manifestations that are believed to be caused by sensory over-sensitivity.
- 124. At a very young age, L.B. was completely bald. Not only was his head bald, but his eyebrows and eyelashes fell out.
- 125. Based on the timeline, L.B.'s hair loss and eczema appear to be causally related to childhood immunizations.
- 126. Victor personally observed L.B.'s severe hair loss and development of eczema following vaccinations.
- 127. L.B.'s hair loss and eczema accelerated with subsequent rounds of childhood immunizations during his first few years of life.
- 128. After L.B. received childhood booster shots, L.B.'s eyebrows and eyelashes fell out.
- 129. L.B.'s pediatrician advised Victor that L.B.'s autoimmunity causes his eczema and alopecia.

- 130. There is a large body of reliable, credible, scientific and medical literature, which supports the conclusion that vaccines cause or substantially contribute to autoimmunity.
- 131. Autoimmunity is the body's immune system attacking itself. Autoimmunity is the body's immune system identifying self as non-self.
- 132. A primary purpose of a vaccine is to provoke a response from the body's immune system so that the body's immune system forms a memory of the foreign virus or bacteria so that the body's immune system can later attack the foreign substance.
- 133. The theory that vaccines cause or substantially contribute to autoimmune conditions of the type suffered by L.B. is credible.
- 134. Victor made an informed and reasonable decision based on his religious convictions for his child L.B. to receive no further vaccinations.
- 135. Victor's decision to not allow L.B. to be administered further vaccinations was made before the enactment of the Minor Consent Act.
- 136. After L.B. stopped receiving vaccinations, his medical conditions improved, and his hair slowly began to grow back.
  - 137. L.B. is still a medically fragile child, with severe hair loss, eczema and asthma.
- 138. L.B. is the only child in his class allowed to wear a baseball cap in class to conceal severe baldness.
  - 139. As a result of his severe hair loss, L.B. is particularly susceptible to peer pressure.
- 140. L.B. very much wants to be a typical kid, who goes to school and socializes with friends and peers.
  - 141. L.B. likes to play sports, and in particular, soccer and baseball.

- 142. Although L.B. received childhood vaccines when he was a baby, in the intervening years, Victor concluded that the vaccines caused his son's autoimmunity.
- 143. Victor has formed sincere religious objections to vaccinations. He is of the sincere religious belief that he should not inject a foreign substance into his son's body that may harm him.
- 144. Victor objects to L.B. receiving both the COVID-19 vaccine and childhood vaccines and will not provide parental consent to administer those vaccines to L.B.
  - 145. Victor adamantly opposes the injection of any more vaccines for his child.
  - 146. L.B. has access to the internet.
- 147. L.B. is well aware that he may receive Mayor Browser's "incentives" if he receives the vaccinations.
- 148. Prior to the start of the 2021-2022 school year, Victor received e-mails from Kipp Academy urging parents to attend Family Workshops on COVID safety via zoom.
- 149. Prior to the start of the 2021-2022 school year, Victor received information from Kipp Academy about two clinics where children could be vaccinated. In August 2021, DC Health also opened a vaccine clinic at Kipp Academy.
- 150. Since school began in September, Victor has received multiple emails from Kipp expressing students should "Get Vaccinated," "Take the Shot" and similar statements. The emails contain hyperlinks to D.C. Government websites designed to encourage and assist students to receive vaccinations.
- 151. L.B. can search the internet and easily find walk-in vaccine clinics throughout D.C. and in D.C. schools, including Kipp.

- 152. On September 1, 2021, Victor received an e-mail from Kipp informing him that as of September 7th, "all KIPP DC students will be <u>automatically enrolled</u> in Kipp's free asymptomatic weekly saliva COVID testing program" (emphasis in original).
- 153. The e-mail from Kipp said that parents could opt children out of the program by completing an online form.
- 154. On September 7, 2021, Victor received a second e-mail from Kipp about the school's universal COVID testing policy, which had the aim of "testing 100% of students, every week" with "non-invasive saliva-based tests." This second e-mail again told parents that they could opt children out of the program by completing an online form.
  - 155. Victor completed the online form to opt L.B. out of Kipp's testing program.
- 156. On September 9, 2021, during third period, L.B.'s class was visited by three women from a testing contractor.
- 157. The testers ordered all the students in the class to remove their things from their desks so they could collect saliva samples.
- 158. L.B. told the testers that his parents had not given him permission to take part in the test.
- 159. Upon hearing this, the testers ordered L.B. to sit out in the hall while they collected samples from the other students.
  - 160. L.B. had to leave the room, in full view of his friends and classmates.
- 161. L.B. was not allowed to reenter the room and was forced to remain in the hallway for the remainder of the class period.
- 162. Because he was confined to the hallway, L.B. did not receive any lectures or assignments.

- 163. L.B. told Victor about these events when he returned home from school. Victor never received a note or other notification from Kipp about these events.
- 164. On September 28, 2021, following Mayor Bowser's announcement that all student athletes age 12 and over must be vaccinated by November 1 to play school sports, Victor received an e-mail from Kipp informing him that to be eligible to try out for winter or spring sports (including basketball, cheerleading, indoor track, track & field, lacrosse, baseball, and softball), L.B. would have to receive the first dose of the Pfizer vaccine by October 11, 2021, and the second dose by November 1, 2021. (The deadline was subsequently extended to December 1, 2021.)
- 165. The e-mail also told Victor, "If you do not want your child to receive the COVID vaccine, they will not be permitted to participate in athletics this school year."
- 166. On September 28, 2021, Victor received an email that contained a video produced by Kipp entitled, "Kipp Conversations Childhood Covid Vaccine." The video featured Dr. Melisa Clarke. The video presented a very one-sided view of the COVID-19 vaccine. The video strongly encouraged the vaccine. It portrayed the COVID-19 vaccine as the ticket to safety and normalcy.
- 167. The Kipp Conversations Childhood Covid Vaccine video featuring Dr. Melisa Clarke states, "What you can do safely after vaccination.", "Hug others who are vaccinated.", "Have social gatherings with others who are vaccinated.", "Go out in Public." Another section, "Addressing Safety Concerns" states, "Vaccination is the way out of the pandemic."
- 168. In the Kipp Conversations Childhood Covid Vaccine video, Dr. Clarke states, "In the history of vaccines, all side effects have occurred within the first two months." This is a highly misleading statement. In reality, vaccine side effects, such as severe and permanent brain

damage, can last a lifetime. Neither Dr. Clarke or any of the Defendants in their statements or publications acknowledge that vaccines can cause death or serious injury, including brain damage.

- 169. On October 5, 2021, Victor received an email which states in part, "Parent/ Guardian of [L.B.], We are following up on Mayor Bowser's announcement last week that all student athletes age 12 and over must be vaccinated by November 1 to play sports in Washington D.C."
- 170. On or about October 24, 2021 Victor received an email with a hyperlink to a D.C. government website, <a href="https://coronavirus.dc.gov/vaccine">https://coronavirus.dc.gov/vaccine</a>, which advertised a vaccine walk in clinic at Kipp on November 2, 2021. The website is run by the Government of the District of Columbia, Muriel Bowser, Mayor. The Defendants' website stated, "Weekly Walk-up Locations for Anyone 12 and Older."
- 171. On October 28, 2021, Victor received an email announcing an "Important Update on Student COVID Testing." The email outlined the "robust, 10-layered mitigation health and safety framework." The email contained a hyper link to **Exhibit 7**,

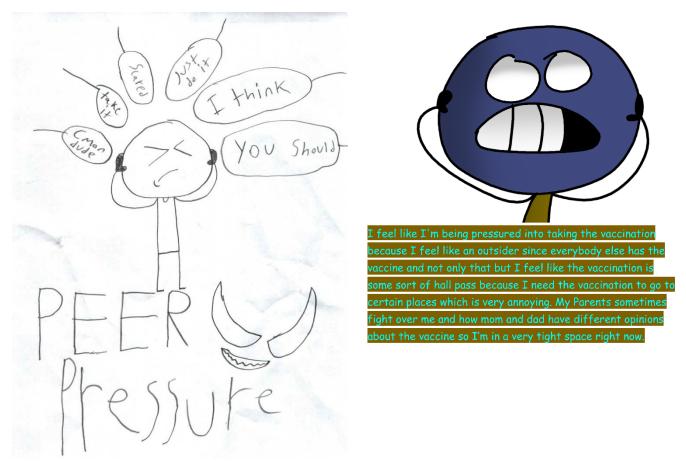
<u>https://www.kippdc.org/healthy-operations/</u>, which partially outlines the school environment.

- 172. On information and belief, the "10-layered mitigation health and safety framework" fosters an environment of fear and compliance.
- 173. The October 28, 2021 email message outlines a new program in which the school will transition from saliva tests "to a shallow nasal swab test for students." The stated goal of nasal swab testing is "testing 100% of students every week."
- 174. The environment of fear created by the Defendants, and in particular the mask mandates, have made L.B. more compliant with the demands of school officials.

- 175. The prolonged use of the type of masks that L.B. and other students are required to wear has psychological impacts on the child. Due to his vaccination status, L.B. is subjected to additional pressure in the form of contact tracing -- pressure that may be relieved by getting the vaccine.
- 176. Victor has been notified that the school will conduct COVID tests every Thursday. There is an extremely high probability, because of his vaccination status, L.B. will be excluded from school for multiple ten-day periods in the future. L.B. is well aware that if he receives the vaccinations, he will not be excluded from school for ten-day periods each time he comes in contact with the someone who later tests positive for COVID-19.
  - 177. The mask mandate has made L.B. more openly defiant of his father.
- 178. Victor has advised L.B. to not put his mask on until he reaches the school building and to take the mask off as soon as he leaves the building.
- 179. Most importantly, Victor has told L.B. to pull his mask down as needed if he has trouble breathing.
  - 180. L.B. has breathing issues due to asthma.
  - 181. L.B. is prescribed a nebulizer for acute asthma.
  - 182. The mask restricts the free flow of oxygen and traps in carbon dioxide.
- 183. Common sense dictates that L.B. should pull down or remove the mask if he has difficulty breathing.
- 184. However, L.B. has been so indoctrinated by Defendants' policies that he will not remove the mask restricting his breathing because he is afraid of school officials.
- 185. In response to Victor's instructions to pull the mask down if he cannot breathe,L.B.'s response is "Dad, I can't pull the mask down. I'll get in trouble."

- 186. At times, L.B. is reluctant to take the mask off outdoors. L.B. increasingly defies Victor's instructions to remove the mask after he leaves the school building. On at least one occasion, Victor had to physically remove the mask from L.B.'s face after leaving school because L.B. defied his father and refused to take the mask off.
- 187. L.B.'s common sense and independent judgment is being crushed by the coercive environment created by Defendants.
  - 188. Contact tracing is another form of pressure being applied to L.B.
- 189. On October 21, 2021, Victor was notified by the school that L.B. must quarantine at home and may not return to school for ten days because he came in contact with a person who tested positive for COVID-19. Upon further investigation, Victor learned that the person L.B. came into contact with was his teacher. Presumably, according to Defendants' regulations, the teacher had been vaccinated.
  - 190. If L.B. had been vaccinated, he would not have had to quarantine for ten days.
- 191. Upon learning that he must stay home from school for 10 days because he was not vaccinated, L.B. became very upset. He cried and was angry that he could not go to school and take his math test. L.B. does not want to participate in remote learning. He wants to go to school. He wants to see his friends. However, because he has not been vaccinated, he cannot go to school. He must isolate himself from his friends.
- 192. Defendants have announced that children who have not been fully vaccinated by December 1, 2021 may not play sports. L.B. wants to play baseball. Denying L.B. the opportunity to play sports and in particular baseball because he is not fully vaccinated is another form of pressure on L.B. to defy his father and receive vaccinations.

- 193. L.B. has become increasingly angry, agitated and upset as a result of the pressure to be vaccinated created by Defendants.
- 194. Victor asked L.B. to draw and explain his feelings. Attached as **Exhibit 10** and **Exhibit 11** are two drawings and illustrations by L.B. that reflect his thoughts and emotions.



195. **Exhibit 10** states, "I feel like I'm being pressured into taking the vaccination because I feel like an outsider since everybody else has the vaccine and not only that but I feel like the vaccination is some sort of hall pass because I need the vaccination to go to certain places which is very annoying. My parents sometimes fight over me and how mom and dad have different opinions about the vaccine so I'm in a very tight space right now."

- 196. The second drawing, **Exhibit 11**, is captioned, "PEER *Pressure*." It also illustrates a child under tremendous pressure, hearing the words, "C'mon dude" "take it" "Sacred" "just do it" "I think" "you should."
- 197. **Exhibits 10** and **11** reflect the thoughts and emotions of a young teenager who is obviously under tremendous pressure to consent to vaccinations.
- 198. L.B. knows that Victor objects to his being vaccinated, but has told Victor words to the effect that based on the rising pressure he has faced from classmates at Kipp, "if I were offered a vaccine, I would take it."
- 199. School is a controlled environment. The pressure in the controlled environment is increased by Defendants' intense media campaign, official pressure, officially fostered peer pressure, monetary coercion to receive the vaccine, saliva testing, nasal swabs and contact tracing with a ten-day isolation penalty for the unvaccinated.
- 200. Defendants actively market vaccines as "safe and effective," and fail to mention the risks of vaccination. Moreover, the vaccines are portrayed as the only means to escape the dangers of COVID-19. Defendants' message is "Vaccination is the way out of the pandemic." This message is contained in the video Kipp Conversations: Childhood COVID Vaccine.
- 201. The pressure cooker environment for L.B. to defy his father has reached a boiling point.
- 202. At the same time as Defendants are directly and indirectly pressuring and coercing L.B. to receive additional vaccinations against his father's sincere religious convictions, Defendants are offering an immediate release from the pressure by making the vaccines readily available to L.B. at his school and multiple other locations throughout the D.C. area.

- 203. On October 24, 2021, Victor received an email from Kipp with a link to the website <a href="https://www.kippdc.org/vaccine-clinic/">https://www.kippdc.org/vaccine-clinic/</a>. On this website anyone can access and register a Kipp student for a walk-in clinic and reserve a "preferred time slot" on November 2, 2021. The website was subsequently updated to add children ages 5-11.
- 204. The D.C. Minor Consent Act and the readily available vaccine clinics provide an extremely tempting release from the pressure placed on L.B. to receive vaccinations against his father's sincere religious beliefs and parental rights.
- 205. As a result of receiving treatment for medical conditions, L.B. has an expansive understanding of both his personal and family medical history.
- 206. On information and belief, if L.B. were to request a vaccine under the Minor Consent Act, a medical provider likely would conclude that he is capable of providing informed consent.
- 207. The Minor Consent Act directly contravenes Victor's right to free exercise of religion and parental rights.

# I. Plaintiff Shameka Williams

- 208. Plaintiff Shameka Williams resides with her minor children, K.G. and R.T., in the District of Columbia.
- 209. K.G. is 13 years old, and is enrolled in Rose L. Hardy Middle School, a public school in the District.
- 210. R.T. is 4 years old, and will be of compulsory attendance age at the start of the 2022-2023 school year. Shameka plans to enroll R.T. in a public school in the District when R.T. reached compulsory attendance age.

- 211. Although K.G. received childhood vaccines when she was a baby, in the intervening years Shameka has formed sincere religious objections to vaccinations.
- 212. Shameka objects to K.G. receiving both the COVID-19 vaccine and childhood vaccines and will not provide parental consent to administer those vaccines to K.G.
- 213. K.G. has been receiving in-person instruction at Rose Hardy since August 30, 2021.
- 214. Prior to the start of the 2021-2022 school year, Shameka and K.G. received several e-mails from Rose Hardy informing them that the COVID vaccine was available to children 12 years and older, and offering incentives (such as iPhones, Air Pods, and gift cards) to children who were vaccinated.
  - 215. In August 2021, DC Health began operating a vaccine clinic at Rose Hardy.
- 216. Information regarding school immunization "pop up clinics" are available on the Hardy Middle School website, <a href="https://www.hardyms.org">https://www.hardyms.org</a>. Hardy Middle School is currently offering vaccine walk in clinics every Saturday. A printout for a walk-in clinic is attached hereto as **Exhibit 12**. Hardy's website contains a link to Mayor Bowser's webpage, <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a> (**Exhibit 2**), which contains regularly updated information for "Walk Up Vaccination sites" and "incentives." The website states, "Childhood"
- 217. The Hardy website also includes a link to <a href="https://dcpsreopenstrong.com/vaccines/">https://dcpsreopenstrong.com/vaccines/</a>
  (Exhibit 6).
- 218. The Hardy website also includes a link to <a href="https://dchealth.dc.gov/page/immunizations">https://dchealth.dc.gov/page/immunizations</a>.

and Covid 19 vaccines available."

- 219. On September 13, 2021, Shameka received an e-mail from Rose Hardy inviting her and her family to get the COVID vaccine at Hardy's vaccine clinic.
- 220. On September 20, 2021, Shameka received a second e-mail from Rose Hardy inviting her and her family to get the COVID vaccine at Hardy's vaccine clinic.
- 221. Shamika has been contacted by the school and encouraged to have K.G. and R.T. receive further vaccinations.
- 222. K.G. has been exposed to the mass media marketing campaign to consent to vaccinations.
- 223. K.G. is well aware of the monetary incentives offered by Defendants to children who receive the vaccinations.
  - 224. K.G. has access to the internet.
- 225. K.G. can easily access the information provided by the defendants as to the time, date and place of vaccine walk in clinics.
  - 226. Walk in vaccine clinics are periodically available at K.G.'s school.
  - 227. K.G. is currently subject to random periodic saliva-based tests.
  - 228. K.G. is subject to peer pressure to consent to the administration of vaccines.
- 229. K.G. wants to play sports and is subject to the pressure of receiving vaccines to play sports.
  - 230. K.G. is subject to the pressure of mask mandates.
- 231. K.G. is subject to contact tracing, including the heighted penalty of a mandatory ten-day quarantine, if she comes within six feet of someone who tests positive for Covid-19. Vaccinated students are not subject to the same automatic ten-day quarantine penalty.

- 232. K.G. can escape the automatic ten-day quarantine period if she consents to vaccinations.
  - 233. K.G. has an understanding of both her personal and family medical history.
- 234. On information and belief, if K.G. were to request a vaccine under the Minor Consent Act, a medical provider would conclude that she was capable of providing informed consent.
- 235. The D. C. Minor Consent Act directly interferes with Shameka's fundamental Constitutional right to raise her child K.G.

# J. Plaintiff Shanita Williams

- 236. Plaintiff Shanita Williams resides with her minor children, N.W. and M.R., in the District of Columbia.
- 237. N.W. is 15 years old, and is enrolled in Kipp College Preparatory, a public charter school in the District.
- 238. M.R. is 10 years old, and is enrolled in Watkins Elementary School, a public charter school in the District.
- 239. Although N.W. received childhood vaccines when he was a baby, in the intervening years Shanita has formed sincere religious objections to vaccinations.
- 240. Shanita objects to N.W. receiving both the COVID-19 vaccine and childhood vaccines and will not provide parental consent to administer those vaccines to N.W.
  - 241. N.W. has been receiving in-person instruction at Kipp since August 30, 2021.
- 242. In August 2021, DC Health opened a vaccine clinic at Kipp, the details of which were reflected on the school website, <a href="https://www.kippdc.org/vaccine-clinic/">https://www.kippdc.org/vaccine-clinic/</a> (Exhibit 4).

- 243. On September 1, 2021, Shanita received an e-mail from Kipp informing her that as of September 7th, "all KIPP DC students will be <u>automatically enrolled</u> in KIPP DC's free asymptomatic weekly saliva COVID testing program" (emphasis in original).
- 244. The e-mail from Kipp said that parents could opt their children out of the program by completing an online form.
  - 245. Shanita completed the online form to opt N.W. out of Kipp's testing program.
- 246. On September 20, 2021, following Mayor Bowser's mandate that all student athletes age 12 and over must be vaccinated by November 1 to play school sports, Shanita received an e-mail from Kipp informing her that to be eligible to try out for winter or spring sports (including basketball, cheerleading, indoor track, track & field, lacrosse, baseball, and softball).
- 247. The e-mail also told Shanita, "If you do not want your child to receive the COVID vaccine, they will not be permitted to participate in athletics this school year."
- 248. On September 28, 2021, Shanita received a second e-mail from Kipp which reiterated that to be eligible to try out for winter or spring sports, N.W. would have to receive the first dose of the Pfizer vaccine by October 11, 2021, and the second dose by November 1, 2021.
- 249. On October 3, 2021, Shanita received a third e-mail from Kipp reiterating that students had to be vaccinated to participate in winter or spring sports, and encouraging students to be vaccinated at a vaccine clinic offered at the Smilow Campus on October 6, 2021.
- 250. The e-mail also stated that Kipp was "working diligently to host additional clinics at other Kipp campuses and look forward to sharing further updates in the coming weeks."
- 251. On November 9, 2021, N.W. was approached at school and asked to submit to a nasal swab COVID-19 test. This occurred despite the fact that his mother, Shanita had previously

submitted written instructions that she did not consent to N. W. being subjected to nasal swab COVID-19 tests at school.

- 252. N.W. wishes to play basketball in the spring of 2022.
- 253. N.W. has been exposed to the mass media marketing campaign to consent to vaccinations.
- 254. N.W. is well aware of the monetary incentives to children who receive the vaccinations.
- 255. The Kipp maintains a website that anyone can access and reserve a time slot to receive vaccinations. *See* Exhibit 4. Kipps's vaccine website\_contains hyperlinks to <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a> (Exhibit 2) and <a href="https://www.vaccines.gov/search/">https://www.vaccines.gov/search/</a> (Exhibit 5).
- 256. N.W. can easily access the information provided in the websites by Defendants as to the time, date and place of vaccine walk in clinics.
  - 257. Walk in vaccine clinics are periodically available at N.W.'s school.
  - 258. N.W. is subject to random periodic saliva based test.
  - 259. N.W. is subject to peer pressure to consent to the administration of vaccines.
  - 260. N.W. is subject to the pressure of receiving vaccines to play sports.
  - 261. N.W. is subject to the pressure of mask mandates.
- 262. N.W. is subject to contact tracing, including the heighted penalty of a mandatory ten-day quarantine if he comes within six feet of someone who tests positive for Covid-19. K.G. is well aware that vaccinated students are not subject to the same automatic ten-day quarantine penalty.

- 263. N.W. is well aware that he can escape the automatic ten-day quarantine period if she consents to vaccinations.
  - 264. N.W. has an understanding of both his personal and family medical history.
- 265. On information and belief, if N.W. were to request a vaccine under the Minor Consent Act, a medical provider likely would conclude that he was capable of providing informed consent.
- 266. The D. C. Minor Consent Act directly interferes with Shanita's fundamental Constitutional right to raise her child N.W.

## K. Plaintiff Jane Hellewell

- 267. Plaintiff Jane Hellewell resides with her minor child, H.B., in the District of Columbia.
- 268. H.B. is 15 years old, and is enrolled in School Without Walls High School, a public magnet high school in the District.
- 269. Because Jane objects to immunizations based on her sincerely held religious beliefs, H.B. has not received any childhood vaccinations.
- 270. Jane objects to H.B. receiving the COVID-19 vaccine and other childhood vaccines and will not provide parental consent to administer those vaccines to H.B.
- 271. H.B. has been receiving in-person instruction at School Without Walls since August 30, 2021.
- 272. Prior to the start of the 2021-2022 school year, Jane and H.B. received several emails from School Without Walls informing them that the COVID-19 vaccine was available to children 12 years and older, that to be fully vaccinated by the first day of school students would have to receive the first dose of the COVID-19 vaccine by July 26th, and that there were free

walk up sites where D.C. residents could receive the Pfizer vaccine, available to students 12 years of age and older.

- 273. Prior to the start of the 2021-2022 school year, Jane and H.B. received several emails from School Without Walls informing them that students who received the COVID-19 vaccine could win incentives such as iPhones, Air Pods, and gift cards.
- 274. On August 30, 2021, Jane attended a meeting for parents of students enrolled at School Without Walls. At the meeting, the chairman suggested sending out an anonymous survey to determine the percentage of students at School Without Walls who were unvaccinated and the reasons why the parents were not having their children vaccinated.
- 275. On September 10, 2021, Jane received an e-mail from the PTA informing parents that they were conducting a poll to determine the number of students who were not yet vaccinated, with the goal to "have as many students and family members as possible vaccinated."
- 276. On September 13, 2021, Jane received an e-mail from School Without Walls informing her that all students would be required to participate in the school's asymptomatic school-based COVID-19 testing program, unless they were opted-out by their parents.
  - 277. Jane completed the online form to opt H.B. out of this testing program.
- 278. On September 21, 2021, following Mayor Bowser's announcement that all student athletes age 12 and over must be vaccinated by November 1 to play school sports, Jane received an e-mail from DCPS stating that to be eligible to try out for winter or spring sports (including basketball, cheerleading, indoor track, track & field, lacrosse, baseball, softball and tennis), all students would have to be fully vaccinated by November 1, 2021.
- 279. On September 23, 2021, Jane received an e-mail from the youth sports league administered by DCPS Athletics, stating that all student athletes would have to be fully

vaccinated by November 1, 2021, and that unvaccinated students would be unable to participate in any team activities.

- staff of the School Without Walls wrote an open letter to Mayor Bowser and the D.C. Council stating, "On behalf of the School Without Walls Home and School Association (SWWHSA), I ask that you exercise powers within the executive and legislative to mandate vaccines for eligible students enrolled in DCS public schools. Like all school communities, we want our school District to provide the safest possible environment in which students learn and educators work. We recently polled our families to determine vaccination rates in our school and how the SWWHSA could help increase rates. Families of over 300 students responded. All but one fully vaccinated and the overwhelming ask was for SWWHSA to advocate for a vaccine mandate." The letter advocates for vaccine mandates and concludes, "We trust it goes without mention that leadership entails both of setting firm lines in the sand AND supporting students and families to get across the finish line toward vaccine compliance." A copy of the letter is attached hereto as Exhibit 13.
- 281. School Without Walls maintains and operates an official website, which contains electronic tabs, pages and hyperlinks to encourage and assist students in locating vaccine walk in clinics, including a link to <a href="https://www.vaccines.gov">https://www.vaccines.gov</a> which states, "Find a COVID-19 Vaccine near you. Use vaccines.gov to find a location near you, then call or visit their website to make an appointment."
  - 282. H.B. wishes to play tennis through School Without Walls in the spring of 2022.
  - 283. Tennis is an extremely important part of his life.
  - 284. Tennis is a key aspect of H.B.'s identity.

- 285. Tennis is critical to H.B.'s social interaction and development.
- 286. H.B. is adamant that he will play tennis this year.
- 287. H.B.'s older sister, who is seventeen years old, received the COVID-19 vaccine in direct opposition to Jane's parental judgment and rights.
- 288. The pressure on H.B. to receive vaccinations is increased by Defendants' intense media campaign, official pressure, officially fostered peer pressure, monetary coercion to receive the vaccine, masks, peers who undergo saliva testing, and contact tracing with a ten-day isolation penalty for the unvaccinated.
- 289. The use of Covid testing, contact tracing and exclusion of the unvaccinated from school has increased, escalating the pressure on H.B. to get vaccinated.
  - 290. H.B. has felt immense pressure to get the vaccine while at School Without Walls.
  - 291. H.B. understands both his personal and family medical history.
- 292. On information and belief, if H.B. were to request a vaccine under the Minor Consent Act, a medical provider likely would conclude that he is capable of providing informed consent.
- 293. The D.C. Minor Consent Act directly interferes with Jane's fundamental Constitutional right to raise her child H.B.

### L. The National Childhood Injury Act of 1986

- 294. Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), codified in 42 U.S.C. § 300aa *et seq*.
- 295. The Vaccine Act expresses Congress's clear intent to occupy the field of law regarding childhood vaccinations.

- 296. Congress enacted the Vaccine Act in response to a growing number of lawsuits alleging neurological and other vaccine injuries.
- 297. The Vaccine Act created the National Vaccine Injury Compensation Program, a no-fault program to stabilize the vaccine market that had been adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).
- 298. As the Supreme Court explained in *Bruesewitz*, the Vaccine Act is based upon the premise that vaccine injury is "unavoidable." If a large enough number of children are vaccinated, some children will be seriously injured and die. Recognized vaccine injuries include severe neurological damage and death. Congress created the Vaccine Injury Compensation Program (VICP) to address these issues.
- 299. Under the Vaccine Act, "[a]s a *quid pro quo*, manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse effects." *Bruesewitz*, 562 U.S. at 229.
- 300. As a result of the Vaccine Act and *Bruesewitz v. Wyeth*, for all practical purposes, citizens have no ability to contest inadequate vaccine safety before a jury in state or federal court.
- 301. Under the Vaccine Act, a vaccine injured person's only remedy is to file a claim under the VICP. A special master of the U.S. Court of Federal Claims hears the petitioner's claim in what is sometimes referred to as "vaccine court." There, the role of the judge is replaced by the "special master," and the Federal Rules of Civil Procedure, Evidence and Discovery do not apply. *See* Vaccine Rules Appendix B, Rules of the United States Court of Federal Claims, Rules 1,3, 7 and 8, *available at*

https://www.uscfc.uscourts.gov/sites/default/files/21.08.02%20FINAL%20Vaccine%20Rules.pd f (accessed November 10, 2021).

- 302. A petitioner may appeal a special master's decision to a judge in the Court of Federal Claims, but the factual record has already been established, and the appeal is subject to the high bar of an "arbitrary and capricious" standard of review. The petitioner may appeal Court of Federal Claims decisions to the Court of Appeals for the Federal Circuit, but the appeal is once again subject to the arbitrary and capricious standard. Finally, there is limited access to the U.S. Supreme Court, and a handful of vaccine-related cases have reached it for decision. *Hazlehurst v. Sec'y of HHS*, 604 F.3d 1343, 1348 (Fed. Cir. 2010).
- 303. In the VICP, the defendant is the Secretary of the Department of Health and Human Services (HHS), who is represented by the U.S. Department of Justice.
- 304. With language three Justices of the Supreme Court described as "confusing," "ambiguous," and "sloppy drafting," Congress took away the right to trial by jury for vaccine injury and replaced it with Vaccine Act rules. *See* Transcript of Oral Argument at 16:18, 28:15, 36:1, and 43:10, *Bruesewitz*, 562 U.S. 223 (No. 09-152), available at <a href="https://www.supremecourt.gov/oral\_arguments/audio/2010/09-152">https://www.supremecourt.gov/oral\_arguments/audio/2010/09-152</a>. A citizen's primary rights under the Vaccine Act include the recording requirements of 42 U.S.C. § 300aa-25, the right to Vaccine Information Statements in accordance with 42 U.S.C. § 300aa-26, and the right to claim compensation for injury under the VICP.
- 305. Congress's comprehensive legislative scheme of informal adjudication is made possible by the Act's Vaccine Injury Table, which lists the vaccines the Act covers; describes each vaccine's compensable, adverse side effects; and indicates how soon after vaccination those side effects must first manifest. *See* **Exhibit 14**.

- 306. If the vaccine injury first manifests during the short time period listed on the Table (referred to as a "table injury"), then the vaccine is presumed to have caused the injury and the child is entitled to compensation, unless HHS can prove an alternative cause of injury. If the child's injury is not listed on the Vaccine Injury Table, or if the injury is listed on the Table but the injury does not manifest until after the short time period listed on the Table, then the petitioner must prove causation. This is referred to as a "non-table injury." These now account for more than 90% of all vaccine injury claims.
- 307. The standard of proof for "non-table injuries" is by a preponderance of the evidence. Petitioners have been awarded compensation in the VICP for the following injuries:

abscess, acute disseminated encephalomyelitis (ADEM), acute liver failure, adhesive capsulitis, aggravation of pre-existing encephalopathy, agoraphobia, anaphylactic shock, anaphylaxis, angioedema, antisynthetase syndrome, angiomatoid fibrous histiocytoma, aplastic anemia, anxiety, arm injury, arthritis, ataxia, atypical fibromyalgia, autism, autoimmune hep type 2, autoimmune encephalitis, autoimmune hemolytic anemia, autoimmune limbic encephalitis, autoimmune meningitis, autoimmune neuroretinitis, behavioral issues, bell's palsy, benign tumor, bilateral peripheral neuropathy, bilateral shoulder pain, bilateral symmetric diaphragmatic palsy, blindness, blood clots, bowel obstruction, brachial neuritis, brachial plexopathy, brachial plexus, neuritis, cardiac injury, celiac disease, cellulitis, central nervous system demyelinating, cerebellitis, cerebral vasculitis, cerebellar ataxia, cerebrovascular accident, chest pain, choreiform, movement disorder, chronic fatigue, chronic gastrointestinal issues, chronic arthritis, chronic fatigue syndrome, chronic headache, chronic inflammatory demyelinating polyneuropathy (CIDP), chronic pain, chronic urticaria, complex regional pain syndrome, demyelinating disease of central nervous system, conversion disorder, demyelinating polyradiculoneuropathy, death, deltoid bursitis, demyelinating condition, demyelinating sensorimotor polyneuropathy, dermatitis, dermatomyositis, diverticulitis, dravet syndrome, developmental delay, devic's disease, eczema, elevated intraocular pressure, encephalitis, encephalopathy, epilepsy, epstein barr virus, erythema multiforme major, evan's syndrome, exacerbation of existing cardiomyopathy, expressive language delay, fainting injuries, fatigue, febrile seizure, fibromyalgia, fibrosis, frozen shoulder, gastrointestinal symptoms, gastrointestinal issues, gastroparesis, GM1 gangliosidosis, guillain-barre syndrome (GBS), glomerulonephritis, hashimoto's thyroiditis, headaches, hemophagocytic lymphohistiocytosis (HLH), heel pain, henoch-schonlein purpura (HSP), hernia, hip impingement syndrome, hodgkin's lymphoma, hypereosinophilia, hypersensitivity, hyperthyroidism,

hypotensive-hyporesponsive shock collapse (HHE), hypoproteinemia, hypotonia, immobile flaccid legs, immune issues, idiopathic intracranial hypertension, immune thrombocytopenia purpura, impingement syndrome, increased risk of cancer, infantile spasms, inflammatory arthritis, inflammatory brachial plexopathy, inflammatory neuropathy, intractable epilepsy, joint pain, juvenile dermatomyositis, joint stiffness, juvenile idiopathic arthritis, juvenile rheumatoid arthritis (JRA), kawasaki disease, keloid scarring, labrum tear, leukocytoclastic vasculitis (LCV), leukodystrophy, leukoencephalopathy, latent herpes simplex virus infection, lichen planus, lipomas, long thoracic nerve palsy, lupus (SLE), lymphangitis, lymphomatoid granulomatosis, macrophagic myofasciitis, meningoencephalitis, metal toxicity, mixed connective tissue disease (MCTD), monoplegia, motor tics, multi organ failure, multiple sclerosis, muscle spasms, muscle weakness, myalgias, myelitis, necrotizing pancreatitis, nerve damage, neurological injury, neuromyelitis optica (NMO), neuropathic arm pain, neuropathy, nodular fasciitis, opsoclonus-myoclonus syndrome (OMS), ocular visual disturbance, optic neuritis, panic, pancreatitis, polyarthralgia pain syndrome, polyarthritis, overlap syndrome, panuveitis, panniculitis, parsonage turner syndrome, pemphigus vulgaris, peripheral neuropathy, permanent spastic tetraparesis, persistent headaches, polyarthralgia, polyneuropathy, post-vaccine encephalopathy, progressive encephalopathy, psoriatic arthritis, pulmonary edema, pyoderma gangrenosum, radial nerve damage, rash, reactivation of herpes simplex virus, reactive inflammatory arthritis, reflex sympathetic dystrophy, residual seizure disorder (RSD), retinal vasculitis, retro seizures, rhabdomyolysis, rheumatoid arthritis, rheumatologic injuries, scarring, seizures, seizure disorder, sensory neuropathy, serum sickness, SIDS, significant aggravation of pre-existing neurodevelopmental disorder, Sirva, small fiber neuropathy, shoulder pain, skin disfigurement, spinal accessory neuropathy, splenic rupture, Sjogren's syndrome, snapping hip syndrome, strep infection, stroke, suprascapular neuropathy, sweets syndrome, syncopal seizure, syncope, synovitis, systemic juvenile idiopathic arthritis, tendonitis, tendinopathy, topical epidermal necrolysis, toxic epidermal necrolysis (TEN), toxic shock syndrome, transverse myelitis (TM), thrombocytopenic purpura, tics, tremors, trigeminal neuralgia, ulcerative colitis, urticaria, undifferentiated connective tissue disease (UTCD), ulceration, ulnar neuropathy, urinary incontinence, urticarial angioedema, uveitis, vasculitis, vasovagal syncope, vertigo, vestibular neuronitis.

See, e.g., USCFC Vaccine-Reported, UNITED STATES COURT OF FEDERAL CLAIMS, <a href="https://uscfc.uscourts.gov/aggregator/sources/7">https://uscfc.uscourts.gov/aggregator/sources/7</a>. This non-exhaustive list was compiled by Wayne Rhode, author *The Vaccine Court*.

308. In accordance with 21 C.F.R. § 201.57, vaccine manufacturers are required to list Adverse Reactions in their product inserts, which state, "This definition does not include all

adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." There are 397 different types of adverse reactions reported pre-and post-licensure, which are listed on vaccine FDA-approved package inserts. See Children's Health Defense, the Defender August 14, 2020 article, entitled, Read the Fine Print, Part Two -Nearly 400 Adverse Reactions Listed in Vaccine Package Inserts.

https://www.google.com/url?q=https://childrenshealthdefense.org/news/read-the-fine-print-part-two-nearly-400-adverse-reactions-listed-in-vaccine-package-

 $\underline{inserts/\&source=gmail\&ust=1636822834616000\&usg=AOvVaw1LXxDylIG3LsRg9LcnQKoe}.$ 

- 309. Congress's legislative scheme depends on recognizing vaccine injuries in a timely manner: not only is timely recognition important for receiving follow-up medical care, but it is also an element of proving that one is entitled to legal compensation for injuries—compensation that may be necessary for a lifetime of care.
- 310. As part of this comprehensive scheme, Congress mandated that (1) the date of administration of the vaccine, (2) the vaccine manufacturer and lot number of the vaccine, (3) the name and address and, of the health care provider and (4) any other identifying information on the vaccine required pursuant to regulations promulgated by the secretary. 42 U.S.C. § 300aa-25(a).
- 311. As part of this scheme, Congress defined "legal representative" as "a parent or an individual who qualifies as a legal guardian under State law." 42 U.S.C. § 300aa-33(2).
- 312. The vaccines in the Vaccine Injury Table have been recommended by CDC's ACIP, and health providers can administer any of them to children under the Minor Consent Act.

ACIP's *Recommended Child and Adolescent Immunization Schedule* is reproduced in **Exhibit**15. (See also The Vaccine Injury Table **Exhibit 14.**)

- 313. The Minor Consent Act subverts the Vaccine Act by requiring health providers to not record the administration of numerous vaccines in Part 3 of the child's Health Certificate, including Diphtheria-Tetanus-Pertussis, Diphtheria-Tetanus, Hemophilius Influenzae B (HIB), Hepatitis B (HBV), Polio, Measles-Mumps-Rubella (MMR), Varicella, Pneumococcal conjugate (PCV), Influenza, or any other vaccine administered under the Minor Consent Act. D.C. Code § 38-602(a)(2). This blatantly violates the federal Vaccine Act. 42 U.S.C. § 300aa-25.
- 314. The Minor Consent Act subverts federal law by creating two different immunization records for the same student: a fake record available to parents, which does not contain vaccines administered under the Minor Consent Act, and a separate, accurate "black book" record available only the school, healthcare providers, the District, and the child.
- 315. The Vaccine Act requires that upon request, a child's parents have access to the child's permanent medical record, which must include each vaccine and the date it was administered; its manufacturer and lot number; the name, address, and title of the health care provider; and any other identifying information on the vaccine required by federal regulations. 42 U.S.C. § 300aa-25.
- 316. The Minor Consent Act directly contradicts the Vaccine Act, which requires the child's parents have access to the child's authentic vaccine records.
- 317. As part of this comprehensive scheme, Congress required reporting of "the occurrence of any event set forth in the Vaccine Injury Table," which are commonly referred to as "vaccine adverse events." Vaccine Act, 42 U.S.C. § 300aa-25(b)(1) requires that "each health care provider and vaccine manufacturer *shall* report to the Secretary" of HHS the following

information: (A) the occurrence of any adverse events pursuant to the Vaccine Injury Table; (B) any adverse vaccine reaction specified in the manufacturer's package insert; and (C) such other matters as the Secretary may by regulation require.

- 318. Congress created the Vaccine Adverse Events Reporting System (VAERS) to capture vaccine adverse events, 42 U.S.C. § 300aa-25(b).
- 319. The Minor Consent Act conflicts with the requirements of the Vaccine Act § 300aa-25(b) and VAERS.
- 320. One of the primary purposes of the Vaccine Act was to establish the Vaccine Injury Compensation Program, which has paid out over \$4.6 billion in compensation since its inception. *See the last page of* **Exhibit 16**.
- 321. Congress's requirements in the Vaccine Act § 300aa-25 are essential because eligibility for compensation is largely based on timely recognition of injuries.
- 322. The Minor Consent Act conflicts with this federal law by commanding medical providers not comply with federal recording requirements mandated by 42 U.S.C. § 300aa-25(a).
- 323. If the child's parent has a religious exemption, no information about any vaccines administered under the Minor Consent Act may be recorded in the student's permanent medical record. The Minor Consent Act requires the medical provider to leave the vaccine record "blank."
- 324. It further deprives potential claimants of vital information necessary to establish eligibility for compensation in the event of vaccine injury.
- 325. Furthermore, Congress required that the HHS Secretary develop and disseminate Vaccine Information Materials for health care providers, parents and others for publication in the Federal Register. 42 U.S.C. § 300aa-26.

- 326. The "Vaccine Information Materials" are commonly referred to as "Vaccine Information Statements" (VIS). The terms "Vaccine Information Materials," "Vaccine Information Statements," and "Vaccine Information Sheets" are commonly used interchangeably. The VISs for the vaccines at issue here are reproduced in **Exhibit 17**.
- 327. VISs are critical to recognition and prevention of vaccine injuries, including severe allergic reactions, brain injury, paralysis, and death.
- 328. By contrast, the Minor Consent Act states that "The [District of Columbia] Department of Health shall produce one or more age-appropriate alternative vaccine information sheets." 22-B D.C.M.R. § 600.9. This directly contravenes the Vaccine Act, which mandates that the *Secretary* must develop and disseminate vaccine information materials. 42 U.S.C. § 300aa-26(a).
- 329. VISs are designed to provide parents with the minimum information needed to understand the benefits and risks of vaccines, so that parents can give informed consent, if they so choose. VISs include information such as a list of persons who should <u>not</u> receive a particular vaccine, the risks of that vaccine, and adverse events to watch for.
  - 330. Additionally, VISs provide parents with information about the VICP.
- 331. Moreover, a primary purpose of VISs is to educate parents about potential adverse events that may result from a vaccine, which may include severe life-threatening allergic reactions, seizures, brain damage, and death. Failing to recognize vaccine adverse events in a child can result in the child not receiving immediate necessary medical care.
- 332. VISs also warn parents that allergic reactions and other adverse events may be precautions and contraindications to further vaccination. Failure to timely recognize vaccine allergic reactions and other adverse events that are precautions or contraindications to further

vaccines places a child at risk of serious injury or death. The precautions and contraindications for childhood vaccines at issue here are in the CDC's *General Best Practice Guidelines for Immunization: Contraindications and Precautions*, which are available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.

- 333. By arrogating authority to the District's Department of Health to develop separate vaccine information materials, the Minor Consent Act conflicts with Vaccine Act, 42 U.S.C. § 300aa-26(b), as the alternative VISs are not developed "in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration."
- 334. The information contained on the federally-approved VISs is critical for parents to prevent serious harm and to inform them about the VICP in the event their child is injured.
- 335. By allowing vaccines to be administered to children without providing parents the required VISs, the Minor Consent Act poses substantial medical risks to children. Congress did not create or contemplate these risks. If a child receives an immunization without a parent's knowledge or consent, the parent in all probability will have no way of recognizing that the child suffered a vaccine injury. Not recognizing that can cause serious medical consequences. If the parent has not been provided the minimum information necessary to recognize a post-vaccination adverse event, the parent will not know to seek immediate medical attention. The parent will also not know that some post vaccine adverse events are listed as precautions and contraindications to further vaccinations. And if VISs are not provided to the parent, she may not discover the VICP or be able to timely document an injury under the Vaccine Injury Table, thus depriving the child of potential compensation in the event of injury.

- 336. The Minor Consent Act also sets the stage for a child to be injured or killed as a result of being excessively vaccinated. Vaccines are designed to be given over specified time periods. Some childhood vaccines are expressly contraindicated to be given with other childhood vaccines. If the child receives vaccinations without the parent's knowledge, there is nothing to prevent the child from receiving additional contraindicated vaccines within too short of a time period. The danger of being over vaccinated is particularly acute, given that Defendants are giving "incentives" in the form of earbuds, iPads, gift cards etc. each time a child receives a vaccine at an almost endless number of locations with vaccine providers who have imperfect or no ways of communicating with each other.
- 337. The Minor Consent Act also directly conflicts with Vaccine Act, 42 U.S.C. §§ 300aa-26(c) and (d), that require that the information in the VISs be up-to-date and from the HHS Secretary. Congress requires that "each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed" by the Secretary. 42 U.S.C. § 300aa-26(d).
- 338. As part of this comprehensive scheme, Congress required that the Secretary's materials "shall be provided prior to the administration of such vaccine" to a child's parent. 42 U.S.C. § 300aa-26(d).
- 339. The Minor Consent Act violates this requirement by commanding that health providers seek consent only from minor children, instead of providing these required materials to parents.

- M. The Minor Consent Act also violates federal law by requiring health providers to keep vaccination information secret from parents, the very people who need that information most.
- 340. The Vaccine Act does not cover the Pfizer-BioNTech COVID-19 vaccines that administered to District students. Pfizer-BioNTech COVID-19 vaccines are not FDA-approved. The Pfizer Comirnaty COVID-19 vaccine is FDA approved, but is not being distributed to District children.
- 341. The Food and Drug Administration (FDA) has authorized the Pfizer-BioNTech COVID-19 vaccines as biologic countermeasures under an Emergency Use Authorization (EUA) in accordance with 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act and Public Readiness and Preparedness Act (PREP Act), 42 U.S.C. § 247.
- 342. Pfizer-BioNTech COVID-19 vaccines utilize a novel messenger RNA (mRNA) technology never before used in healthy people; it previously was used only as gene therapy for individuals with cancer.
- 343. Under the PREP Act, vaccine manufacturers, healthcare providers and government planners cannot be held liable for any injuries, except for "willful misconduct" by a clear and convincing standard. No matter how defective or unreasonably dangerous, vaccine manufacturers cannot be held liable for design or manufacturing defects alone.
- 344. Theoretically, a person injured by the Pfizer-BioNTech COVID-19 vaccine can file a claim for compensation under the Countermeasures Injury Compensation Program (CICP). However, no one has yet to been paid compensation for a vaccine injury by the Pfizer-BioNTech COVID-19 vaccines. Unlike the VICP, the CICP does not pay attorney fees or expert witness fees, providing no financial incentive for attorneys to bring legal actions there.

- 345. The EUA requires that "fact sheets" must be provided to recipients. A copy of the Pfizer-BioNTech vaccine fact sheet is attached hereto as **Exhibit 18**.
- 346. According to the CDC, 66 deaths from COVID-19 have occurred in children aged 5 to 11 between Oct. 3, 2020 and Oct. 2 2021. This figure is likely inflated because it includes those who may have died with serious comorbid conditions. *See* Jefferson Jones, U.S. Centers for Disease Control and Prevention, *Epidemiology of COVID-19 in Children Aged 5-11 Years, available at* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-COVID-Jefferson-508.pdf (accessed November 10, 2021).
- 347. The risks of death or injury from the Pfizer-BioNTech COVID-19 vaccine are unknown.
- 348. The long-term effects of the Pfizer-BioNTech COVID-19 vaccine are unknown, yet there are many COVID vaccine deaths among children already listed in Vaccine Adverse Event Reporting System (VAERS).
- 349. VAERS data reveal unprecedented levels of death and other adverse events since the FDA issued EUAs for COVID vaccines.
- 350. Only a tiny fraction of adverse events is actually reported to VAERS, however. When Massachusetts General-Brigham Hospital evaluated the rate of anaphylaxis in employees post-COVID vaccination, which can lead to death. It found anaphylaxis rates approximately 50-100 times greater than the rates the CDC calculated using VAERS data. If this degree of underestimation holds true for other adverse events using the VAERS database, then the safety of COVID vaccines is considerably worse than it currently appears. *See* K.G. Blumethal, L.B. Robinson, C.A. Carmago, et. al, *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, 325 J.

- Am. MED. Ass'n 15, 1562-1565 (Mar. 8, 2021), *available at*<a href="https://jamanetwork.com/journals/jama/fullarticle/2777417">https://jamanetwork.com/journals/jama/fullarticle/2777417</a> (accessed November 10, 2021).
- 351. As of October 29, 2021, a total of 856,919 adverse events have been reported to VAERS among all age groups for COVID-19 vaccines. See National Vaccine Information Center, Search Results, available at

https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=O

N&VAX=COVID19 (accessed November 10, 2021).

- 352. As of October 29, 2021, a total of 18,078 deaths have been reported to VAERS for COVID-19 vaccines. *See* National Vaccine Information Center, *Search Results*, *available at* <a href="https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=O">https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=O</a> <a href="https://
- 353. Excluding "foreign reports" to VAERS, 634,609 adverse events have been reported between Dec. 14, 2020, and Oct. 29, 2021. See National Vaccine Information Center, Search Results, available at

https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VA
X=COVID19&STATE=NOTFR (accessed November 10, 2021).

- 354. Excluding "foreign reports" to VAERS, 8,284 deaths have been reported in the U.S. between Dec. 14, 2020, and Oct. 29, 2021. *See* National Vaccine Information Center, *Search Results, available at*
- https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VA

  X=COVID19&DIED=Yes&STATE=NOTFR (accessed November 10, 2021).
- 355. As for the age group of 12 to 17-year-olds, 22,584 total adverse events have been reported to VAERS. *See* National Vaccine Information Center, *Search Results*, *available at*

https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&VAXTYPES=COVID-

19&STATE=NOTFR&WhichAge=range&LOWAGE=12&HIGHAGE=18 (accessed November 10, 2021).

- 356. As for the age group of 12 to 17-year-old data, 40 deaths have been reported, including foreign reports. *See* National Vaccine Information Center, *Search Results*, *available at* <a href="https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes&WhichAge=range&LOWAGE=12&HIGHAGE=18">https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes&WhichAge=range&LOWAGE=12&HIGHAGE=18</a> (accessed November 10, 2021).
- 357. One of the most disturbing trends in VAERS is data regarding myocarditis and pericarditis, i.e., inflammation and damage of the heart muscle known as myocardium. Pericarditis is swelling and irritation of the pericardium, a thin, sac-like tissue surrounding the heart.

358.

pericarditis in children in the 0-18 age group. See National Vaccine Information Center, Search Results, available at

<a href="https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&SY-MPTOMS[]=Myocarditis+%2810028606%29&SYMPTOMS[]=Pericarditis+%2810034484%29-&VAX=COVID19&WhichAge=range&LOWAGE=0&HIGHAGE=19-(accessed November 10, 2021).</a>

As of October 29, 2021, VAERS data reflected 975 reports of myocarditis and

359. As of October 29, 2021, VAERS data reflected 728 reports of myocarditis and pericarditis in the 12 to 17 age group. See National Vaccine Information Center, Search Results, available at

https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&SY

MPTOMS[]=Myocarditis+%2810028606%29&SYMPTOMS[]=Pericarditis+%2810034484%29

&VAX=COVID19&WhichAge=range&LOWAGE=12&HIGHAGE=18 (accessed November 10, 2021).

- 360. Pfizer is well aware that its COVID-19 vaccine carries a significant risk of myocarditis and pericarditis. On October 26, 2021, Pfizer submitted a document entitled "Vaccines and Related Biological Products Advisory Committee Meeting October 26, 2021, FDA Briefing Document, EUA amendment for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age," a copy of which is available at <a href="https://www.fda.gov/media/153447/download">https://www.fda.gov/media/153447/download</a>. The document's purpose was to obtain EUA for the Pfizer-BioNTech Covid-19 vaccine for use in children 5 through 11 years of age.
- 361. Page 13 of the October 26, 2021 FDA briefing document, EUA amendment for Pfizer-BioNTech Covid-19 vaccine for children 5 through 11 years of age, states:

### Myocarditis and pericarditis

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

362. This section further states: "Although some cases of vaccine-associated myocarditis/pericarditis have required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae and outcomes in affected individuals, or whether the vaccine might be associated initially with

subclinical myocarditis (and if so, what are the long-term sequelae). A mechanism of action by which the vaccine could cause myocarditis and pericarditis has not been established.

Myocarditis and pericarditis were added as important identified risks... included in the Warnings sections of the vaccine Fact Sheets and Prescribing Information. The Sponsor is conducting additional post-authorization/post-marketing studies to assess known serious risks of myocarditis and pericarditis as well as to identify an unexpected serious risk of subclinical myocarditis" (emphasis added).

- 363. Page 14 states in part: "EUA AMENDMENT REQUEST FOR THE PFIZER-BIONTECH COVID-19 VACCINE FOR USE IN CHILDREN 5-11 YEARS OF AGE: On October 6, 2021, Pfizer and BioNTech submitted a request to amend this EUA to include use of a 2-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine (10 µg each dose, administered 3 weeks apart) in individuals 5-11 years of age for active immunization to prevent COVID-19 caused by severe acute coronavirus 2 (SARS-CoV-2).
- 364. Page 14 further states: "Authorization is being requested for a modified formulation of the Pfizer-BioNTech COVID-19 Vaccine." (emphasis added).
- 365. Page 14 further states: "Vaccine formulation. To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11 years of age uses tromethamine (Tris) buffer instead of the phosphate- buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride."
- 366. Tromethamine is commonly used to treat heart attack or cardiac bypass surgery patients. Upon information and belief, Pfizer has changed its buffer to Tromethamine given the significant risk of myocarditis and pericarditis in children, underscoring the clear understood risk for heart complications in children.

- 367. COVID-19 vaccine profits are unprecedented. Pfizer anticipates \$36 billion for 2021 and \$29 billion for 2022. *See* Pfizer, *Pfizer Reports Third-Quarter 2021 Results*, Nov. 2, 2021, *available at* <a href="https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-THIRD-QUARTER-2021-RESULTS/default.aspx">https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-THIRD-QUARTER-2021-RESULTS/default.aspx</a> (accessed November 10, 2021).
- 368. Pfizer generated approximately \$29 billion through Oct. 2021. See Nasdaq.com, Pfizer Stock: Vaccine Maker Poised for Big 2022, Nov. 4. 2021, available at <a href="https://www.nasdaq.com/articles/pfizer-stock%3A-vaccine-maker-poised-for-big-2022-2021-11-">https://www.nasdaq.com/articles/pfizer-stock%3A-vaccine-maker-poised-for-big-2022-2021-11-</a>
  04 (accessed November 10, 2021).
- 369. There are tremendous financial conflicts of interest between the pharmaceutical giants that have monopolized the vaccine industry and the FDA. *See*<a href="https://childrenshealthdefense.org/defender/fda-pfizer-covid-kids-pharma/">https://childrenshealthdefense.org/defender/fda-pfizer-covid-kids-pharma/</a>; *see also*<a href="https://www.bmj.com/content/375/bmj.n2635">https://www.bmj.com/content/375/bmj.n2635</a>.
- 306 Vaccine manufacturers make tens of billions of dollars in profits each year. With booster shots, the manufacturers will make tens of billions more. When there is no liability, there is no incentive for safety. Truly the only thing standing between rapacious vaccine manufacturers and children are their parents, and the Minor Consent Act purports to remove even parents, in violation of federal law.
  - N. The Religious Freedom Restoration Act of 1993 (RFRA)
- 307. In 1993, Congress adopted the Religious Freedom Restoration Act (RFRA). 42 U.S.C. § 2000bb *et. seq.*
- 308. It adopted RFRA because "neutral" laws towards religion may burden the First Amendment free exercise right as surely as laws intended to interfere with religious free exercise. 42 U.S.C. § 2000bb(a)(1)-(2).

- 309. Congress adopted RFRA to provide a claim or defense to persons whose religious exercise is substantially burdened by government and to create a cause of action for such persons to vindicate those rights. 42 U.S.C. § 2000bb(b)(2); 42 U.S.C. § 2000bb-1(c).
  - 310. The District is a "covered entity" under RFRA. 42 U.S.C. § 2000bb-2(1) and (2).
- 311. Congress has mandated that government shall not substantially burden a person's exercise of religion, even if the burden results from a rule of general applicability, unless it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest. 42 U.S.C. § 2000bb-1(a) and (b).
- 312. Congress defines "free exercise" broadly to include "any exercise of religion, whether or not compelled by, or central to, a system of religious beliefs." 42 U.S.C. § 2000bb-2(4); 42 U.S.C. § 2000cc-5(7)(A).
- 313. The District recognizes a legal right of parents to claim a religious exemption from vaccinations by filing an objection in good faith and filing a statement with the chief official of the school that vaccinations violate their religious beliefs. A good faith statement that a parent has sincere religious beliefs against childhood immunizations is sufficient to obtain the exemption. D.C. Code § 38-506(1).
- 314. For Victor, Shameka, Shanita and Jane, vaccinating their children violates sincerely held religious beliefs. They have all exercised those rights by claiming religious exemptions pursuant to D.C. CODE § 38-506(1).
- 315. The Minor Consent Act did not amend D.C. CODE § 38-506(1) to eliminate the religious exemptions.

- 316. Instead, the Minor Consent Act specifically states that vaccinations can be administered to the minor children of parents who have exercised their right to claim a *religious exemption*, without the parents' knowledge or consent. 22-B D.C.M.R. § 600.9(d)(1).
- 317. Moreover, the Minor Consent Act states that if vaccinations are administered to the minor children of parents who have claimed a religious exemption, "the healthcare provider shall leave blank part 3 of the immunization record, and submit the immunization record directly to the minor student's school." D.C. Code § 38-602(a)(2).
- 318. The Minor Consent Act reflects blatant state-sponsored hostility to religion, violating the First Amendment and recent Supreme Court precedent. *Masterpiece Cakeshop*, *LTD.*, et al, v. Colorado Civil Rights Commission et al. 138 S. Ct. 1719 (2018).
- 319. Moreover, the Minor Consent Act states that if vaccinations are administered to the minor children of parents who have exercised their right to claim a religious exemption, insurers shall not send an Explanation of Benefits (EOB) to the parents for services provided under the Minor Consent Act. 22-B D.C.M.R. § 600.9(d)(2).
- 320. On October 6, 2020, the District's Chief Financial Officer, Jeffrey S. DeWitt, issued a Fiscal Impact Statement on the Minor Consent Act to the Honorable Phil Mendelson, Chairman of the D.C. Council. Mr. DeWitt concluded: "[t]he bill requires providers to leave the immunization record blank on the Universal Health Certificate form when a parent is utilizing a religious exemption for vaccinations or is opting their child out of receiving the Human Papillomavirus vaccine. If the immunization record is left blank, providers must submit the Universal Health Certificate direction to the minor's school. Schools must keep this record confidential unless shared with D.C. Health or the school-based health center."

- 321. The Minor Consent Act thus subverts the decision of parents who have exercised their religious rights by claiming a lawful religious exemption for their children.
- 322. It substantially burdens the free exercise rights of religious parents, by overriding their express religiously-motivated decisions.
- 323. The Minor Consent Act is not limited to a pandemic context or other health emergency; it applies to all ACIP-recommended vaccines, in emergency and non-emergency circumstances. Indeed, when the D.C. Council passed the Minor Consent Act in March 2021, neither the FDA nor CDC allowed or recommended children under 16 to receive the COVID-19 vaccines.

#### O. The Constitutional Rights of Parents

- 324. In *Troxel v. Granville*, 530 U.S. 57 (2000), the Supreme Court recognized that one of the oldest fundamental liberty interests protected by the Constitution is the interest of parents in the care, custody, and control of their children.
- 325. In *Santosky v. Kramer*, 455 U.S. 745 (1982), the Court declared that "freedom of personal choice in matters of family life is a fundamental liberty interest protected by the Fourteenth Amendment."
- 326. In *Wisconsin v. Yoder*, 406 U.S. 2 05 (1972), the Court declared that "the history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition."
- 327. In *Cleveland Board of Education v. LaFleur*, 414 U.S. 632 (1974), the Court warned that "freedom of personal choice in matters of . . . family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment."

- 328. In *Parham v. J.R.*, 442 U.S. 584 (1979), the Court stated that "our constitutional system long ago rejected any notion that a child is 'the mere creature of the State,' and, on the contrary, asserted that parents generally 'have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations.' Surely, this includes a 'high duty' to recognize symptoms of illness and to seek and follow medical advice. The law's concept of the family rests on the presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions."
- 329. The fundamental rights of parents are implicated when the state intervenes and substitutes its decision making for that of the parents.
- 330. A fit parent's decision with respect to the care, custody, and control of his or her child cannot be overridden by the government unless it has a compelling interest, and its actions are narrowly tailored to accomplish that compelling interest.
- 331. Victor, Shameka, Shanita and Jane are fit parents, who have exercised their legal rights under D.C. Code § 38-506(1) to exempt their children from vaccinations because of their sincere religious beliefs.
- 332. By authorizing the vaccination of children whose parents have claimed religious exemptions, the Minor Consent Act substitutes the District's own medical preferences over those of the children's parents lawful rights.

#### **FIRST CAUSE OF ACTION**

28 U.S.C. § 2201 and 42 U.S.C. § 1983

Adoption and Enforcement of an Unconstitutional Statute that Deprives Parents of Federal Statutory Rights Guaranteed by the National Childhood Vaccine Injury Act of 1986, in violation of Article VI and the Fifth Amendment of the Constitution

- 370. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference herein.
- 371. Article VI, clause 2 of the U.S. Constitution states that the Constitution and laws of the United States shall be the supreme law of the land.
- 372. By adopting the National Vaccine Act, Congress expressed a clear intent to occupy the field of law as to the administration of childhood vaccinations.
- 373. Congress has mandated that before vaccines may be administered to children, parents must receive a detailed Vaccine Information Statement (VIS) and that detailed information about each vaccine—including date of administration, the manufacturer and lot number, and the name and address of the health care provider administering the vaccine—be recorded in the child's permanent, available health record.
- 374. Contrary to the Vaccine Act, the Minor Consent Act allows a child to be injected without the parent's knowledge or consent and conceals that information from the child's parent. By intentionally and surreptitiously stripping parents of their decision-making rights regarding the medical care of their children, and placing that decision-making squarely in the hands of the government, the Minor Consent Act subverts the protections of the Vaccine Act, in violation of Article VI and the Fifth Amendment of the Constitution of the United States.
- 375. Contrary to the Vaccine Act, the Minor Consent Act commands that a child's immunization record be confidential so as to hide from the parent that the child has been

vaccinated. It also requires that any information about vaccinations administered shall not be added to the child's permanent health record, but shall instead be recorded only in a record maintained by the school and inaccessible to the parent. By intentionally depriving parents of any knowledge that their children have received immunizations, the Minor Consent Act subverts the protections of the National Vaccine Act, in violation of Article VI and the Fifth Amendment of the Constitution of the United States.

- 376. Contrary to the National Vaccine Act, the Minor Consent Act prevents the parent from receiving federally mandated Vaccine Injury Statements at the time the child is vaccinated and subverts Congress's intent to protect children by depriving parents of any knowledge that their child may be at increased risk of serious harm or death. The Minor Consent Act thus usurps the responsibility and authority of federal health agencies, to which Congress assigned the development and publication of Vaccine Information Statements. The Minor Consent Act thus violates the Supremacy Clause of Article VI and the Due Process Clause of Fifth Amendment of the Constitution.
- 377. Because the Minor Consent Act prevents providers from disclosing the administration of vaccinations to parents, Victor, Shameka, Shanita and Jane will receive no formal notice that their rights under the Vaccine Act have been subverted, much less prior notice and an opportunity to assert those rights before they are deprived of them. By giving license to these surreptitious acts, the Minor Consent Act erects barriers that make it difficult if not impossible for parents like Victor to vindicate their legal rights.
- 378. By allowing the District to develop its own alternative VISs for distribution to children, the Minor Consent Act deprives parents of a VIS developed by the HHS Secretary, developed in consultation with the CDC and FDA, as Congress required.

- 379. The plain language of the Minor Consent Act, combined with the public statements of the D.C. Council in adopting it and the subsequent actions and public statements of Defendants, and statements by L.B., K.G., N.W., and H.B., have caused Victor, Shameka, Shanita and Jane to realistically fear that L.B., K.G., R.T., N.W., M.R., H.B., may be pressured into submitting to vaccination without their parental knowledge or consent.
- 380. Victor, Shameka, Shanita and Jane ask this Court to declare the Minor Consent Act illegal and to issue an injunction preventing the Mayor, D.C. Health, and DCPS from enforcing it.

#### **SECOND CAUSE OF ACTION**

28 U.S.C. § 2201, 42 U.S.C. § 1983, and 42 U.S.C. § 2000bb

Adoption and Enforcement of an Unconstitutional Statute In violation of the Religious Freedom Restoration Act of 1993

- 381. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference herein.
- 382. The District has recognized a legal right of parents to claim a religious exemption from vaccinations, by filing an objection in good faith and filing a statement with the chief official of the school that vaccinations would violate the parents' religious beliefs. The Minor Consent Act does not amend the D.C. Code to eliminate that religious exemption.
- 383. The Minor Consent Act substantially burdens free exercise rights by authorizing the actual *administration* of vaccines to minor children of parents who have exercised their right to claim a religious exemption, without the parent's knowledge or consent.

- 384. The Minor Consent Act does not identify any compelling interest that would justify overriding parents' decisions to decline childhood vaccines based on sincere religious beliefs.
- 385. The District has no compelling interest in offering parents a religious exemption with one hand and surreptitiously taking away the exemption protections with the other.
- 386. The Minor Consent Act is not narrowly tailored to further any compelling interest that might justify overriding parents' religious decisions.
- 387. Because the Minor Consent Act prevents providers from disclosing the administration of vaccinations to parents, Victor, Shameka, Shanita and Jane will receive no formal notice if their free exercise rights are subverted, much less prior notice and an opportunity to assert those rights before they are deprived.
- 388. The plain language of the Minor Consent Act, combined with the public statements of the D.C. Council in adopting it and the subsequent actions and public statements of Defendants, and statements by L.B., K.G., N.W., and H.B., have caused Victor, Shameka, Shanita and Jane to realistically fear that L.B., K.G., R.T., N.W., M.R., and H.B., will be pressured to receive one or more vaccinations and that this will occur without Victor, Shameka, Shanita and Jane's knowledge or consent.
- 389. Victor, Shameka, Shanita and Jane ask this Court to declare the Minor Consent Act illegal, and to issue an injunction preventing the Mayor, D.C. Health, and DCPS from enforcing it.

#### **THIRD CAUSE OF ACTION**

#### 42 U.S.C. § 1983

## Adoption and Enforcement of an Unconstitutional Statute in Violation of the First Amendment to the U.S. Constitution

- 390. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference herein.
- 391. The First Amendment to the U. S. Constitution states, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." The First Amendment clearly applies to state and local governments. *Cantwell v. Connecticut*, 310 U.S. 296 (1940).
- 392. The D.C. Minor Consent Act directly conflicts with the free exercise clause of the First Amendment because it is state action actively hostile toward religion. This blatant violation of the free exercise clause is actionable by 42 U.S.C. § 1983.
- 393. "The Constitution commits government itself to religious tolerance, and upon even slight suspicion that proposals for state intervention stem from animosity to religion or distrust of its practices, all officials must pause to remember their high duty to the Constitution and to the rights it secures." *Masterpiece Cakeshop, LTD.*, v. Colorado Civil Rights Commission 138 S. Ct. 1719, 1731 (2018) (internal citations omitted).
- 394. The Minor Consent Act is unconstitutional on its face. Specifically, the Amendment to D.C. Code § 38-602(b)(2) states: "if a minor is utilizing a religious exemption for vaccinations...the health care provider shall leave blank part 3 of the immunization record." This part of the Minor Consent Act is openly hostile to free exercise of religion because the Minor Consent Act is specifically targeting and endangering children whose parents have claimed a

lawful religious exemption. This is directly contrary to the religious neutrality that the Constitution requires. *Id.* 

- 395. The State has a "duty under the First Amendment not to base laws or regulations on hostility to a religion or religious viewpoint." *Masterpiece Cakeshop*. 138 S. Ct. at 1721, yet this is exactly what the D.C. Minor Consent Act does. As the Supreme Court explained in *Masterpiece Cakeshop*, the government's "hostility was inconsistent with the First Amendment's guarantee that our laws be applied in a manner that is neutral toward religion." *Id*. The D.C. Minor Consent Act is not neutral toward religion; it specifically targets children whose parents have exercised their lawful religious rights. And not only have parents' rights been trampled, but their children's health and welfare are endangered.
- 396. The plain language of the Minor Consent Act, combined with the public statements of the D.C. Council in adopting it and the subsequent actions and public statements of Defendants, as well as statements by L.B., K.G., N.W., and H.B. have caused Victor, Shameka, Shanita and Jane to fear that L.B., K.G., R.T., N.W., M.R., and H.B., will be pressured to receive one or more vaccinations and that this will occur without their knowledge or consent.
- 397. Victor, Shameka, Shanita and Jane ask this Court to declare the Minor Consent Act illegal and to issue an injunction preventing the Mayor, D.C. Health, and DCPS from enforcing the Act.

#### **FOURTH CAUSE OF ACTION**

28 U.S.C. § 2201 and 42 U.S.C. § 1983

Adoption and Enforcement of an Unconstitutional Statute that Deprives Parents of Their Fundamental Right to Direct the Upbringing of their Children in Violation of the Fifth Amendment of the U.S. Constitution

- 398. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference herein.
- 399. It is clearly established both in this Circuit and the District of Columbia that fit parents have a fundamental right to direct the upbringing of their children.
- 400. The Minor Consent Act surreptitiously subverts that legal right. With one hand, the District has extended to parents a statutory right to exempt their children from vaccinations; with the other, the District takes away from those same parents the protection of that lawful exemption, without their knowledge or consent.
- 401. The Minor Consent Act does not hinge on any finding of parental unfitness. On the contrary, the Minor Consent Act permits healthcare providers to administer vaccines to minor children without any consideration of the parents' fitness—and, indeed, to the children of fit parents—based on the provider's sole assessment of whether the minor child can provide informed consent.
- 402. Moreover, the Minor Consent Act states that if vaccinations are administered to the minor children of parents who have exercised their right to claim a religious exemption, this administration shall be kept secret from the parents. Specifically, healthcare providers are prohibited from recording the vaccinations in part 3 of the child's immunization records and are barred from sending an Explanation of Benefits to the parents for any vaccinations they administer under the Minor Consent Act.

- 403. The Minor Consent Act does not account for, much less rebut, the presumption that fit parents act in the best interests of their children.
- 404. The Minor Consent Act does not accord special weight to the decisions of fit parents; on the contrary, it disregards the decisions of fit parents.
- 405. The Minor Consent Act does not identify any compelling interest that would justify overriding the decision of fit parents to decline childhood vaccines.
- 406. The Minor Consent Act is not narrowly tailored to further any compelling interest that might justify overriding the decision of fit parents to decline childhood vaccines.
- 407. Pursuant to this unconstitutional Minor Consent Act, a medical provider at a hospital, clinic, or school office could administer vaccinations to L.B., K.G., R.T., N.W., M.R., and H.B., without Victor, Shameka, Shanita or Jane's prior knowledge or consent, subverting their fundamental rights under the Fifth Amendment to claim a lawful exemption from vaccinations for their minor children. Because the Minor Consent Act prevents providers from disclosing the administration of vaccines to parents, Victor Shameka, Shanita and Jane will receive no formal notice if their parental rights are subverted, much less prior notice and an opportunity to assert those rights.
- 408. The plain language of the Minor Consent Act, combined with the public statements of the D.C. Council in adopting it and the subsequent actions and public statements of the defendants, as well as statements by L.B., K.G., N.W., and H.B., have caused Victor, Shameka, Shanita and Jane to realistically fear that L.B., K.G., R.T., N.W., M.R., and H.B., will be pressured to receive one or more vaccinations and that this will occur without their knowledge or consent.

- 409. Regardless of whether L.B., K.G., R.T., N.W., M.R., and H.B., ever buckle under pressure, defy their parents, and receive vaccinations against their parents' better judgment, the constitutional rights of the parents to raise their children and the children's constitutional rights to be raised by their parents are being violated by the Minor Consent Act. In short, the Minor Consent Act undermines parents' authority and ability to raise their children.
- 410. Victor Shameka, Shanita and Jane ask this Court to declare the Minor Consent Act illegal, and to issue an injunction preventing the Mayor, D.C. Health, and DCPS from enforcing it.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that this Court:

- A. Issue a declaratory judgment that the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 conflicts with National Childhood Vaccine Injury Act of 1986, thereby depriving parents and children of their statutory rights to have prior knowledge and consent before vaccines are administered to minor children;
- B. Issue a declaratory judgment that because the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 conflicts with the National Childhood Vaccine Injury Act of 1986, it is an unconstitutional violation of the Supremacy Clause of the Constitution;
- C. Issue a declaratory judgment that the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 substantially and unlawfully burdens the rights of parents who have lawfully objected to vaccinations on the basis of sincerely held religious beliefs, in violation of the Religious Freedom Restoration Act of 1993;
- D. Issue a declaratory judgment that the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 substantially and unlawfully burdens the rights of parents

who have lawfully objected to vaccinations on the basis of sincerely held religious beliefs, in violation of the free exercise clause of the First Amendment to the Constitution of the United States;

- E. Issue a declaratory judgment that the District of Columbia Minor Consent for Vaccinations Amendment Act of 2020 deprives parents of their fundamental right to direct the care and upbringing of their children, in violation of the Due Process Clause of the Fifth Amendment to the Constitution of the United States;
  - E. Award Plaintiffs' costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and
  - F. Grant such other and further relief as the Court deems proper.

Respectfully submitted this 15th day of November, 2021:

/s Rolf G. S. Hazlehurst

Robert F. Kennedy, Jr.

Rolf G. S. Hazlehurst

Children's Health Defense

1227 North Peachtree Parkway,

Suite 202

Peachtree City, GA

30269

731-267-1663

rolf.hazlehurst@childrenshealthdefense.org

Admitted Pro Hac Vice

Lead Counsel for Plaintiffs

/s James R. Mason III

James R. Mason III

D.C. Bar No. 978781

Parental Rights Foundation

One Patrick Henry Circle

Purcellville, VA 20132

Phone: (540) 338-5600

Fax: (540) 338-1952

E-mail: jim@hslda.org

Local Counsel for Plaintiffs

#### **VERIFICATION OF VICTOR BOOTH**

- I, Victor Booth, declare as follows:
- 1. I am a Plaintiff in the above captioned matter and a citizen of the United States of America, who resides in the District of Columbia.
- 2. I have personal knowledge of myself, my activities, and my intentions, including those set out in the foregoing *Verified Complaint for Declaratory and Injunctive Relief*, and if called on to testify I would competently testify as to the matters stated herein.
- 3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in this *Verified Complaint* concerning myself, my activities, and my intentions are true and correct.

Executed on the 15th day of November, 2021.



Victor Booth\*

<sup>\*</sup> In accordance with LCvR 5.4(b)(5), the original signed document is in the possession of Counsel of Record, and is available for review upon request by a party or by the Court.

#### **VERIFICATION OF SHAMEKA WILLIAMS**

- I, Shameka Williams, declare as follows:
- 1. I am a Plaintiff in the above captioned matter and a citizen of the United States of America, who resides in the District of Columbia.
- 2. I have personal knowledge of myself, my activities, and my intentions, including those set out in the foregoing *Verified Complaint for Declaratory and Injunctive Relief*, and if called on to testify I would competently testify as to the matters stated herein.
- 3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in this *Verified Complaint* concerning myself, my activities, and my intentions are true and correct.

Executed on the 15th day of November, 2021.

Shameka Williams

/s Shameka Williams

Shameka Williams\*

\* In accordance with LCvR 5.4(b)(5), the original signed document is in the possession of the attorney and is available for review upon request by a party or by the Court.

#### **VERIFICATION OF SHANITA WILLIAMS**

- I, Shanita Williams, declare as follows:
- 1. I am a Plaintiff in the above captioned matter and a citizen of the United States of America, who resides in the District of Columbia.
- 2. I have personal knowledge of myself, my activities, and my intentions, including those set out in the foregoing *Verified Complaint for Declaratory and Injunctive Relief*, and if called on to testify I would competently testify as to the matters stated herein.
- 3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in this *Verified Complaint* concerning myself, my activities, and my intentions are true and correct.

Executed on the 15th day of November, 2021.

Sharita Williams
E2535AFF669A49C...

/s Shanita Williams

Shanita Williams

<sup>\*</sup> In accordance with LCvR 5.4(b)(5), the original signed document is in the possession of the attorney and is available for review upon request by a party or by the Court.

#### VERIFICATION OF JANE HELLEWELL

I, Jane Hellewell, declare as follows:

1. I am a Plaintiff in the above captioned matter and a citizen of the United States of

America, who resides in the District of Columbia.

2. I have personal knowledge of myself, my activities, and my intentions, including

those set out in the foregoing Verified Complaint for Declaratory and Injunctive Relief, and if

called on to testify I would competently testify as to the matters stated herein.

3. I verify under penalty of perjury under the laws of the United States of America

that the factual statements in this *Verified Complaint* concerning myself, my activities, and my

intentions are true and correct.

Executed on the 15th day of November, 2021.

Jane Tuke Hellewell
CB26F1796D1D4E5...

/s Jane Hellewell

Jane Hellewell\*

\* In accordance with LCvR 5.4(b)(5), the original signed document is in the possession of the attorney and is available for review upon request by a party or by the Court.

## IN THE UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA

VICTOR M. BOOTH,	
individually and as next friend of )	
L.B. a minor child,	
3017 Central Avenue NE,	
Washington, D.C. 20018;	
SHAMEKA WILLIAMS,	Case No. 21-1857
individually and as next friend of	
K.G. and R.T., minor children;	
3744 Foote Street NE,	APPENDIX OF EXHIBITS
Washington, D.C. 20019;	SUBMITTED IN SUPPORT
washington, D.C. 2001),	OF VERIFIED AMENDED
SHANITA WILLIAMS,	COMPLAINT FOR
individually and as next friend of	DECLARATORY AND
N.W. and M.R., minor children,	INJUNCTIVE RELIEF
404 13th Street SE,	INJUNCTIVE RELIEF
Washington, D.C. 20003; and	
washington, D.C. 20003, and	
JANE HELLEWELL,	
individually and as next friend of	
H.B., a minor child,	
648 Lexington Place NE,	
Washington, D.C. 20002,	
Plaintiffs,	
)	
vs.	
MURIEL BOWSER,	
in her official capacity as Mayor of the	
District of Columbia,	
1350 Pennsylvania Avenue NW	
Washington, D.C. 20004;	
washington, D.C. 2000+,	
LAQUANDRA NESBITT,	
In her official capacity as	
Director of the District of Columbia	
Department of Health,	
825 North Capitol Street SE	
Washington, D.C. 20002; and	
)	

LEWIS FEREBEE,	)
In his official capacity as	)
Chancellor of the District of Columbia	)
Public Schools,	)
1200 First Street NE	)
Washington, D.C. 20002,	)
	)
Defendants.	)
	)

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

# EXHIBIT 1

## DC HEALTH Universal Health Certificate

Use this form to report your child's physical health to their school/child care facility. This is required by DC Official Code §38-602. Have a licensed medical professional complete part 2 - 4. Access health insurance programs at https://dchealthlink.com/ You may contact the Health Suite Personnel through the main office at your child's school

Bank 4. Child Bank							Treditir 50	1001	mer eme	agii tiic	. main oni	cc at yo	ir crina s scriooi.
Part 1: Child Perso	onal Inform	ation   To				ian.							
Child Last Name:			C	hild First Na	ame:					Date	of Birth:		
School or Child Care Fac	ility Name:						Gender:		Male	<u> </u>	emale	U <sub>N</sub>	on-Binary
Home Address:				Apt:	City:				Sta	te:		ZIP:	
Ethnicity: (check all that app	ly) 🔲 Hisp	anic/Latino	☐ Non-	Hispanic/No	on-Latino			Other			Prefer no	ot to ar	iswer
Race: (check all that apply)		erican Indian ka Native	n/ 🗖 Asian		Native Ha		n/ 🔲	Black/A			White		Prefer not to answer
Parent/Guardian Name:						Parer	nt/Guardi	an Phon	ie:				
Emergency Contact Nan	ne:					Emer	gency Co	ntact Ph	one:				
Insurance Type:	Medicaid $\Box$	Private	☐ None	Insurance	e Name/ID	#:							
Has the child seen a den	tist/dental pro	ovider within	n the last yea	r?	☐ Yes		☐ No						
I give permission to the sappropriate DC Governm from civil liability for acts understand that this forr Parent/Guardian Signati	ent agency. In s or omissions un n should be cor	addition, I h under DC Lav	ereby acknow w 17-107, exc	rledge and a ept for crim	agree that t iinal acts, in	the Dis tention year.	strict, the onal wron	school,	its emp	loyees	and agen	ts shall	be immune
Part 2: Child's Hea		. Exam. a	nd Recom	mendati	ons I To		mpleted	by lice	nsed h	ealth (	care prov	vider.	
Date of Health Exam:	BP:	,		eight:	□ LB	3	Height		□ IN	ВМ		ВМ	11 rcentile:
Vision Left eye: 20/	Rig		_ ABINE	Correct	ted	3		Wears g		$\overline{}$	eferred		Not tested
Hearing Screening: (check	k all that apply)			Pass	Fail			Not test	hat		lses Devic		Referred
Does the child have any of the following health concerns? (check all that apply and provide details below)  Asthma													
TB Assessment   Posit	tive TST should b	be referred t	o Primary Care	Physician fo	or evaluation	n. For	questions	call T.B.	Control	at 202-	698-4040		
What is the child's risk  ☐ High → complete and/or Quantiferor	skin test	Skin Test I Skin Test I Quantifer	Results:				<b>Quar</b> XR Negativ	ntiferon	Positiv	e, CXR I		☐ P	ositive, Treated
Low Results: Negative Positive Positive, Treated  Additional notes on TB test:													
Lead Exposure Risk Screening   All lead levels must be reported to DC Childhood Lead Poisoning Prevention. Call 202-654-6002 or fax 202-535-2607.													
ONLY FOR CHILDREN UNDER AGE 6 YEARS	1 <sup>st</sup> Test Date:		nust be reporte  1 <sup>st</sup> Result:	_	Abno  Developme	rmal,			all 202-	554-600	1 <sup>st</sup> Seru Stick Le	um/Fin	ger
Every child must have 2 lead tests by age 2	2 <sup>nd</sup> Test Date	: :	2 <sup>nd</sup> Result: [	Normal	Abno Developme	rmal,					2 <sup>nd</sup> Ser Stick Le		-
HGB/HCT Test Date: HGB/HCT Result:													

Part 3: Immunization Information	<b>1</b>   To be o	completed by lice	ensed health c	are provider.			
Child Last Name:		Child First Nar	me:		Date o	of Birth:	
Immunizations	In the boxe	es below, provide	the dates of im	munization (N	1M/DD/YY)		
Diphtheria, Tetanus, Pertussis (DTP, DTaP)	1	2	3	4	5		
DT (<7 yrs.)/ Td (>7 yrs.)	1	2	3	4	5		
Tdap Booster	1						
Haemophilus influenza Type b (Hib)	1	2	3	4			
Hepatitis B (HepB)	1	2	3	4			
Polio (IPV, OPV)	1	2	3	4			
Measles, Mumps, Rubella (MMR)	1	2					
Measles	1	2					
Mumps	1	2					
Rubella	1	2					
Varicella	1	2	Child had Chick Verified by:	ken Pox (mont	h & year):	(name & title)	
Pneumococcal Conjugate	1	2	3	4			
Hepatitis A (HepA) (Born on or after 01/01/2005)	1	2					
Meningococcal Vaccine	1	2					
Human Papillomavirus (HPV)	1	2	3				
Influenza (Recommended)	1	2	3	4	5	6 7	
Rotavirus (Recommended)	1	2	3				
Other	1	2	3	4	5	6 7	
The child is <b>behind on immunizations</b> at	nd there is a	plan in place to ge	t him/her back	on schedule. <b>N</b>	lext appointment	: is:	
Medical Exemption (if applicable)							
I certify that the above child has a valid medic	al contraindi	ication(s) to being i	immunized at th	ne time agains	t:		
Diphtheria Tetanus Per	tussis	Hib	П	ІерВ	Polio	☐ Measles	
☐ Mumps ☐ Rubella ☐ Var	ricella	Pneumococcal	□ н	lepA	Meningococo	cal HPV	
Is this medical contraindication pe	rmanent or	temporary?	Permanent	☐ Ter	nporary until:	(date)	
Alternative Proof of Immunity (if applicable) I certify that the above child has laboratory ev	.:			******		•-	
	_	_			_		
Diphtheria Tetanus Per	_	<b>⊿</b> Hib		lepB	■ Polio	☐ Measles	
Mumps Rubella Var	icella	Pneumococcal	П	lepA	Meningococo	al 🔲 HPV	
Part 4: Licensed Health Practitioner's Certifications   To be completed by licensed health care provider.							
This child has been appropriately examined and health history reviewed and recorded in accordance with the items specified on this form. At the time of the exam, this child is <b>in satisfactory health</b> to participate in all school, camp, or child care activities except as noted on page one.							
This child is cleared for <b>competitive sports.</b> N/A No Yes Yes, pending additional clearance from:							
	<b>—</b> 11/A	_ 110 _ 103	, <u> </u>	name addition	ar elearance from	·	_
I hereby certify that I examined this child and the information recorded here was determined as a result of the examination.							
Licensed Health Care Provider Office Stamp  Provider Name:							
Provider Phone:							
	Pr	ovider Signature:				Date:	
OFFICE USE ONLY   Universal Healt	h Certificat	e received by Sch	nool Official ar	nd Health Sui	te Personnel.		
School Official Name:	Official Name: Signature: Date:			Date:			
Health Suite Personnel Name:		Sian	ature:			Date:	

 $\textit{DC Health} \mid \textit{899 North Capitol Street, N.E., Washington, DC 20002} \mid \textit{202.442.5925} \mid \textit{dchealth.dc.gov}$ 

version 04.02.19 pg2

# EXHIBIT 2

Mask Guidance for Indoor Settings (Effective July 31, at 5 am)









### **Get Vaccinated**



Take the Shot, DC.

11/14/21, 1:58 AM Case 1:21-cv-01857-TNM Document 3 և Հաևրա File ների մեն 1/21 Page 9 of 131

## WALK-UP VACCINATION SITES FOR

**SUNDAY, NOVEMBER 14** 



FREE COVID-19 vaccine | No appointment needed.

No District-operated walk-up sites are open today. Find other opportunities to get vaccinated, including at pharmacies and clinics across all eight wards, at vaccines.gov.

Find appointments at pharmacies, clinics and health care providers across DC: Vaccines.gov

**#TakeTheShotDC #DCHOPE** 



Children 5 to 11 years old are now eligible to get vaccinated. The vaccine is safe and lowers the chance of children getting and spreading COVID-19. The vaccine is 90% effective at preventing symptoms of COVID-19. Children will receive a smaller dose of the Pfizer-BioNTech COVID-19 vaccine than adolescents and adults, approximately one-third the dose that people 12 and older get.

- Find vaccination sites for 5- to 11-year-olds
- Find walk-up vaccination sites for 5- to 11-year-olds

#### Vaccination Sites for 5- to 11- year-olds

Ward Facility Name
Ward 1Children's National
Hospital – Columbia
Heights

Address

Notes

3336 14th St. NW

https://childrensnational.org/

11/14/21, 1:58 AM	57-TNM Documenta	31/alcinateil@drahal/145/21 Page 10 of 131
Ward Facility Name	Address	Notes
Community of Hope – Marie Reed Health Center	2155 Champlain Street NW	https://www.communityofhopedc.org/healthcare
Giant Pharmacy 378	1345 Park Rd. NW	https://giantfood.com/pages/covid-info
Howard University Family	2041 Georgia Ave.	http://huhealthcare.com/healthcare/hospital/
Practice Plan	NW, 3300 Tower	coronavirus-vaccine-information
Kalorama Pharmacy	1841 Columbia Rd. NW	https://www.kaloramapharmacy.com/
Mary's Center – Ontario Road	2333 Ontario Rd. NV	V <u>https://www.maryscenter.org/</u>
Safeway Pharmacy – Columbia Road	1747 Columbia Rd. NW	https://www.safeway.com/pharmacy/covid-19.html
Unity Health Care, Inc. –	3020 14th Street NW	/ https://www.unityhealthcare.org/
Upper Cardozo Health Center		
Walgreens Store 17712	1306 U St NW	https://www.walgreens.com/topic/promotion/covid- vaccine.jsp
Ward 2Alpha Peoples Drugs	1638 R St NW STE 1	Walk In (https://www.alphapeoplesdrugs.com/)
Associates – Foggy Bottor	n 800	https://childrensnational.org/primary-care
Michelle Barnes Marshall,		
MD PC	Suite 317	
Safeway Pharmacy – Corcoran Street	1701 Corcoran St NW	https://www.safeway.com/pharmacy/covid-19.html
Safeway Pharmacy – Wisconsin Avenue	1855 Wisconsin Ave NW	https://www.safeway.com/pharmacy/covid-19.html
Ward 3Safeway Pharmacy –	5545 Connecticut	https://www.safeway.com/pharmacy/covid-19.html
Connecticut Avenue Spring Valley Pediatrics	Ave NW	http://www.springvalleypediatrics.net/
Spring valley rediatries	Ave, NW, Suite 200	<u>nttp.//www.springvalleypediatries.net/</u>
Walgreens Store 4445	3301 New Mexico	https://www.walgreens.com/topic/promotion/covid-
	Ave. NW	<u>vaccine.jsp</u>
Ward 4Children's National		https://childrensnational.org/
Hospital – Shepherd Park		
Mary's Center – Georgia	3912 Georgia	https://www.maryscenter.org/
Avenue	Avenue NW	https://www.cofo.vov.com/phorpo.co/covid 10 html
Safeway Pharmacy – Georgia Avenue	3830 Georgia Ave NW	https://www.safeway.com/pharmacy/covid-19.html
Safeway Pharmacy – Pine Branch		https://www.safeway.com/pharmacy/covid-19.html
Ward 5Children's National	111 Michigan Ave	https://childrensnational.org/
Hospital	NW	

	Address	Notes
Community of Hope Family Health & Birth	801 17th Street NE	https://www.communityofhopedc.org/healthcare
	4440.	
	NE Suite 200	https://www.curacapitol.com/
Mary's Center – Ft. Totten	100 Gallatin St NE	https://www.maryscenter.org/
Safeway Pharmacy – Maryland Avenue	1601 Maryland Ave NE	https://www.safeway.com/pharmacy/covid-19.html
Unity Health Care, Inc. –		https://www.unityhealthcare.org/
		https://childrensnational.org/
	041 5 Street NVV	TICEPS.// CHIIGI CHISHACIONAI.OI g/
•	326 F Capitol St NF	https://www.grubbspharmacy.com/
·	•	https://healthy.kaiserpermanente.org/maryland-
·	1700 ZHA SCINE	virginia-washington-dc/health
11111		-wellness/coronavirus-information/vaccine-
		<u>appointments</u>
Perry School	128 M Street NW	https://www.perryschool.org/
•	#50	
Safeway Pharmacy – 4th Street	1100 4th St SW	https://www.safeway.com/pharmacy/covid-19.html
Safeway Pharmacy – 14th Street	415 14th St SE	https://www.safeway.com/pharmacy/covid-19.html
Safeway Pharmacy – L Street	490 L St NW	https://www.safeway.com/pharmacy/covid-19.html
	3839 1/2 Alabama	https://childrensnational.org/primary-care
		•
Safeway Pharmacy –	322 40th St NE	https://www.safeway.com/pharmacy/covid-19.html
	2845 Alahama Ave	https://www.safeway.com/pharmacy/covid-19.html
		nteps.//www.sareway.com/pnarmacy/covia_rs.ntm
		https://www.unityhealthcare.org/
•	•	rice ps.// www.armeyrreaterrear e.or. 8/2
		https://www.unityhealthcare.org/
•		rice ps.// www.arricy/realtricure.or.8/
		https://www.unityhealthcare.org/
	Terrace NE	
Parkside		
Parkside 8Children's National		https://childrensnational.org/
<b>8</b> Children's National	2101 Martin Luther	https://childrensnational.org/
	2101 Martin Luther King Jr Ave SE	https://childrensnational.org/
	Facility Name Community of Hope Family Health & Birth Center CuraCapitol  Mary's Center – Ft. Totten Safeway Pharmacy – Maryland Avenue Unity Health Care, Inc. – Brentwood 6Children's National Hospital – Shaw Grubb's Pharmacy Kaiser Permanente Capito Hill  Perry School  Safeway Pharmacy – 4th Street Safeway Pharmacy – 14th Street Safeway Pharmacy – L Street 7Children's Pediatricians & Associates – Fort Davis Elaine Ellis Center of Health	Facility Name Community of Hope Family Health & Birth Center CuraCapitol  Mary's Center - Ft. Totten Safeway Pharmacy - Brentwood  Hospital - Shaw Grubb's Pharmacy  Kaiser Permanente Capitol 700 2nd St NE Hill  Perry School  Safeway Pharmacy - Hospital - Shaw Grubb's Pharmacy  Safeway Pharmacy - Hill  Perry School  Hill  Perry School  Safeway Pharmacy - Hill  Perry School  Hill  Hill  Perry School  Hill  Perry School  Hill  Hill  Hill  Perry School  Hill  Hill  Hill  Hill  Per

11/14/21, 1:58 AM Case 1:21-cv-01857-TNM Document@dvalcina@itedrolal/dis/21 Page 12 of 131

Ward Facility Name Address Notes

Community of Hope 4 Atlantic Street SW <a href="https://www.communityofhopedc.org/healthcare">https://www.communityofhopedc.org/healthcare</a>

Conway Health & Resource Center

Family and Med 2041 Martin L. King <a href="https://www.fmcsinc.org/">https://www.fmcsinc.org/</a>

Counseling Jr. Ave. SE, Suite 303

Giant #384 1535 Alabama Ave. <a href="https://giantfood.com/pages/covid-info">https://giantfood.com/pages/covid-info</a>

SE

Unity Health Care, Inc. – 1500 Galen St SE <a href="https://www.unityhealthcare.org/">https://www.unityhealthcare.org/</a>

Anacostia

#### Walk-Up Clinics for Children 5-11 Years Old through November 20

Unable to bring your child to the District's pop-up vaccination site yourself? Print and sign the <u>Trusted Party Consent and Verification Forms</u> so someone you trust can be present when your child receives their vaccination. Please note that the Trusted Party MUST bring an ID in order for your child to be vaccinated. Please complete one form per child.

Formulario de consentimiento y verificación para vacunación contra COVID-19/Coronavirus

#### 250 doses per site | First come, first served

#### Friday, November 5

- Ft. Stanton Recreation Center (1812 Erie Street SE) (Pfizer, Ages 5-11) (3:30pm)
- Takoma Community Center (300 Van Buren Street NW) (Pfizer, Ages 5-11) (3:30pm)

#### Saturday, November 6

• Hillcrest Recreation Center (3100 Denver St SE) (Pfizer, Ages 5-11) (10am)

#### Sunday, November 7

- Palisades Recreation Center (5200 Sherier Pl NW) (Pfizer, Ages 5-11) (10am)
- North Michigan Park Recreation Center (1333 Emerson St NE) (Pfizer, Ages 5-11) (10am)

#### Monday, November 8

- Noyes Elementary School (2725 10th St NE) (Pfizer, Ages 5-11) (3:30pm)
- Ingenuity Prep Public Charter School/Statesman Academy (4600 Livingston Rd SE) (Pfizer, Ages 5-11) (3:30pm)
- Dorothy I. Height Elementary School (1300 Allison St NW) (Pfizer, Ages 5-11) (3:30pm)

#### Tuesday, November 9

• Kimball Elementary School (3375 Minnesota Ave SE) (Pfizer, Ages 5-11) (3:30pm)

11/14/21, 1:58 AM Case 1:21-cv-01857-TNM Document@1valcinafeiledrolal/f15/21 Page 13 of 131

- Bancroft Elementary School (1755 Newton St NW) (Pfizer, Ages 5-11) (3:30pm)
- Center City Public Charter School Brightwood Campus (6008 Georgia Ave NW) (Pfizer, Ages 5-11) (3:30pm)

#### Wednesday, November 10

- Patterson Elementary School (4399 South Capitol Terrace SW) (Pfizer, Ages 5-11) (3:30pm)
- Kennedy Recreation Center (1401 7th St NW) (Pfizer, Ages 5-11) (3:30pm)
- KIPP DC Heights Academy (2600 Douglass Rd SE) (Pfizer, Ages 5-11) (3:30pm)

#### Thursday, November 11

• Clinics closed in observance of Veterans Day

#### Friday, November 12

- Sela Public Charter School (6015 Chillum Pl. NE) (Pfizer, Ages 5-11) (9am)
- Marie Reed Elementary School (2201 18th St NW) (Pfizer, Ages 5-11) (3:30pm)
- Friendship Blow Pierce Elementary & Middle (725 19th St. NE) (Pfizer, Ages 5-11) (3:30pm)
- Thomson Elementary School (1200 L St NW) (Pfizer, Ages 5-11) (3:30pm)

#### Saturday, November 13

- Ben Murch Elementary School (4810 36th St NW) (Pfizer, Ages 5-11) (10am)
- Payne Elementary School (1445 C St SE) (Pfizer, Ages 5-11) (10am)
- Smothers Elementary School (1300 44th St NE) (Pfizer, Ages 5-11) (10am)

#### Sunday, November 14

• No pediatric walk-up clinics

#### Monday, November 15

No pediatric walk-up clinics

#### Tuesday, November 16

- Palisades Recreation Center (5200 Sherier Pl NW) (Pfizer, Ages 5-11) (3:30pm)
- KIPP DC LEAD Academy PCS (421 P St NW) (Pfizer, Ages 5-11) (3:30pm)
- Excel Academy Public School (2501 Martin Luther King Jr Ave SE) (Pfizer, Ages 5-11) (3:30pm)

#### Wednesday, November 17

- Plummer Elementary School (4601 Texas Ave SE) (Pfizer, Ages 5-11) (3:30pm)
- Garrison Elementary School (1200 S St NW) (Pfizer, Ages 5-11) (3:30pm)

• Center City Public Charter School - Trinidad Campus (1217 West Virginia Ave NE) (Pfizer, Ages 5-11) (3:30pm)

#### Thursday, November 18

- Bunker Hill Elementary School (1401 Michigan Ave NE) (Pfizer, Ages 5-11) (3:30pm)
- Center City Public Charter School: Congress Heights (220 Highview Pl SE) (Pfizer, Ages 5-11) (3:30pm)
- E.L Haynes Public Charter School (4501 Kansas Ave NW) (Pfizer, Ages 5-11) (3:30pm)

#### Friday, November 19

- Thomas Elementary School (650 Anacostia Ave NE) (Pfizer, Ages 5-11) (3:30pm)
- Lafayette Elementary School (5701 Broad Branch Rd NW) (Pfizer, Ages 5-11) (3:30pm)
- Janney Elementary School (4130 Albemarle St NW) (Pfizer, Ages 5-11) (3:30pm)

#### Saturday, November 20

- Whittier Elementary School (6201 5th St NW) (Pfizer, Ages 5-11) (10am)
- Turner Elementary School (3264 Stanton Rd SE) (Pfizer, Ages 5-11) (10am)
- DC Bilingual Public Charter School (33 Riggs Road NE) (Pfizer, Ages 5-11) (10am)

#### Weekly Walk-Up Locations for Anyone 12 and Older

Walk-Up Site	Address	Normal Days / Hours	Vaccine
Fort Stanton Recreation Center * \$51 gift card & giveaway site	1812 Erie Street, SE	Tuesday and Wednesday: 10 am - 6 pm	Pfizer (Ages 12+)
gire cara a giveaway site	30 000, 32	Thursday: 12 pm - 6 pm Saturday: 12 pm - 5 pm	Moderna (Ages 18+)
		Last walk-ups will be accepted 15 minutes prior to clinic closure.	Flu Shots (Ages 3+)
		Last day: December 31, 2021	
Dorothy Height/Benning Library *\$51 gift card & giveaway site	3935 Benning Road, NE	Tuesday and Wednesday: 11 am - 5:30 pm Thursday: 12 pm - 6 pm Saturday: 12 pm - 5 pm Last walk-ups will be accepted 15 minutes prior to clinic closure. Last day: December 31, 2021	Pfizer (Ages 12+) Johnson & Johnson (Ages 18+) Moderna (Ages 18+)
			Flu Shots (Ages 3+)

11/14/21, 1:58 AM	NM Documei	nt@dvalcinaTeiledrahal/da5/21 Page 15 of	131
Walk-Up Site	Address	Normal Days / Hours	Vaccine
Columbia Heights Educational Campu * \$51 gift card & giveaway site	s 3101 16th Si NW	t Tuesday and Thursday: 2 pm – 6 pn Saturday: 10 am – 2 pm Last walk-ups will be accepted 15 minutes prior to clinic closure. Last day: November 20, 2021	Moderna (Ages 12+) Moderna (Ages 18+) Flu Shots (Ages 3+)

Find other opportunities to get vaccinated today, including at pharmacies and clinics across all eight wards, at <u>vaccines.gov</u>

Can't leave your home? Call 1-855-363-0333 and we'll come to you!

For any questions regarding the vaccine program, please email vaccinatedc@dc.gov.

Don't Wait. Vaccinate!

• Check the status of the wait times at the walk-up sites at coronavirus.dc.gov/dontwait.

# Vaccine Exchange Program for District Employers and Community-Based and Faith-Based Organizations to Host a Vaccine Clinic for Employees or Members

The Vaccine Exchange Program connects District organizations, including faith-based and community-based organizations as well as District employers, with vaccine providers that can assist with providing COVID-19 vaccinations to large groups in the community or workplace. Through the program, organizations are now able to submit requests for a vaccine clinic and vaccine providers are able to accept those requests and schedule clinics. <u>Organizations interested in offering a vaccination clinic can submit a request here</u>.

#### **Veterans**

• DC Veterans and spouses can call the <u>DC VA Medical Center</u> to schedule appointment at (202) 745-4342.

#### **Hospital Patients**

#### **Schedule a Hospital Appointment**

- <u>Children's National Hospital</u>
- Howard University Hospital
- MedStar Georgetown University Hospital

11/14/21, 1:58 AM Case 1:21-cv-01857-TNM Document@1valcinafeiledrohal/115/21 Page 16 of 131

- MedStar Washington Hospital Center
- GW Medical Faculty Associates
- United Medical Center
- Kaiser Permanente members should visit <u>kp.org/DCvaccine</u> for the latest information on COVID vaccines.

#### **Schedule a Health Center Appointment**

If you are a patient at one of the following health centers, please contact them to see if there is any schedule availability for appointments.

- Mary's Center please visit website
- Community of Hope please call (202) 470-3081
- <u>Unity (Upper Cardoza)</u> please visit eCW portal, website, or call (202) 469-4699
- <u>Unity (Brentwood)</u> please visit eCW portal, website, or call (202) 469-4699
- Bread for the City please visit eCW portal or our website
- La Clinica del Pueblo please visit website
- Elaine Ellis Center of Health please call (202) 803-2340
- Whitman-Walker Health please visit website
- Family and Medical Counseling Service, Inc please call (202) 889-7900
- Providence Health System please visit website or call (202) 854-7629
- Metro Health Center please visit website

#### **Need Transportation?**

The District's Medicaid Managed Care Organizations (MCOs) cover all transportation (free of charge), to and from, all medically necessary covered services and appointments. To request transportation, the Enrollee should call the following number to schedule the service:

- AmeriHealth Caritas DC | Call 1-800-315-3485. Rides available 24 hours a day, 7 days a week
- CareFirst Community Health Plan DC | Call MTM1 at 1-855-824-5693. Rides available 24 hours a day, 7 days a week
- Health Services for Children with Special Needs | Call SET Transportation at 1-866-991-5433
- MedStar Family Choice DC | Call 1-866-201-9974

Sign up to get vaccine updates here

Learn more about the COVID-19 vaccines



**Additional Websites** 

**Resources** 

Guides

Videos

CDC

**US State Department** 

DC Health

**HSEMA** 

Mayor

Tax & Revenue

Accessibility Privacy & Terms

# EXHIBIT 3

Mask Guidance for Indoor Settings (Effective July 31, at 5 am)









Children 5 to 11 years old are now eligible to get vaccinated. The vaccine is safe and lowers the chance of children getting and spreading COVID-19. The vaccine is 90% effective at preventing symptoms of COVID-19. Children will receive a smaller dose of the Pfizer-BioNTech COVID-19 vaccine than adolescents and adults, approximately one-third the dose that people 12 and older get.

Booster shots are now available for residents who are over 65 years of age; 18 years and older with an underlying medical condition; a resident of a Long-Term Care Facility; or 18-64 years of age with increased risk for COVID-19 exposure and transmission because of occupational or institutional settings AND received your second dose of Pfizer or Moderna vaccine on or before May 12, 2021.

Booster shots are now available for residents who are 18 and older and received a Johnson and Johnson vaccination on or before September 9, 2021.

> Find a Booster or Child Vaccination Location Near You

## **DC COVID-19 Vaccination Data**

DC Residents

ESSIVMANEDO CARGE DE BARO EMRO LAGAY

ADRUNUS DERBUS BANASIDE DEC

The DC Government urges you to help flatten the curve:

- Get Vaccinated
- Practice social distancing
- Wear a mask or face covering
- Wash your hands
- Stay home if you feel sick

On this site, we also have have information on how to register for vaccination, testing resources, funeral assistance, help with rent, help with utilities, food resources, resources for businesses and individuals, operating status of DC Government, and more. Please bookmark and share this portal with your community.

## What You Should Know

## **How to Protect Yourself**

**Get Vaccinated** 



- Wash hands with soap and water for at least 20 seconds multiple times a day. An alcohol-based hand sanitizer can be used if soap and water are not available
- Avoid touching eyes, nose and mouth with unwashed hands
- Avoid close contact with people who are sick
- Stay home when feeling sick
- Cover your cough or sneeze with a tissue, then throw the tissue in the trash
- Clean and disinfect frequently touched objects and surfaces

**FAQs** 

# I Have Symptoms What Should I Do?

The symptoms that are currently being seen with COVID-19 are cough, fever, headache, new loss of taste or smell, repeated shaking with chills, sore throat, shortness of breath, and muscle pain.

- Stay home and self-quarantine until you are free of fever, signs of a fever, and any other symptoms for at least 24 hours and without the use of fever-reducing or other symptom-altering medications.
  - Seek medical attention if you have reason to believe you have been exposed to coronavirus or influenza. Call your healthcare provider before visiting a healthcare facility.

**COVID-19 Toolkit** 

### **Coronavirus Testing**

### **Pre-registration for Public Testing**

It's best to get testing through your provider, but if you need to use public testing, you can save time in line by visiting <u>coronavirus.dc.gov/register</u> to create a profile from your smartphone, tablet, or computer.

# Unemployment Benefits

With Mayor Bowser adjusting the District of Columbia's operating status in response to coronavirus (COVID-19), **District residents may file for unemployment compensation.**More information on how to file available at <u>Recovery</u>

# COVID-19 Resources in Your Language

Press Releases

Newsletters

11/12/2021 Coronavirus Data for November 10-11, 2021

11/12/2021 Public Notice: Payment Delays

11/10/2021 Coronavirus Data for November 9, 2021

11/09/2021 Coronavirus Data for November 8, 2021

11/08/2021 Coronavirus Data for November 5-7, 2021

More »



**Additional Websites Resources** 

CDC Guides

Videos **US State Department** 

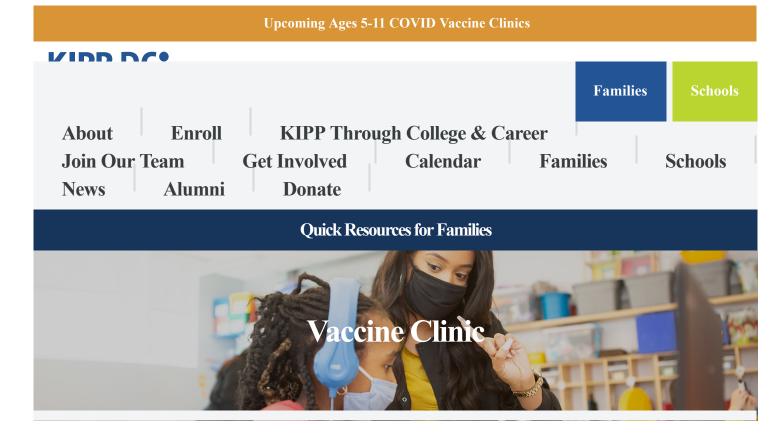
DC Health

**HSEMA** 

Mayor

Tax & Revenue

Accessibility Privacy & Terms



KIPP DC is committed to it's students, families, and staff having access to the COVID-19 vaccine. Below are upcoming vaccination clinics hosted by KIPP DC and open to students, families and staff. For a full list of COVID vaccine locations, search
vaccine.gov's database. Once fully vaccinated, please remember to submit your vaccine card to KIPP DC's human resources or athletics department to be compliant with current District polices.

### **COVID VACCINE FAQS**

Alternate Ages 5-11 Vaccination Clinics

If you are unable to accompany your child, you may fill out this form and send your child with a trusted adult to the clinic. If you need a print copy of the form, reach out to your child's teacher and they can print it and send it home in your child's backpack.

### **Clinics for Ages 12+**

## **Tuesday, November 16 3:30 pm – 7:30 pm**

NOTE: Please only sign your child up if they are between the ages of 5 and 11.

"\*" indicates required fields

### **Information on Person Being Vaccinated**

Please fill out this form/register for each person getting vaccinated

Child's Name*	
First	
Last	
Parent/Guardian Phone *	
Tareno Guardian Fnonc	
Parent/Guardian Email *	
Tareno Guardian Eman	
Child's Date of Birth *	
mm/dd/yyyy	
KIPP DC School *	
MITI De School	

REGISTER

Contact Us

Procurement

**Public Information** 

KIPP DC Staff Portal

Media

Forms & Policies

Title IX

**COVID** Data

STAY CONNECTED



KIPP DC Headquarters · 2600 Virginia Ave NW · Suite 900 · Washington, DC 20037 · Phone: 202-265-5477

© Copyright 2020 KIPP DC Public Charter School. All Rights Reserved.

DESIGNED BY SUNDARAM





Need help finding a COVID-19 vaccine in the U.S.? Call <u>1-800-232-0233</u> (TTY <u>888-720-7489</u>)

## Find COVID-19 Vaccines Powered by VaccineFinder 5-digit Zip Code Zip Code **Search Radius** 25 miles **Vaccine Options** Pfizer-BioNTech (age 5-11) Moderna (age 18+) ☐ Pfizer-BioNTech (age 12+) Johnson & Johnson/Janssen (age 18+) Search for COVID-19 Vaccines

<u>I'm looking for flu vaccines</u> →

Exhibit 5<sub>1/3</sub>







11/12/21, 8:13 PM Case 1:21-cv-01857-TNM Document -31 for File to 11/12/21 (actionage 32 of 131

Contact Us

COVID-19 Vaccine FAQ

Provider Resources

Privacy

CDC Website Exit Disclaimer

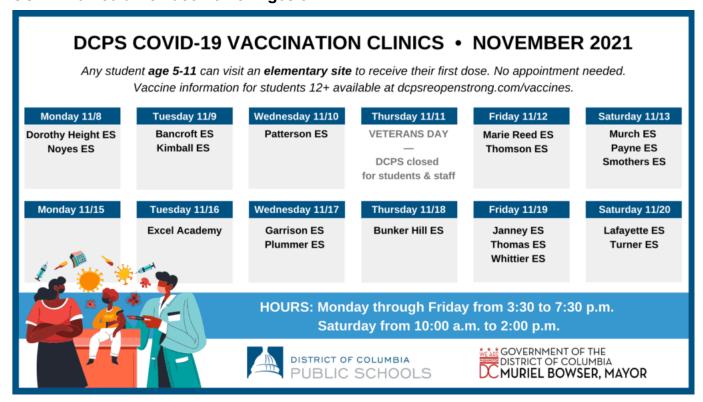
Nondiscrimination

### **Vaccinations for Students**

#### Jump to Section

- COVID-19 Pediatric Vaccine for Ages 5-11
- COVID-19 Vaccine for Ages 12+ and Student-Athlete Requirement
- · Incentives for Youth Who Receive the COVID-19 Vaccine
- · Childhood Immunizations and Wellness Exams
- · COVID-19 Vaccine: Family FAQ

#### **COVID-19 Pediatric Vaccine For Ages 5-11**





The COVID-19 vaccine is the best way for us to help stop the spread of the virus and keep our community safe. On November 2, the Centers for Disease Control and Prevention (CDC) announced that children ages 5 and older are now eligible to receive the pediatric Pfizer-BioNTech vaccine. We encourage all DCPS families to take the life-saving step of getting the vaccine as soon as possible.

The COVID-19 vaccine is safe, effective, and free. The Pfizer-BioNTech's COVID-19 vaccine for children 5-11 years old will be available at more than 60 pharmacies, hospitals, and health centers (https://mayor.dc.gov/release/mayor-bowser-and-dc-health-encourage-families-get-children-5-11-years-old-vaccinated-against) as well as health clinics throughout the community, including at DCPS locations across all eight wards.

School Clinic (5-11 year olds)	Address	Ward	1st Dose Date	Hours
Dorothy I. Height Elementary School	1300 Allison St NW	4	Monday, November 8, 2021	3:30 to 7:30 pm
Noyes Elementary School	2725 10th St NE	5	Monday, November 8, 2021	3:30 to 7:30 pm
Bancroft Elementary School	1755 Newton St NW	1	Tuesday, November 9, 2021	3:30 to 7:30 pm
Kimball Elementary School	3375 Minnesota Ave SE	7	Tuesday, November 9, 2021	3:30 to 7:30 pm
Patterson Elementary School	4399 South Capitol Terrace SW	8	Wednesday, November 10, 2021	3:30 to 7:30 pm
Marie Reed Elementary School	2201 18th St NW	1	Friday, November 12, 2021	3:30 to 7:30 pm
Thomson Elementary School	1200 L St NW	2	Friday, November 12, 2021	3:30 to 7:30 pm
Ben Murch Elementary School	4810 36th St NW	3	Saturday, November 13, 2021	10:00 am to 2:00 pm
Payne Elementary School	1445 C St SE	6	Saturday, November 13, 2021	10:00 am to 2:00 pm
Smothers Elementary School	1300 44th St NE	7	Saturday, November 13, 2021	10:00 am to 2:00 pm
Excel Academy Public School	2501 Martin Luther King Jr Ave SE	8	Tuesday, November 16, 2021	3:30 to 7:30 pm

#### 11/14/21, 12:58 PM Case 1:21-cv-01857-TNM Documenting the student entering the student student entering the studen

Garrison Elementary School	1200 S St NW	2	Wednesday, November 17, 2021	3:30 to 7:30 pm
Plummer Elementary School	4601 Texas Ave SE	7	Wednesday, November 17, 2021	3:30 to 7:30 pm
Bunker Hill Elementary School	1401 Michigan Ave NE	5	Thursday, November 18, 2021	3:30 to 7:30 pm
Janney Elementary School	4130 Albemarle St NW	3	Friday, November 19, 2021	3:30 to 7:30 pm
Thomas Elementary School	650 Anacostia Ave NE	7	Friday, November 19, 2021	3:30 to 7:30 pm
Whittier Elementary School	6201 5th St NW	4	Friday, November 19, 2021	3:30 to 7:30 pm
Lafayette Elementary School	5701 Broad Branch Rd NW	4	Saturday, November 20, 2021	10:00 am to 2:00 pm
Turner Elementary School	3264 Stanton Rd SE	8	Saturday, November 20, 2021	10:00 am to 2:00 pm

Parents who are unable to bring their child to a clinic will have the option to <u>print and sign a form</u> (<a href="https://coronavirus.dc.gov/sites/default/files/dc/sites/coronavirus/page\_content/attachments/PopUpConsentFINAL.pdf">https://coronavirus.dc.gov/sites/default/files/dc/sites/coronavirus/page\_content/attachments/PopUpConsentFINAL.pdf</a>), allowing a trusted family member to accompany their child to the pop-up vaccine clinics. The trusted family member should bring the printed forms along with a photo ID.

Getting your child vaccinated will help keep your student safe and in the classroom, where we know students learn best. Students who are fully vaccinated do not need to quarantine if they come in close contact with someone in or outside of the school who tests positive for COVID-19. Learn more about our health and safety measures when there is a COVID-19 case at school at <a href="decirity-depreopenstrong.com/health/response/">depreopenstrong.com/health/response/</a>).

### COVID-19 Vaccine For Ages 12+ And Student-Athlete Requirement



#### 11/14/21, 12:58 PM Case 1:21-cv-01857-TNM Documenting the studentee ob and studentee of the studentee of the

Per Mayor's Order, any DCPS student age 12 and older participating in any school-based extracurricular athletics must be <u>fully vaccinated against</u> <u>COVID-19 (https://45biv636w8lm1agg3ozqtqg1-wpengine.netdna-ssl.com/wp-content/uploads/2021/10/Get-Vaccinated-by-November-1.pdf)</u>, unless the student-athlete has received a religious or medical exemption. This applies to all fall, winter, and spring sports.

Student athletes who are age 12 or older have until December 1, 2021, to submit paperwork confirming they have received a full course of vaccination against COVID-19. Students who have not yet been vaccinated should use this time to receive the COVID-19 vaccine. If a student athlete needs both doses of the COVID-19 vaccine, they should receive their first dose no later than Tuesday, November 9 to ensure they have time to receive both doses by December 1.

In November, students 12 and older can visit the following DCPS school vaccination clinics or find location at <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a>).

Vaccination Site for Students and Residents Ages 12+	Address	Ward	Dates	Hours
Columbia Heights Education Campus (Youth Incentive Site)	3101 16th St NW	1	Tuesday and Thursday and Saturday	2:00 to 6:00 p.m. on weekdays 10:00 to 2:00 p.m. on Saturdays
Roosevelt High School	4301 13th St NW	4	Saturday, November 6, 2021	10:00 a.m. to 2:00 p.m.
Ballou High School	3401 4th St SE	8	Saturday, November 6, 2021	10:00 a.m. to 2:00 p.m.
McKinley High School	151 T St NE	5	Saturday, November 13, 2021	10:00 a.m. to 2:00 p.m.
HD Woodson High School	540 55th St NE	7	Saturday, November 13, 2021	10:00 a.m. to 2:00 p.m.

#### **FAQ For Student Athletes**

#### What happens after December 1?

- Student athletes who have not received a full course of vaccination against COVID-19 are to be excluded from all school-based
  extracurricular athletics, including tryouts, practices, drills, conditioning, and competitions (including fall playoffs and championships) until
  they provide proof of a full course of vaccination.
- Student athletes will need to have exemption requests processed and approved BEFORE beginning to play, or they are to be excluded from playing until either their exemption request is approved, or they show proof of a full course of vaccination.
- For student athletes who turn 12 years old after November 1, 2021, the deadline for vaccination is two months after their birthday. This means they should be vaccinated as soon as possible after their 12th birthday.

#### How can student athletes submit their proof of COVID-19 vaccination?

- Students who have received two doses of the vaccine should provide a photocopy of their COVID-19 vaccination card to their school's
   Athletic Director. If you are 18 years or older and received the one-dose Johnson & Johnson COVID-19 vaccine, please complete this step
   as well.
- Lost or misplaced your COVID-19 vaccination card? You can securely download a copy online at <a href="https://dchealth.dc.gov/page/dc-myir">https://dchealth.dc.gov/page/dc-myir</a>).

#### How can student athletes apply for a religious or medical exemption from receiving the COVID-19 vaccine?

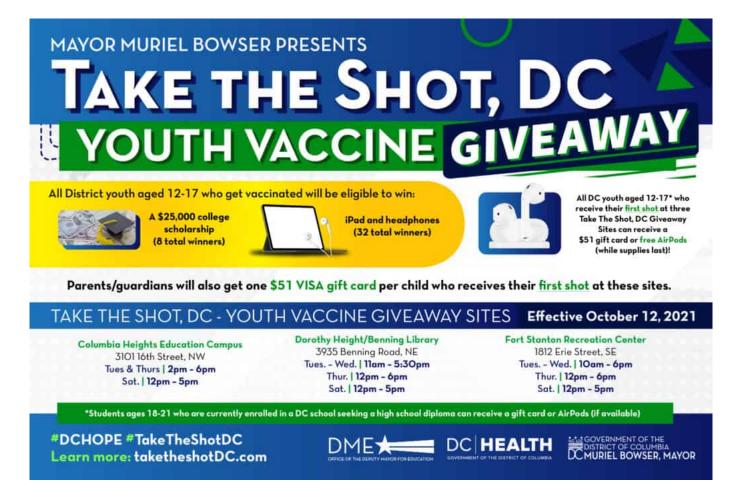
- The deadline for student-athletes to submit a medical or religious exemption for review prior to December 1 is Monday, November 15.
- Parents or guardians of students wishing to request a religious exemption are strongly encouraged to utilize the electronic submission
  process <u>OSSE COVID-19 Vaccine Religious Exemption Form For Student Athletes (https://dcgov.seamlessdocs.com/f/g2r91x2ltx84)</u>.
   Students must express a deeply held religious belief that precludes them from vaccination for COVID-19. Forms completed online will be
  automatically shared with the DCIAA office for review. The <u>COVID-19 Vaccination Religious Exemption Certificate</u>

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page\_content/attachments/COVID-

19%20Vaccine%20Religious%20Exemption%20Form%20For%20Student%20Athletes%2010.15.21.pdf) can also be submitted to your child's school-based Athletic Director. The Athletic Director will screen the form prior to submitting it to the DCPS Athletics Department. Forms will generally be reviewed within 5 business days of receipt.

• To request a medical exemption, students must present a signed note or form from a doctor\* stating that no COVID-19 vaccine is medically advisable due to a person's medical condition. The signed doctor's note or form must contain the physician's contact information and submitted to your student's Athletic Director. The Athletic Director will submit the doctor's note to the DCPS Athletics Department for review.

#### Incentives For Youth Who Receive The COVID-19 Vaccine



Youth vaccination incentives are available to students ages 12-17 who receive their first shot at the three sites above. Students can receive a \$51 gift card or a pair of AirPods by receiving their first shot, while supplies last In addition, all students in DC who are eligible to receive the COVID-19 vaccine will also be eligible to win an iPad or a \$25,000 college scholarship.

Visit <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a>) to learn more about the COVID-19 vaccine.

#### **Childhood Immunizations And Wellness Exams**

## **Put Vaccines On Your** Back-to-School List

Vaccines are the best protection against vaccine-preventable diseases.

All DC students must have their immunizations up-to-date before the next school year begins. The COVID-19 vaccine is also available for eligible age groups.

dchealth.dc.gov/immunizations



#### **Immunization One-Pager for Families**

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page\_content/attachments/Immunization\_Flyer\_update\_052521\_FINAL.pdf) (May 2021)

Español (https://osse.dc.gov/sites/default/files/dc/sites/osse/page content/attachments/Immunization Flyer update 032921-en-es-R-C.pdf)l Amharic (አማርኛ)

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page\_content/attachments/Immunization\_Flyer\_update\_032921-en-am-T-C.pdf) | French (Français)

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page\_content/attachments/lmmunization\_Flyer\_update\_032921-en-fr-T-C.pdf) | Vietnamese (Tiếng Việt)

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page\_content/attachments/Immunization\_Flyer\_update\_032921-en-vi-T-C.pdf) I Korean (한국어)

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page content/attachments/Immunization Flyer update 032921-en-ko-T-C.pdf) I Chinese (中文)

(https://osse.dc.gov/sites/default/files/dc/sites/osse/page content/attachments/Immunization Flyer update 032921-en-zh cn-T-C.pdf)

DC Public Schools encourages you to visit your family's pediatrician for your student's annual wellness exam. Scheduling an appointment with your child's doctor will help make sure your child is up-to-date on important immunizations to prevent illness.

DC law requires that families submit their student's immunization record by the twentieth day at school. To see a list of required immunizations for your child, visit dchealth.dc.gov/immunizations (https://t.e2ma.net/click/t5d62h/xsquxmu/d56zfqc).

If you have not already submitted your child's immunization records, here is what you need to do now:

- · Step 1: Make an appointment with your child's doctor. DC offers resources to help you find a health provider (https://dcgis.maps.arcgis.com/apps/webappviewer/index.html?id=c7207c4eb04b4ddfa46042e9da6267cf) or if you do not have health insurance.
- Step 2: Have the doctor complete DC's Universal Health Certificate, available here (https://dchealth.dc.gov/sites/default/files/dc/sites/doh/service content/attachments/DOH%20Universal%20Health%20Certificate 2019 0.pdf). Your health provider may also provide a different proof of immunization document or an exemption explanation.
- · Step 3: Submit your paperwork to your child's school. You can drop it off at your school or call the school's main office to if you have questions about how to submit your form.

**COVID-19 Vaccine: Family FAQ** 

#### 11/14/21, 12:58 PM Case 1:21-cv-01857-TNM Documents of Studenterile ob and State and S

#### Q: What is the Pediatric Vaccination Program for 5-11 Years Old Children?

A: The DC Health Pediatric Vaccination Program for 5- to 11-Year-Old Children is an initiative to provide COVID-19 vaccinations to children ages 5-11 years old. This program involves partnerships with DC Health and over 40 different facilities, including District of Columbia Public Schools, District of Columbia Public Charter Schools, Department of Parks and Recreation Centers, and other community-based sites.

#### Q: Who can receive a COVID-19 vaccine through this program?

A: At this time, only District residents ages 5-11 will be offered the pediatric COVID-19 vaccine through this program.

### Q: Can parents/guardians/other family members over 12 years of age receive the COVID-19 vaccine onsite at a DCPS elementary school?

A: No. At this time, only District residents ages 5-11 will be offered the pediatric COVID-19 vaccine. Residents 12 years or older can visit the Columbia Heights Education Campus vaccination clinic or other sites available around the city. For the full list, visit <a href="https://coronavirus.dc.gov/page/get-vaccinated">https://coronavirus.dc.gov/page/get-vaccinated</a>) or vaccines.gov for convenient locations across the District.

#### Q: Do families need to schedule an appointment to receive the COVID-19 vaccine?

A: No. DCPS COVID-19 vaccination clinics are walk-up sites and no appointment is necessary.

#### Q. What COVID-19 vaccine is available to students who are 5-11 years old?

A: The Pfizer-BioNTech pediatric vaccine is the only COVID-19 vaccine currently available for children ages 5-11. Similar to what was seen in adult vaccine trials, vaccination was nearly 91 percent effective in preventing COVID-19 among children aged 5-11 years. In clinical trials, vaccine side effects were mild, self-limiting, and similar to those seen in adults and with other vaccines recommended for children. The most common side effect was a sore arm.

#### Q: Who will be providing vaccinations to students?

A: DC Health will serve as the clinical provider at all pediatric clinics in the program, including those at DC Public School locations. A trained pediatric medical professional will administer the vaccine.

#### Q: Will children require a parent/guardian for consent to receive vaccines?

A: Yes. Per provider requirements, children ages 17 and under must be accompanied by a parent or legal guardian, who must sign a COVID-19 Immunization Screening and Consent Form for each child receiving a vaccination. Please bring proof of identification and / or DC residency to the clinic site. Parents/legal guardians who are unable to bring their child will have the option to print and sign an additional Trusted Party Consent and Verification Form allowing a trusted family member to accompany their child to the pop-up vaccine clinics; these forms will be made available on coronavirus.dc.gov. This trusted family member must be at least 18 years of age and provide valid personal identification at the clinic.

#### Q: How will children receive their second dose of Pfizer?

A: The clinical provider will schedule the second dose appointment on-site. This second dose will be scheduled 21 days following the first dose at the same location as the first dose. Parents have the additional option of completing the second dose through a different provider/program.

#### Q: What if my child feels unwell after getting vaccinated and needs to miss a day of school?

A: If your student does not feel well after receiving their vaccination, please contact your pediatrician or healthcare provider for any medical questions or concerns. If your student will miss school due to not feeling well, please submit a note so that the absence will be excused. Additionally, please be sure to connect with your child's teacher to access any assignments, programs, or activities that may be appropriate to support learning at home.

#### Q: How much will the immunizations cost?

A: The COVID-19 vaccine is free. It will not require out of pocket costs or bills to the family.

#### Q: I have questions about the COVID-19 vaccine for my child. Who can I talk to?

#### 11/14/21, 12:58 PM Case 1:21-cv-01857-TNM Documentin 3 for \$tuderite ob and keylen strongge 41 of 131

A: For any questions about pediatric clinic options and the COVID-19 vaccine, email <a href="mailto:vaccinatedc@dc.gov">vaccinatedc@dc.gov</a> (mailto:vaccinatedc@dc.gov) or call the DC COVID-19 Call Center at 1-855-363-0333.

Children's National also has helpful resources for families who have questions about vaccinating children to protect them from COVID-19. Visit <a href="https://childrensnational.org/visit/resources-for-families/wellness-resources/coronavirus/vaccine-faqs">https://childrensnational.org/visit/resources-for-families/wellness-resources/coronavirus/vaccine-faqs</a> for information in English and Spanish.

Page updated: November 4, 2021

Address: District of Columbia Public Schools

1200 First Street Washington, DC 20002

Phone: (202) 442-5885



(https://dcps.dc.gov/)



En español (https://dcpsreopenstrong.com

(https://dcpsreopenstrong.com/enespanol/)

አጣርኛ (https://dcpsreopenstrong.com/amharic/) Contact (https://dcpsreopenstrong.com/contactus/) For staff (https://dcpsreopenstrong.com/for-staff/)

SY20-(https:

Y

witter.com/dcpublicschools) (h

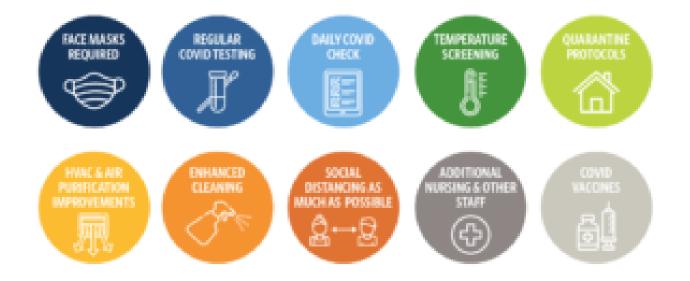
(https://www.facebook.com/dcpublicschools)

(https://www.instagram.com/dcpublicschools/)

(https://www.youtube.com/user/dcpublicschools)



KIPP DC is committed to putting the health and safety of our students, staff, and families first inside our school buildings as we gradually return to in-person programming. This page details the health and safety protocols we have implemented, in line with public health guidance and informed by the voices of our school communities, to minimize health risks and produce the best learning environments in our schools for students to succeed.



**Face Masks Required:** All adults and students, regardless of vaccination status, will be required to wear masks while in our school buildings and on school grounds. Masks may be removed during lunch periods and nap times.

**Regular COVID Testing:** Through a combination of individual and pool testing, all staff and students will regularly be tested for COVID-19. In the event of a positive test for COVID-19 through KIPP DC or elsewhere, all families and staff at a school are alerted, regardless of if their child was in a class with the covid-positive individual or needs to quarantine.

**Daily COVID Check:** All staff and students will be emailed a COVID check each morning to assess if they have any symptoms of COVID-19 or have recently been exposed. Staff, students, and guests who fail the check should not enter the building.

**Temperature Screening:** All students and guests entering the building will have their temperature screened.

**Quarantine Protocols:** While fully vaccinated staff and students will not need to quarantine, all others will quarantine and learn remotely if exposed to a COVID positive individual.

**HVAC & Air Purification Improvements:** All classroom and large gathering spaces have been equipped with HEPA filters or UV-C light to increase air circulation and improve air quality.

**Enhanced Cleaning:** We're prioritizing cleaning high traffic areas, such as restrooms, hallways, etc., to mitigate the spread of germs in schools.

**Social Distancing As Much As Possible:** School routines, in-classroom activities, and desk layouts will foster as much social distancing as possible.

Additional Nursing & Other Staff: Extra medical and operational staff will be onsite to ensure staff and students are following protocols and addressing any issues that may arise.

**COVID Vaccines:** We encourage all staff and eligible students to take the COVID vaccine. In the coming weeks, we'll be hosting COVID Vaccine clinics at our schools to increase access to our communities.

Contact Us

Procurement

**Public Information** 

KIPP DC Staff Portal

Media

Forms & Policies

Title IX

**COVID** Data

STAY CONNECTED



KIPP DC Headquarters · 2600 Virginia Ave NW · Suite 900 · Washington, DC 20037 · Phone: 202-265-5477

© Copyright 2020 KIPP DC Public Charter School. All Rights Reserved.

DESIGNED BY SUNDARAM

## BRITISH MEDICAL JOURNAL No 7070 Volume 313: Page 1448, 7 December 1996.

#### **CIRP Introduction**

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

This judgment established a new standard of ethical medical behavior for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

This code also recognizes that the risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.

This code recognizes that doctors should avoid actions that injure human patients.

The principles established by this code for medical practice now have been extened into general codes of medical ethics.

### The Nuremberg Code (1947)

### **Permissible Medical Experiments**

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person

11/14/21, 2:12 AM Case 1:21-cv-01857-TNM Document 31h1NuFiled 4.1/15/21 Page 49 of 131 which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

- 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
- 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
- 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
- 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
- 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
- 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

For more information see <u>Nuremberg Doctor's Trial</u>, *BMJ* 1996;313(7070):1445-75.

#### Cite as:

• The Nuremberg Code (1947) In: Mitscherlich A, Mielke F. *Doctors of infamy: the story of the Nazi medical crimes*. New York: Schuman, 1949: xxiii-xxv.

(File revised 09 June 2002)

Return to CIRP library

DIR Parent Directory

http://www.cirp.org/library/ethics/nuremberg/



### School Year 2021-22

### Student Athletes: COVID-19 Vaccination Religious Exemption Certificate

Pursuant to Mayor's Order 2021-109, effective Nov. 1, 2021, no student age 12 or older shall practice, compete or otherwise participate in school-based extracurricular athletics (including both interscholastic and intramural sports), unless the student has received a full course of vaccination against coronavirus (COVID-19). This certificate may be used to document requested exemption from this requirement based on sincerely held religious beliefs. Student athletes who have received an approved religious exemption shall wear a mask in athletic events (even if the current indoor masking order is rescinded or superseded), shall be tested weekly for COVID-19 and shall provide the school a negative COVID-19 test result on a weekly basis in order to report to their school-based athletic activity.

This certificate shall be completed annually by a parent/guardian or student age 18 or older ("the requestor") and submitted directly to the student's enrolled school and/or school site requesting proof of COVID-19 vaccination or exemption for extracurricular athletics.

#### Instructions for completing this form:

**Section 1:** Requestor enter student information.

**Section 2:** Requestor initial, complete narrative, sign and date.

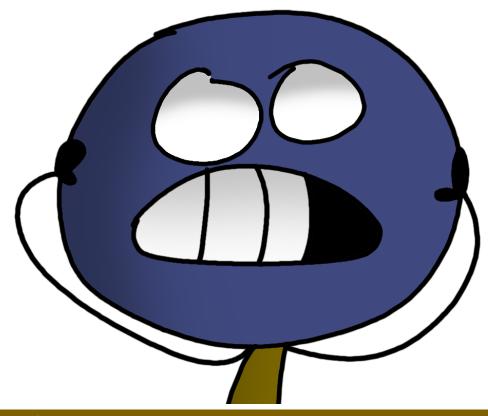
**Section 3:** School leader or designee review, approve or deny, sign and date.

**Attachments:** The requestor may attach additional written pages and other information to this form to support proof of sincerely held religious beliefs, such a signed letter from a religious/spiritual leader, member or person with personal knowledge from the religious organization attended by the requestor explaining the doctrine/beliefs that prohibit all immunizations and/or the COVID-19 immunization.

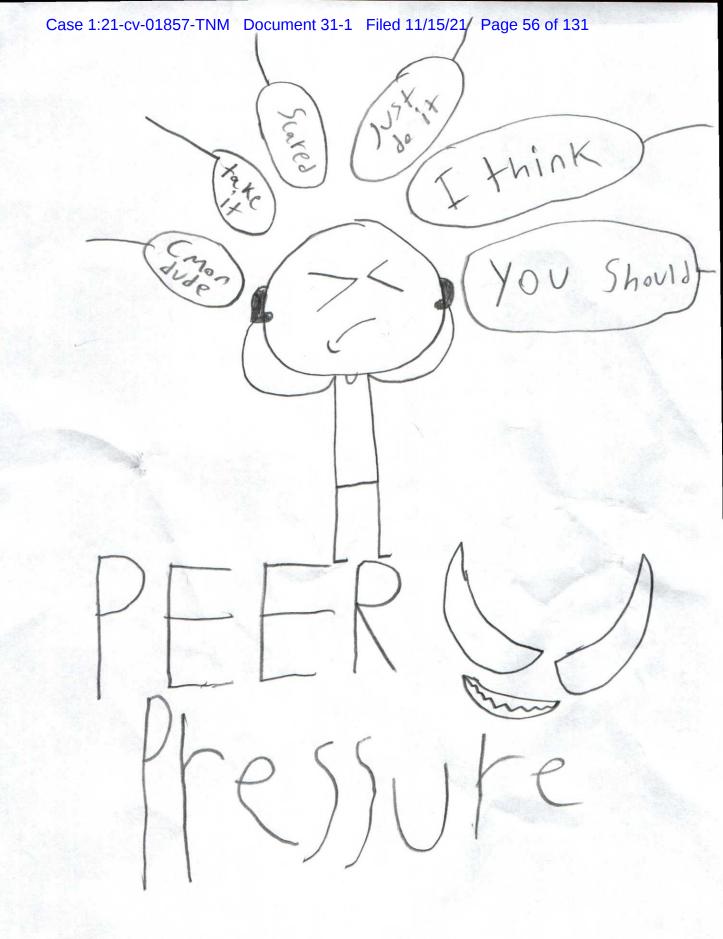
Section 1: Student Information (to be completed by the requestor)					
Name of School:					
Student Name:			Date of Birth:	Grade:	
Home Street Address: City:		City:	ZIP Code:	Phone:	
Section 2: COVID-1	19 Vaccine Exemption (to be completed	by the requestor)			
Initials:	I request that the above-named student be exempt from the COVID-19 vaccine based on my sincerely held religious beliefs. I understand that if an outbreak of COVID-19 should occur, an exempt student may be excluded from school and school activities by the school administrative head for a period of time as determined by the DC Department of Health based on a case-by-case analysis of public health risk.				
Initials:	I understand the benefits of the COVID-19 vaccine in decreasing the risk of severe illness, hospitalization, and death. I understand and assume the risks of refusing to receive the COVID-19 vaccine based on my sincerely held religious beliefs. I know that I may alter my decision at any time and complete the required vaccination.				
Initials:	I understand that student athletes with an approved religious exemption must: (1) wear a mask in athletic events (even if the current indoor masking order is rescinded or superseded); (2) be tested weekly for COVID-19; and (3) provide the school a negative COVID-19 test result on a weekly basis in order to report to their school-based extracurricular athletic activity.				

### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 52 of 131

Initials:	I understand that this religious exemption is only valid for the 2021-22 school year. I acknowledge that I am required to submit a new request for religious exemption for any subsequent policy change or on expiration of an approved religious exemption.			
Initials:	I affirm that all information provided in this request for religious exemption is true and accurate of my sincerely held religious belief.			
student, the religio immunizations, and additional documen	rsonal written statement on why you are seeking a religious us principles that guide your objection to immunization, and if not, the religious basis on which you object to the COVID-ntation, if necessary, and you may provide the name and contact who can corroborate your beliefs.	whether you are opposed to all 19 immunization. You may attach		
Print Name of Pare	nt/Guardian or Student if 18 Years Old or Older:			
Signature of Parent	/Guardian or Student if 18 Years Old or Older:	Date:		
Section 3: School R	esponse (to be completed by the school)			
This religious exemption request shall be reviewed by the school leader or the designee. After review, if the school leader or designee is unable to make a determination because of inadequate information about the nature of the sincerely held religious belief, they may request additional information from the requestor before approval or denial.  School leader or designee shall select from the following. This religious exemption request is (select one):  Approved on the ground of sincerely held religious belief and no undue burden to accommodate the exemption				
Denied (select all that apply): No sincerely held religious belief Undue burden to accommodate the exemption				
Print Name of School Leader or Designee:				
Signature of School	Leader or Designee:	Date:		



I feel like I'm being pressured into taking the vaccination because I feel like an outsider since everybody else has the vaccine and not only that but I feel like the vaccination is some sort of hall pass because I need the vaccination to go to certain places which is very annoying. My Parents sometimes fight over me and how mom and dad have different opinions about the vaccine so I'm in a very tight space right now.



# EXHIBIT 12

# Wellness of DC



#### **Connect with us!**







Facebook: Wellness of DC

Instagram:
@Wellness of DC

Email: wellnessofdc@gmail.com

**Phone:** (202) 487-5176

Now Offering Vaccines for

#### **ABOUT US**

Wellness of DC seeks to deliver vaccines to children living within the nation's capital.

- Open to children ages 0-18!
- Accepting all insurance, except for Kaiser!
- Affordable out-of-pocket costs for vaccine shots if not covered by insurance\*
- Currently providing every vaccine except for chicken pox!

DCPS!

\*Some children w/o insurance may be able to receive vaccine at no cost.

#### **Vaccine Clinics**

Every Saturday, 9am-1pm 2141 K St NW, Suite 808 Washington, DC, 20037

Interested in setting up a vaccine clinic at your school? Contact Dr. Julian Safran, MD, at (202) 487-5176 or juliansafran@gmail.com.

# EXHIBIT 13

# Open Letter from SWWHSA to Mayor and DC Council: Mandate COVID-19 vaccine for eligible students

Covid-19, AdvocacyOctober 4, 2021

Dear Mayor Bowser and Chairman Mendelson,

On behalf of the School Without Walls Home and School Association (SWWHSA), I ask that you exercise powers within the executive and legislative to mandate vaccines for eligible students enrolled in DC's public schools.

Like all school communities, we want our school district to provide the safest possible environment in which students learn and educators work. We recently polled our families to determine vaccination rates in our school and how the SWWHSA could help increase rates. Families of over 300 students responded. All but one fully vaccinated and the overwhelming ask was for the SWWHSA to advocate for a vaccine mandate.

Our community appreciates and supports the efforts undertaken by DC Government to encourage families to vaccinate, if eligible. We support the mandate for staff vaccination, and for vaccination of student athletes who are vaccine-eligible. However, we worry that the pace of vaccinations for eligible ages under 18 will not be sufficient to slow down the current wave driven by the Delta variant or future variants.

We have heard the Mayor, DME, Chancellor, Principal, and community leaders say COVID-19 vaccines are safe, effective and vaccinating is the strongest way to protect our school community. We support this and, in turn, hope the DC government will join the State of California (and George Washington University, where our campus is located) in serving as a leader in keeping schools safe and open for in-person learning by immediately implementing a mandate (and legislation, if necessary) that all students who are eligible for vaccine be required to be fully vaccinated against COVID-19 by December 31, 2021.

We trust it goes without mention that leadership entails both setting firm lines in the sand AND supporting students and families to get across the finish line toward vaccine compliance.

Thank you in advance for your support,

Maan Sacdalan

#### **SWWHSA** President

Samantha	Gina Lynn	Dawn Leijon,	Marilyn
Caruth, Vice	Anderson,	Treasurer &	Nowalk, MUN
President	Secretary	Boosters	Treasurer
		Treasurer	
Elizabeth	Deidra		Malene
Dranitze, At-	Barksdale,	Shandrika	Lawrence, At-
Large	At-Large	Donawana	Large and LSAT
		Johnkins At-	Representative
Sandra	Karen Quarles,	Large and LSAT	•
Moscoso, At-	At-Large	Representative	Malcolm,
Large		•	Willoughby,
C	Esperanza	Jane Tobler, At-	<b>HSA Staff</b>
Marion	Roman, LSAT	Large	Representative
Babcock, Acting	Representative		•
LSAT Co-Chair			To:
			pmendelson@dcc

ouncil.us, muriel.bowser@dc.gov

CC:

doh@dc.gov, LaQuandra.Nesbitt@dc.gov, bnadeau@dccouncil.us, Paul.Kihn@dc.gov, bpinto@dccouncil.us, mcheh@dccouncil.us, jlewisgeorge@dccouncil.us, kmcduffie@dccouncil.us, callen@dccouncil.us, vgray@dccouncil.us, twhite@dccouncil.us, rwhite@dccouncil.us, chenderson@dccouncil.us, abonds@dccouncil.us, esilverman@dccouncil.us, rlancaster@dccouncil.us, ehanson@dccouncil.us, mporcello@dccouncil.us,

wperkins@dccouncil.us, ballen@dccouncil.us, lmarks@dccouncil.us, tnorflis@dccouncil.us, tgjackson@dccouncil.us, afowlkes@dccouncil.us, mshaffer@dccouncil.us, dmeadows@dccouncil.us, srosenamy@dccouncil.us, ljordan@dccouncil.us, zachary.parker@dc.gov, emily.gasoi@dc.gov, jacque.patterson@dc.gov, allister.changl@dc.gov, ruth.wattenberg@dc.gov, Frazier.OLeary@dc.gov, jessica.sutter@dc.gov, eboni-rose.thompson@dc.gov, carlene.reid@dc.gov, John-Paul.Hayworth@dc.gov,

#### **PREVIOUS**

Missed the 50th Anniversary Open House? Here are the Videos!

NEXT

50th Anniversary Open House is Friday, Oct 8 - Bring on the 10s and (gulp) 20s!



**SCHOOL WITHOUT** WALLS HIGH SCHOOL 2130 G ST NW WASHINGTON, DC 20037

**QUICK** LINKS

Donate

**FOLLOW US** ON SOCIAL

(, (, (,

Photography by the School Without Walls Yearbook Team. The SWWHSA is a registered 501c3. EIN 52-02303014 © The School Without Walls Home and School Association

# EXHIBIT 14

#### **Vaccine Injury Table**

Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after March 21, 2017

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis B. Brachial Neuritis	≤4 hours. 2-28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV)	A. Anaphylaxis B. Encephalopathy or encephalitis	≤4 hours. 5-15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IV. Vaccines containing rubella virus ( <i>e.g.</i> , MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus ( <i>e.g.,</i> MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IX. Haemophilus influenzae type b (Hib) vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	7-42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	E. Vasovagal syncope	≤1 hour.
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3-42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVI. Human papillomavirus (HPV) vaccine	es A. Anaphylaxis	≤4 hours.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1hour.

- (b) Provisions that apply to all conditions listed. (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.
- (2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.
- (3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.
- (c) Qualifications and aids to interpretation. The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:
- (1) Anaphylaxis. Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.
- (2) *Encephalopathy*. A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.
  - (i) Acute encephalopathy. (A) For children less than 18 months of age who present:
- (1) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.
- (2) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.

- (B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:
- (1) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);
- (2) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and
  - (3) A seizure associated with loss of consciousness.
- (C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.
- (D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.
- (ii) Exclusionary criteria for encephalopathy. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:
- (A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or perinatal central nervous system (CNS) injury); or
- (B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.
- (3) *Encephalitis*. A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.
- (i) Acute encephalitis. Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.
  - (A) Evidence of neurologic dysfunction consists of either:
- (1) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or
  - (2) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.
- (B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm³ in children >2 months of age and adults; >15 WBC/mm³ in children <2 months of age); or at least two of the following:

- (1) Fever (temperature ≥ 100.4 degrees Fahrenheit);
- (2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or
- (3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.
- (ii) Exclusionary criteria for encephalitis. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:
  - (A) An underlying malignancy that led to a paraneoplastic encephalitis;
- (B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or
- (C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or
  - (D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.
- (4) Intussusception. (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.
- (ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:
  - (A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;
- (B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;
- (C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);
- (D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal

hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

- (E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).
- (5) Chronic arthritis. Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.
- (i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:
- (A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and
- (B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and
  - (C) Medical documentation of an antibody response to the rubella virus.
- (ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.
- (6) *Brachial neuritis*. This term is defined as dysfunction limited to the upper extremity nerve plexus (*i.e.*, its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:
- (i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;
  - (ii) Weakness;
- (A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.
- (B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.

- (iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and
- (iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.
- (7) Thrombocytopenic purpura. This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm<sup>3</sup> with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.
- (8) Vaccine-strain measles viral disease. This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.
- (9) *Vaccine-strain polio viral infection*. This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.
- (10) Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
  - (ii) Pain occurs within the specified time-frame;

- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).
- (11) Disseminated varicella vaccine-strain viral disease. Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7- 42 days after vaccination.
- (12) Varicella vaccine-strain viral reactivation disease. Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.
- (13) Vasovagal syncope. Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.
- (14) Immunodeficient recipient. Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.
- (15) Guillain-Barré Syndrome (GBS). (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

- (ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:
  - (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
  - (B) A monophasic illness pattern;
  - (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
  - (E) The absence of an identified more likely alternative diagnosis.
- (iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:
  - (A) Bilateral ophthalmoparesis;
  - (B) Bilateral reduced or absent tendon reflexes:
  - (C) Ataxia;
- (D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);
  - (E) A monophasic illness pattern;
  - (F) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);
  - (H) No alteration in consciousness;
  - (I) No corticospinal track signs; and
  - (J) The absence of an identified more likely alternative diagnosis.
- (iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with

a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

- (v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.
- (vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.
- (d) Glossary for purposes of paragraph (c) of this section—(1) Chronic encephalopathy. (i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.
- (ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.
- (2) *Injected* refers to the intramuscular, intradermal, or subcutaneous needle administration of a vaccine.
- (3) Sequela means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.
- (4) Significantly decreased level of consciousness is indicated by the presence of one or more of the following clinical signs:
- (i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).
- (5) Seizure includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

- (e) Coverage provisions. (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.
- (2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.
  - (3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.
- (4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.
  - (5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.
- (6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.
- (7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.
- (8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the FEDERAL REGISTER to announce the effective date of such a tax.

# EXHIBIT 15



#### **Table 1.** Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

Always make recommendations by determining needed vaccines based on age (Table 1), determining appropriate intervals for catch-up, if needed (Table 2), assessing for medical indications (Table 3), and reviewing special situations (Notes).



#### **COVID-19 Vaccination**

ACIP recommends use of COVID-19 vaccines for everyone ages 12 and older within the scope of the Emergency Use Authorization for the particular vaccine. COVID-19 vaccine and other vaccines may be administered on the same day. See the COVID-19 Vaccine Product Information page for additional information about COVID-19 vaccines authorized for use in the United States.

Table 1. By age

Table 2. Catch-up

Table 3. By medical indications

Schedule Changes & Guidance

Parentfriendly schedule Resources for health

- 8.5"x11" print color 🔼 [8 pages]
- 8.5"x11" print black and white
  [8 pages]
- Compliant version of this schedule

 Vaccines in the Child and Adolescent Immunization Schedule

• Learn how to display current schedules from your website.

Download Schedules App



#### Legend

Range of recommended ages for all children Range of recommended ages for catchup immunization Range of recommended ages for certain high-risk groups Recommended based on shared clinical decision-making or \*can be used in this age group

No recommendatio n/Not applicable

#### Birth to 15 Months

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Hepatitis B (1) (HepB)	1 <sup>st</sup> dose		-2 <sup>nd</sup> se→			←3 <sup>rd</sup> dose→		
Rotavirus (1) (RV) RV1 (2-dose series); RV5 (3-dose series)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See notes			
Diphtheria, tetanus, & acellular pertussis (1) (DTaP: <7 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose			←4 <sup>th</sup> dose→
Haemophilus influenzae type b (1) (Hib)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See notes			or 4 <sup>th</sup> dose, notes→

**Exhibit 15** 

Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 79 of 131								
Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Pneumococcal conjugate (1) (PCV13)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose		<b>←</b> 4 <sup>t</sup>	<sup>h</sup> dose→
Inactivated poliovirus (1) (IPV: <18 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose		←3	<sup>rd</sup> dose→	
Influenza (IIV) 🕦					Annu	ıal vaccir	nation 1 d	or 2 doses
or Influenza (LAIV4) 🕦								
Measles, mumps, rubella 📵 (MMR)					See n	otes	<b>←</b> 1'	<sup>st</sup> dose→
Varicella <b>⊕</b> (VAR)							<b>←</b> 1 <sup>s</sup>	<sup>st</sup> dose→
Hepatitis A 🚯 (HepA)					See n	otes		ose series, notes→
Tetanus, diphtheria, & acellular pertussis  (Tdap: ≥7 yrs)								
Human papillomavirus 🚯 (HPV)								
Meningococcal  (1)  (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)					Se	e notes		
Meningococcal B () (MenB)								
Pneumococcal polysaccharide (1) (PPSV23)								

#### 18 Months to 18 Years

Vaccines	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13- 15 yrs	16 yrs	17- 18 yrs
Hepatitis B (1) (HepB)	←3 <sup>rd</sup> dose→								
Rotavirus (1) (RV) RV1 (2-dose series); RV5 (3-dose series)									
Diphtheria, tetanus, & acellular pertussis (1) (DTaP: <7 yrs)	←4 <sup>th</sup> dose→			5 <sup>th</sup> dose					
Haemophilus influenzae type b   (Hib)									, hih

Case 1:21-cv-01857-TNN	Docur	nent 31	-1 Fil	ed 11/1	5/21	Page 8	30 of 2	131	
Vaccines	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13- 15 yrs	16 yrs	17- 18 yrs
Pneumococcal conjugate (1) (PCV13)									
Inactivated poliovirus (1) (IPV: <18 yrs)	←3 <sup>rd</sup> dose→			4 <sup>th</sup> dose					
Influenza (IIV) 🕦	Annual	vaccinatio	on 1 or 2	doses	А	nnual vad	ccination	n 1 dose	only
or Influenza (LAIV4) 📵			vaccir	inual nation 1 or doses		nnual vad	ccination	n 1 dose	only
Measles, mumps, rubella (1) (MMR)				2 <sup>nd</sup> dose					
Varicella (1) (VAR)				2 <sup>nd</sup> dose					
Hepatitis A 🕦 (HepA)	← 2-dose								
Tetanus, diphtheria, & acellular pertussis  (Tdap: ≥7 yrs)						Tdap			
Human papillomavirus (1) (HPV)					*	See notes			
Meningococcal <b>①</b> (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)		Se	ee notes			1 <sup>st</sup> dose		2 <sup>nd</sup> dose	
Meningococcal B (1) (MenB)							See n	otes	
Pneumococcal polysaccharide (1) (PPSV23)				!	Se	ee notes			

Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

#### **Notes**

# Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule,

#### Additional information

#### COVID-19 Vaccination

ACIP recommends use of COVID-19 vaccines for everyone ages 12 and older within the scope of the Emergency Use Authorization for the particular vaccine. COVID-19 vaccine and other vaccines may be administered on the same day. See the COVID-19 Vaccine Product Information page for additional information about COVID-19 vaccines authorized for use in the United States.

- Consult relevant ACIP statements for detailed recommendations.
- For information on contraindications and precautions for the use of a vaccine, consult the *General Best Practice Guidelines for Immunization* and relevant ACIP statements.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12-18), a dash (-) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization.
- Information on travel vaccination requirements and recommendations is available at https://www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization*, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics, 2018:67–111).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All routine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see www.hrsa.gov/vaccinecompensation/index.html 🖸 .

### Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

#### Routine vaccination

- 5-dose series at 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

#### Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

#### Special situations

• Wound management in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see <a href="https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm">www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm</a>.

# *Haemophilus influenzae* type b vaccination (minimum age: 6 weeks)

#### Routine vaccination

- ActHIB, Hiberix, or Pentacel: 4-dose series at 2, 4, 6, 12–15 months
- PedvaxHIB: 3-dose series at 2, 4, 12-15 months

#### Catch-up vaccination

- Dose 1 at age 7–11 months: Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age 12–15 months or 8 weeks after dose 2 (whichever is later).
- Dose 1 at age 12-14 months: Administer dose 2 (final dose) at least 8 weeks after dose 1.
- Dose 1 before age 12 months and dose 2 before age 15 months: Administer dose 3 (final dose) 8 weeks after dose 2.
- 2 doses of PedvaxHIB before age 12 months: Administer dose 3 (final dose) at age 12–59 months and at least 8 weeks after dose 2.
- 1 dose administered at age 15 months or older: No further doses needed
- Unvaccinated at age 15-59 months: Administer 1 dose.
- Previously unvaccinated children age 60 months or older who are not considered high risk: Do not require catch-up vaccination
- For other catch-up guidance, see Table 2.

#### Special situations

· Chemotherapy or radiation treatment:

#### 12-59 months

- o Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- o 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.

- Hematopoietic stem cell transplant (HSCT):
  - o 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant regardless of Hib vaccination history
- Anatomic or functional asplenia (including sickle cell disease):

#### 12-59 months

- o Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- o 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

#### Unvaccinated\* persons age 5 years or older

- o 1 dose
- · Elective splenectomy:

#### Unvaccinated\* persons age 15 months or older

- 1 dose (preferably at least 14 days before procedure)
- HIV infection:

#### 12-59 months

- o Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- o 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

#### Unvaccinated\* persons age 5-18 years

- 1 dose
- Immunoglobulin deficiency, early component complement deficiency:

#### 12-59 months

- o Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- o 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

#### Hepatitis A vaccination

(minimum age: 12 months for routine vaccination)

#### Routine vaccination

 2-dose series (minimum interval: 6 months) beginning at age 12 months

#### Catch-up vaccination

- Unvaccinated persons through age 18 years should complete a 2-dose series (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix**®, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

#### International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (http://www.cdc.gov/travel/)
  - Infants age 6-11 months: 1 dose before departure; revaccinate with 2 doses, separated by at least 6 months, between age 12-23 months.
  - Unvaccinated age 12 months or older: Administer dose 1 as soon as travel is considered.

#### Hepatitis B vaccination (minimum age: birth)

#### Birth dose (monovalent HepB vaccine only)

- Mother is HBsAg-negative: 1 dose within 24 hours of birth for all medically stable infants ≥2,000 grams. Infants <2,000 grams: Administer 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams).
- · Mother is HBsAg-positive:
  - Administer HepB vaccine and hepatitis B immune globulin (HBIG) (in separate limbs) within 12 hours of birth, regardless of birth weight. For infants <2,000 grams, administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose.
- Mother's HBsAg status is unknown:
  - Administer HepB vaccine within 12 hours of birth, regardless of birth weight.
  - For infants <2,000 grams, administer **HBIG** in addition to HepB vaccine (in separate limbs) within 12 hours of birth. Administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Determine mother's HBsAg status as soon as possible. If mother is HBsAg-positive, administer HBIG to infants
     ≥2,000 grams as soon as possible, but no later than 7 days of age.

#### Routine series

- 3-dose series at 0, 1-2, 6-18 months (use monovalent HepB vaccine for doses administered before age 6 weeks)
- Infants who did not receive a birth dose should begin the series as soon as feasible (see Table 2).
- Administration of **4 doses** is permitted when a combination vaccine containing HepB is used after the birth dose.
- Minimum age for the final (3rd or 4th ) dose: 24 weeks
- Minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks (when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations)

#### Catch-up vaccination

• Unvaccinated persons should complete a 3-dose series at 0. 1–2. 6 months.

#### 

- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation Recombivax HB only).
- Adolescents age 18 years or older may receive a 2-dose series of HepB (Heplisav-B<sup>®</sup>) at least 4 weeks apart.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).
- For other catch-up guidance, see Table 2.

#### Special situations

- Revaccination is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- Revaccination may be recommended for certain populations, including:
  - o Infants born to HBsAg-positive mothers
  - Hemodialysis patients
  - o Other immunocompromised persons
- For detailed revaccination recommendations, see http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.

#### Human papillomavirus vaccination (minimum age: 9 years)

#### Routine and catch-up vaccination

- HPV vaccination routinely recommended at age 11–12 years (can start at age 9 years) and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
  - Age 9 –14 years at initial vaccination: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - Age 15 years or older at initial vaccination: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- Interrupted schedules: If vaccination schedule is interrupted, the series does not need to be restarted.
- No additional dose recommended after completing series with recommended dosing intervals using any HPV vaccine.

#### Special situations

- Immunocompromising conditions, including HIV infection: 3-dose series as above
- **History of sexual abuse or assault:** Start at age 9 years.
- Pregnancy: HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while
  pregnant; pregnancy testing not needed before vaccination

### Influenza vaccination (minimum age: 6 months [IIV], 2 years [LAIV4], 18 years [recombinant influenza vaccine, RIV4])

#### Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - 2 doses, separated by at least 4 weeks, for children age 6 months–8 years who have received fewer than 2 influenza vaccine doses before July 1, 2020, or whose influenza vaccination history is unknown (administer dose 2 even if the child turns 9 between receipt of dose 1 and dose 2)
  - 1 dose for children age 6 months-8 years who have received at least 2 influenza vaccine doses before July 1, 2020
  - o 1 dose for all persons age 9 years or older
- For the 2021–22 season, see the 2021–22 ACIP influenza vaccine recommendations.

#### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 85 of 131

- Egg allergy, hives only: Any influenza vaccine appropriate for age and health status annually
- Egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress, need for emergency medical services or epinephrine): Any influenza vaccine appropriate for age and health status annually. If using an influenza vaccine other than Flublok or Flucelvax, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
- Severe allergic reactions to vaccines can occur even in the absence of a history of previous allergic reaction. All vaccination providers should be familiar with the office emergency plan and certified in cardiopulmonary resuscitation.
- A previous severe allergic reaction to influenza vaccine is a contraindication to future receipt of any influenza vaccine.
- LAIV4 should not be used in persons with the following conditions or situations:
  - History of severe allergic reaction to a previous dose of any influenza vaccine or to any vaccine component (excluding egg, see details above)
  - o Receiving aspirin or salicylate-containing medications
  - o Age 2-4 years with history of asthma or wheezing
  - o Immunocompromised due to any cause (including medications and HIV infection)
  - o Anatomic or functional asplenia
  - Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
  - Pregnancy
  - Cochlear implant
  - Cerebrospinal fluid-oropharyngeal communication
  - Children less than age 2 years
  - Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days

### Measles, mumps, and rubella vaccination (minimum age: 12 months for routine vaccination)

#### Routine vaccination

- 2-dose series at 12–15 months, 4–6 years
- Dose 2 may be administered as early as 4 weeks after dose 1.

#### Catch-up vaccination

- Unvaccinated children and adolescents: 2-dose series at least 4 weeks apart
- The maximum age for use of MMRV is 12 years.

#### Special situations

#### International travel

- Infants age 6–11 months: 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
- Unvaccinated children age 12 months or older: 2-dose series at least 4 weeks apart before departure

# Meningococcal serogroup A, C, W, Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra], 2 years [MenACWY-TT, MenQuadfi])

#### Routine vaccination

• 2-dose series at 11-12 years, 16 years

#### Catch-up vaccination

- Age 13-15 years: 1 dose now and booster at age 16-18 years (minimum interval: 8 weeks)
- Age 16-18 years: 1 dose

#### Special situations

Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

#### Menveo

- Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
- Dose 1 at age 3-6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
- o Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- o Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

#### Menactra

- Persistent complement component deficiency or complement inhibitor use:
  - Age 9–23 months: 2-dose series at least 12 weeks apart
  - Age 24 months or older: 2-dose series at least 8 weeks apart
- o Anatomic or functional asplenia, sickle cell disease, or HIV infection:
  - Age 9–23 months: Not recommended
  - Age 24 months or older: 2-dose series at least 8 weeks apart
  - Menactra must be administered at least 4 weeks after completion of PCV13 series.

#### MenQuadfi

o Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel in countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj

(http://www.cdc.gov/travel/):

- Children age less than 24 months:
  - Menveo (age 2–23 months)
    - Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
    - Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous
      dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later
      and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Menactra (age 9–23 months)
    - 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose Menveo, Menactra, or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:

• 1 dose Menveo, Menactra, or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease (e.g., those with complement deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- Children for whom boosters are not recommended (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent

Exhibit 15

schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Note:** Menactra should be administered either before or at the same time as DTaP. For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see <a href="https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm">https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm</a>.

### Meningococcal serogroup B vaccination (minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba])

#### Shared Clinical Decision-Making

- Adolescents not at increased risk age 16–23 years (preferred age 16–18 years) based on shared clinical decision-making:
  - Bexsero: 2-dose series at least 1 month apart
  - **Trumenba:** 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3rd dose at least 4 months after dose 2.

#### Special situations

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- Bexsero: 2-dose series at least 1 month apart
- Trumenba: 3-dose series at 0, 1-2, 6 months

Bexsero and Trumenba are not interchangeable; the same product should be used for all doses in a series. For MenB booster dose recommendations for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

### Pneumococcal vaccination (minimum age: 6 weeks [PCV13], 2 years [PPSV23])

#### Routine vaccination with PCV13

• 4-dose series at 2, 4, 6, 12-15 months

#### Catch-up vaccination with PCV13

- 1 dose for healthy children age 24–59 months with any incomplete\* PCV13 series
- For other catch-up guidance, see Table 2.

#### Special situations

Underlying conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during same visit. Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

#### Age 2-5 years

- Any incomplete\* series with:
  - o 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

#### Age 6-18 years

• No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

#### Cerebrospinal fluid leak, cochlear implant:

#### Age 2-5 years

- Any incomplete\* series with:
  - o 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - o Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

#### Age 6-18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23

Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

#### Age 2-5 years

- Any incomplete\* series with:
  - o 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a 2nd dose of PPSV23 5 years

#### Age 6-18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2nd dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

#### Chronic liver disease, alcoholism:

#### Age 6–18 years

• No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

\*Incomplete series = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Tables 8, 9, and 11 in the in the ACIP pneumococcal vaccine recommendations (https://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf ) for complete schedule details.

#### Poliovirus vaccination (minimum age: 6 weeks)

#### Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

#### Catch-up vaccination

• In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.

#### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 89 of 131

• IPV is not routinely recommended for U.S. residents age 18 years or older.

#### Series containing oral polio vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See https://www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
     For guidance to assess doses documented as "OPV," see
     http://www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm.
- For other catch-up guidance, see Table 2.

#### Rotavirus vaccination (minimum age: 6 weeks)

#### Routine vaccination

- Rotarix: 2-dose series at 2 and 4 months
- RotaTeq: 3-dose series at 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

#### Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

# Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

#### Routine vaccination

- Adolescents age 11-12 years: 1 dose Tdap
- Pregnancy: 1 dose Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

#### Catch-up vaccination

- Adolescents age 13–18 years who have not received Tdap: 1 dose Tdap, then Td or Tdap booster every 10 years
- Persons age 7–18 years not fully vaccinated\* with DTaP: 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- Tdap administered at age 7-10 years
  - Children age 7-9 years who receive Tdap should receive the routine Tdap dose at age 11-12 years.
  - Children age 10 years who receive Tdap do not need the routine Tdap dose at age 11–12 years.
- DTaP inadvertently administered on or after age 7 years:
  - **Children age 7–9 years**: DTaP may count as part of catch-up series. Administer routine Tdap dose at age 11–12 years.
  - Children age 10–18 years: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.

#### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 90 of 131

• Wound management in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap. For detailed information, see https://www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

#### Varicella vaccination (minimum age: 12 months)

#### Routine vaccination

- 2-dose series at 12–15 months, 4–6 years
- Dose 2 may be administered as early as 3 months after dose 1 (a dose administered after a 4-week interval may be counted).

#### Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf ) have a 2-dose series:
  - o Age 7-12 years: routine interval: 3 months (a dose administered after a 4-week interval may be counted)
  - Age 13 years or older: routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of MMRV is 12 years.

#### Vaccines in the Child and Adolescent Immunization Schedule

Vaccines	Abbreviations	Trade Names
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel <sup>®</sup> Infanrix <sup>®</sup>
Diphtheria, tetanus vaccine	DT	No Trade Name
Haemophilus influenzae type B vaccine	Hib (PRP-T) Hib (PRP-OMP)	ActHIB <sup>®</sup> Hiberix <sup>®</sup> PedvaxHIB <sup>®</sup>
Hepatitis A vaccine	НерА	Havrix <sup>®</sup> Vaqta <sup>®</sup>
Hepatitis B vaccine	НерВ	Engerix-B <sup>®</sup> Recombivax HB <sup>®</sup>
Human papillomavirus vaccine	HPV	Gardasil 9®
Influenza vaccine (inactivated)	IIV	Multiple
Influenza vaccine (live, attenuated)	LAIV4	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	MMR	M-M-R® II

<sup>\*</sup>Fully vaccinated = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older.

Case 1:21-cv-01857-TNM Document	31-1 Filed 11/15/21 I	Page 91 of 131
Vaccines	Abbreviations	Trade Names
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D MenACWY-CRM MenACWY-TT	Menactra <sup>®</sup> Menveo <sup>®</sup> MenQuadfi <sup>®</sup>
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero <sup>®</sup> Trumenba <sup>®</sup>
Pneumococcal 13-valent conjugate vaccine	PCV13	Prevnar 13®
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax <sup>®</sup> 23
Poliovirus vaccine (inactivated)	IPV	IPOL®
Rotavirus vaccine	RV1 RV5	Rotarix <sup>®</sup> RotaTeq <sup>®</sup>
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel <sup>®</sup> Boostrix <sup>®</sup>
Tetanus and diphtheria vaccine	Td	Tenivac® TDvax™
Varicella vaccine	VAR	Varivax <sup>®</sup>

#### **Combination Vaccines**

(Use combination vaccines instead of separate injections when appropriate)

Vaccines	Abbreviations	Trade Names
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix <sup>®</sup>
DTaP, inactivated poliovirus, and <i>Haemophilus influenzae</i> type B vaccine	DTaP-IPV/Hib	Pentacel <sup>®</sup>
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix <sup>®</sup> Quadracel <sup>®</sup>
DTaP, inactivated poliovirus, <i>Haemophilus influenzae</i> type b, and hepatitis B vaccine	DTaP-IPV-Hib- HepB	Vaxelis®
Measles, mumps, rubella, and varicella vaccines	MMRV	ProQuad <sup>®</sup>

This schedule is recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics (AAP (), American Academy of Family Physicians (AAFP ()), American College of Obstetricians and Gynecologists (ACOG (), American College of Nurse-Midwives (ACNM (), American Academy of Physician Assistants (AAPA (), and National Association of Pediatric Nurse Practitioners (NAPNAP ()).

The comprehensive summary of the ACIP recommended changes made to the child and adolescent immunization schedule can be found in the February 12, 2021 *MMWR*.

#### Report

• Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department

#### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 92 of 131

• Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov 🖸 or (800-822-7967)

#### Helpful information

- Complete ACIP recommendations
- General Best Practice Guidelines for Immunization
- Outbreak information (including case identification and outbreak response), see Manual for the Surveillance of Vaccine-Preventable Diseases
- ACIP Shared Clinical Decision-Making Recommendations

Page last reviewed: February 12, 2021

# EXHIBIT 16



### **Data & Statistics**

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions. In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

### What does it mean to be awarded compensation?

Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 60 percent of all compensation awarded by the VICP comes as result of a
  negotiated settlement between the parties in which HHS has not concluded, based upon review
  of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded
  compensation by the Court, if certain minimal requirements are met. In those circumstances,
  attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee,
  including a contingency fee, for his or her services in representing a petitioner in the VICP.

### What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition guickly

#### How many petitions have been awarded compensation?

According to the CDC, from 2006 to 2019 over 4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 8,551 petitions were adjudicated by the Court, and of those 6,086 were compensated. This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated.

Since 1988, over 24,538 petitions have been filed with the VICP. Over that 30-year time period, 20,400 petitions have been adjudicated, with 8,439 of those determined to be compensable, while 11,961 were dismissed. Total compensation paid over the life of the program is approximately \$4.6 billion.

This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving petitions for compensation under the VICP.

National Vaccine Injury Compensation Program Monthly Statistics Report

VICP Adjudication Categories, by Alleged Vaccine for Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2019

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2019 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non- Compensable Total	Grand Total
DT	794,777	1	0	2	9	4	10
DTaP	109,991,074	24	24	116	164	129	293
DTaP-Hep B-IPV	79,798,141	9	7	30	43	64	107
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	31,439,498	0	0	5	5	4	6
DTap-IPV-HIB	74,403,716	7	4	6	17	39	26
DTP	0	1	1	3	5	3	8
DTP-HIB	0	1	0	2	3	1	4
Нер А-Нер В	17,946,038	8	1	18	22	8	30
Нер В-НІВ	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	203,339,060	8	9	47	61	38	26
Hepatitis B (Hep B)	216,772,259	12	12	73	26	94	191
HIB	137,675,315	7	1	11	14	10	24
НРУ	132,062,306	18	14	115	147	232	379
Influenza	1,842,400,000	1,230	226	2,917	4,373	748	5,121
IPV	78,237,532	1	1	4	9	5	11
Measles	135,660	0	0	1	1	0	1
Meningococcal	119,054,485	8	5	44	57	21	78
MMR	116,647,585	24	16	93	133	134	267

Page 2

Page 3

National Vaccine Injury Compensation Program Monthly Statistics Report

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2019 (Source: CDC)	Compensable	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non- Compensable Total	Grand
MMR-Varicella	32,226,723	12	0	14	26	20	46
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	44	47
OPV	0	1	0	0	1	2	9
Pneumococcal Conjugate	986'206'697	88	3	29	100	61	161
Rotavirus	125,787,826	21	4	23	48	20	89
Rubella	422,548	0	1	1	2	0	2
Тд	71,408,785	14	9	29	28	28	115
Тдар	294,534,882	151	22	367	540	113	653
Tetanus	3,836,052	15	2	47	64	21	82
Unspecified	0	T	1	4	9	293	299
Varicella	127,901,171	6	7	32	48	25	73
Grand Total	4,092,757,049	1,606	398	4,114	980'9	2,465	8,551

# Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2019 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were formultiple vaccines later identified in the Special Masters' decisions

National Vaccine Injury Compensation Program Monthly Statistics Report

# Definitions

Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. (Court), or a settlement between the parties.

- Concession: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation Court Decision: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence (e.g., that the injury was not caused by the vaccine).
  - For injury petitions, compensable court decisions are based in part on one of the follow ing determinations by the court:
- The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
- Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Settlement: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- Non-compensable/Dismissed: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the
- The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
- The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement)
- The injured person voluntarily withdrew his or her petition.

National Vaccine Injury Compensation Program Monthly Statistics Report

# Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 11/01/2021

Vaccines	Filed Injury	Filed Death	Filed Grand	Compensated	Dismissed
			Total		
DTaP-IPV	16	0	16	5	4
DT	69	9	78	26	52
DTP	3,288	696	3,984	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	478	87	565	245	269
DTaP-Hep B-IPV	97	39	136	44	64
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	51	21	72	17	39
Td	232	3	235	133	79
Tdap	1,058	8	1,066	549	118
Tetanus	173	3	176	87	48
Hepatitis A (Hep A)	135	7	142	62	39
Hepatitis B (Hep B)	738	62	800	288	442
Нер А-Нер В	42	0	42	22	9
Hep B-HIB	8	0	8	5	3
HIB	48	3	51	21	20
HPV	553	17	570	147	260
Influenza	7,987	203	8,190	4,441	790
IPV	269	14	283	9	271
OPV	282	28	310	158	152
Measles	145	19	164	56	107
Meningococcal	117	3	120	58	22
MMR	1,023	62	1,085	415	596
MMR-Varicella	59	2	61	26	19
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal	298	22	320	106	77
Conjugate					
Rotavirus	111	6	117	71	31
Rubella	190	4	194	71	123
Varicella	111	10	121	68	37
Nonqualified <sup>1</sup>	114	11	125	3	117
Unspecified <sup>2</sup>	5,426	9	5,435	10	5,416
Grand Total	23,178	1,360	24,538	8,439	11,961

National Vaccine Injury Compensation Program Monthly Statistics Report

### **Petitions Filed**

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	447
FY 2011	386
FY 2012	402
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	1,282
FY 2020	1,192
FY 2021	2,057
FY 2022	87
Total	24,538

Updated 11/01/2021

<sup>&</sup>lt;sup>1</sup> Nonqualified petitions are those filed for vaccines not covered under the VICP.

 $<sup>^{2}\,\</sup>mbox{Unspecified}$  petitions are those submitted with insufficient information to make a determination.

National Vaccine Injury Compensation Program Monthly Statistics Report

### **Adjudications**

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	330	510
FY 2011	266	1,742	2,008
FY 2012	265	2,533	2,798
FY 2013	369	651	1,020
FY 2014	370	194	564
FY 2015	520	145	665
FY 2016	700	187	887
FY 2017	696	204	900
FY 2018	544	199	743
FY 2019	642	184	826
FY 2020	710	217	927
FY 2021	748	241	989
FY 2022	48	11	59
Total	8,439	11,961	20,400

# National Vaccine Injury Compensation Program Monthly Statistics Report

Number of Fiscal Year Compensated Awards	er of nsated ds	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dism issed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
1989	9	\$1,317,654.78	\$54,107.14	0	\$0.00	0	\$0.00	\$1,371,761.92
1990	88	\$53,252,510.46	\$1,379,005.79	4	\$57,699.48	0	\$0.00	\$54,689,215.73
1991	114	\$95,980,493.16	\$2,364,758.91	30	\$496,809.21	0	\$0.00	\$98,842,061.28
1992	130	\$94,538,071.30	\$3,001,927.97	118	\$1,212,677.14	0	00.0\$	\$98,752,676.41
1993	162	\$119,693,267.87	\$3,262,453.06	272	\$2,447,273.05	0	\$0.00	\$125,402,993.98
1994	158	\$98,151,900.08	\$3,571,179.67	335	\$3,166,527.38	0	\$0.00	\$104,889,607.13
1995	169	\$104,085,265.72	\$3,652,770.57	221	\$2,276,136.32	0	\$0.00	\$110,014,172.61
FY 1996	163	\$100,425,325.22	\$3,096,231.96	216	\$2,364,122.71	0	\$0.00	\$105,885,679.89
1997	179	\$113,620,171.68	\$3,898,284.77	142	\$1,879,418.14	0	\$0.00	\$119,397,874.59
1998	165	\$127,546,009.19	\$4,002,278.55	121	\$1,936,065.50	0	00'0\$	\$133,484,353.24
1999	96	\$95,917,680.51	\$2,799,910.85	117	\$2,306,957.40	0	\$0.00	\$101,024,548.76
2000	136	\$125,945,195.64	\$4,112,369.02	80	\$1,724,451.08	0	\$0.00	\$131,782,015.74
2001	26	\$105,878,632.57	\$3,373,865.88	25	\$2,066,224.67	0	00.0\$	\$111,318,723.12
2002	80	\$59,799,604.39	\$2,653,598.89	20	\$656,244.79	0	00'0\$	\$63,109,448.07
2003	9	\$82,816,240.07	\$3,147,755.12	69	\$1,545,654.87	0	00'0\$	\$87,509,650.06
2004	25	\$61,933,764.20	\$3,079,328.55	69	\$1,198,615.96	0	00'0\$	\$66,211,708.71
2005	64	\$55,065,797.01	\$2,694,664.03	71	\$1,790,587.29	0	00'0\$	\$59,551,048.33
2006	89	\$48,746,162.74	\$2,441,199.02	54	\$1,353,632.61	0	\$0.00	\$52,540,994.37
2007	82	\$91,449,433.89	\$4,034,154.37	19	\$1,692,020.25	0	00'0\$	\$97,175,608.51
2008	141	\$75,716,552.06	\$5,191,770.83	74	\$2,531,394.20	2	\$117,265.31	\$83,556,982.40
5009	131	\$74,142,490.58	\$5,404,711.98	36	\$1,557,139.53	28	\$4,241,362.55	\$85,345,704.64
2010	173	\$179,387,341.30	\$5,961,744.40	59	\$1,933,550.09	22	\$1,978,803.88	\$189,261,439.67
2011	251	\$216,319,428.47	\$9,572,042.87	403	\$5,589,417.19	28	\$2,001,770.91	\$233,482,659.44
2012	249	\$163,491,998.82	\$9,241,427.33	1,020	\$8,649,676.56	28	\$5,420,257.99	\$186,803,360.70
2013	375	\$254,666,326.70	\$13,543,099.70	704	\$7,012,615.42	09	\$1,454,851.74	\$276,676,893.56
2014	365	\$202,084,196.12	\$12,161,422.64	208	\$6,824,566.68	38	\$2,493,460.73	\$223,563,646.17
2015	508	\$204,137,880,22	\$14 445 776 29	118	\$3 546 785 14	05	89 207 080 53	\$225 210 030 33

National Vaccine Injury Compensation Program Monthly Statistics Report

10	.80	.59	3.61	.94	66:	1.39	.54	7.22
Total Outlays	\$252,682,931.80	\$282,094,720.59	\$226,503,978.61	\$225,457,657.94	\$217,864,272.99	\$244,760,654.39	\$12,867,500.54	\$4,689,096,485.22
Interim Attorneys' Fees/Costs Payments	\$3,502,709.91	\$3,363,464.24	\$5,151,148.78	\$5,457,545.23	\$5,090,482.24	\$4,675,724.68	\$459,879.08	\$48,498,224.95
Number of Payments to Interim Attorneys'	69	25	89	99	92	54	9	625
Attorneys' Fees/Costs Payments (Dismissed Cases)	\$2,741,830.10	\$4,439,538.57	\$5,106,382.65	\$4,791,157.52	\$5,747,755.82	\$6,942,253.81	\$311,923.28	\$97,897,104.41
Number of Payments to Attorneys (Dismissed Cases)	66	131	112	102	113	140	14	5,720
Attorneys' Fees/Costs Payments	\$16,298,140.59	\$22,045,785.00	\$16,658,440.14	\$18,991,247.55	\$20,165,357.38	\$24,884,274.59	\$1,905,941.82	\$253,091,027.23
Petitioners' Award Amount	\$230,140,251.20	\$252,245,932.78	\$199,588,007.04	\$196,217,707.64	\$186,860,677.55	\$208,258,401.31	\$10,189,756.36	\$4,289,610,128.63
Number of Compensated Awards	689	902	521	653	733	719	92	8,369
Fiscal Year	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total

NOTE: Some previous fiscalyear data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals, "Compensated" are petitions that have been paid as a result of a settlement betw een parties or a decision made by the U.S. Court of Federal Claims (Court). The # of aw ards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. How ever, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation. Trust Fund by fiscal year. payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition,

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

# EXHIBIT 17

# Polio Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

Polio vaccine can prevent polio.

Polio (or poliomyelitis) is a disabling and lifethreatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis.

Most people infected with poliovirus have no symptoms, and many recover without complications. Some people will experience sore throat, fever, tiredness, nausea, headache, or stomach pain.

A smaller group of people will develop more serious symptoms that affect the brain and spinal cord:

- Paresthesia (feeling of pins and needles in the legs),
- Meningitis (infection of the covering of the spinal cord and/or brain), or
- Paralysis (can't move parts of the body) or weakness in the arms, legs, or both.

Paralysis is the most severe symptom associated with polio because it can lead to permanent disability and death.

Improvements in limb paralysis can occur, but in some people new muscle pain and weakness may develop 15 to 40 years later. This is called "post-polio syndrome."

Polio has been eliminated from the United States, but it still occurs in other parts of the world. The best way to protect yourself and keep the United States polio-free is to maintain high immunity (protection) in the population against polio through vaccination.

### 2. Polio vaccine

**Children** should usually get 4 doses of polio vaccine at ages 2 months, 4 months, 6–18 months, and 4–6 years.

Most **adults** do not need polio vaccine because they were already vaccinated against polio as children. Some adults are at higher risk and should consider polio vaccination, including:

- People traveling to certain parts of the world
- Laboratory workers who might handle poliovirus
- Health care workers treating patients who could have polio
- Unvaccinated people whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees)

Polio vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Polio vaccine may be given at the same time as other vaccines.

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

 Has had an allergic reaction after a previous dose of polio vaccine, or has any severe, lifethreatening allergies

In some cases, your health care provider may decide to postpone polio vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting polio vaccine.

Not much is known about the risks of this vaccine for pregnant or breastfeeding people. However, polio vaccine can be given if a pregnant person is at increased risk for infection and requires immediate protection.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

 A sore spot with redness, swelling, or pain where the shot is given can happen after polio vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

### 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

# 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="https://www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at www.cdc.gov/vaccines.

# **Hepatitis B Vaccine:**

### What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

**Hepatitis B vaccine** can prevent **hepatitis B**. Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- Acute hepatitis B infection is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- Chronic hepatitis B infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a pregnant person has hepatitis B, their baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

### 2. Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6–18 months of age. The birth dose of hepatitis B vaccine is an important part of preventing long-term illness in infants and the spread of hepatitis B in the United States.

**Children and adolescents** younger than 19 years of age who have not yet gotten the vaccine should be vaccinated.

**Adults** who were not vaccinated previously and want to be protected against hepatitis B can also get the vaccine.

Hepatitis B vaccine is also recommended for the following people:

- People whose sex partners have hepatitis B
- Sexually active persons who are not in a long-term, monogamous relationship
- People seeking evaluation or treatment for a sexually transmitted disease
- Victims of sexual assault or abuse
- Men who have sexual contact with other men
- People who share needles, syringes, or other druginjection equipment
- People who live with someone infected with the hepatitis B virus
- Health care and public safety workers at risk for exposure to blood or body fluids
- Residents and staff of facilities for developmentally disabled people
- People living in jail or prison
- Travelers to regions with increased rates of hepatitis B



 People with chronic liver disease, kidney disease on dialysis, HIV infection, infection with hepatitis C, or diabetes

Hepatitis B vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Hepatitis B vaccine may be given at the same time as other vaccines.

# 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

 Has had an allergic reaction after a previous dose of hepatitis B vaccine, or has any severe, lifethreatening allergies

In some cases, your health care provider may decide to postpone hepatitis B vaccination until a future visit.

Pregnant or breastfeeding people should be vaccinated if they are at risk for getting hepatitis B. Pregnancy or breastfeeding are not reasons to avoid hepatitis B vaccination.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

• Soreness where the shot is given or fever can happen after hepatitis B vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

## 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

# 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="https://www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at <a href="www.fda.gov/">www.fda.gov/</a> <a href="www.fda.gov/">waccines-blood-biologics/vaccines</a>.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at www.cdc.gov/vaccines.

# Haemophilus influenzae type b (Hib) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

Hib vaccine can prevent *Haemophilus influenzae* type b (Hib) disease.

Haemophilus influenzae type b can cause many different kinds of infections. These infections usually affect children under 5 years of age but can also affect adults with certain medical conditions. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Severe Hib infection, also called "invasive Hib disease," requires treatment in a hospital and can sometimes result in death.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the lining of the brain and spinal cord. It can lead to brain damage and deafness.

Hib infection can also cause:

- Pneumonia
- Severe swelling in the throat, making it hard to breathe
- Infections of the blood, joints, bones, and covering of the heart
- Death

### 2. Hib vaccine

Hib vaccine is usually given in 3 or 4 doses (depending on brand).

**Infants** will usually get their first dose of Hib vaccine at 2 months of age and will usually complete the series at 12–15 months of age.

Children between 12 months and 5 years of age who have not previously been completely vaccinated against Hib may need 1 or more doses of Hib vaccine.

Children over 5 years old and adults usually do not receive Hib vaccine, but it might be recommended for older children or adults whose spleen is damaged or has been removed, including people with sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. Hib vaccine may also be recommended for people 5 through 18 years old with HIV.

Hib vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

Hib vaccine may be given at the same time as other vaccines.

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

 Has had an allergic reaction after a previous dose of Hib vaccine, or has any severe, life-threatening allergies

In some cases, your health care provider may decide to postpone Hib vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting Hib vaccine.

Your health care provider can give you more information.



### 4. Risks of a vaccine reaction

 Redness, warmth, and swelling where the shot is given and fever can happen after Hib vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

### 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

### 6. The National Vaccine Injury **Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at www.cdc.gov/vaccines.

# HPV (Human Papillomavirus) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

HPV (human papillomavirus) vaccine can prevent infection with some types of human papillomavirus.

HPV infections can cause certain types of cancers, including:

- cervical, vaginal, and vulvar cancers in women
- penile cancer in men
- anal cancers in both men and women
- cancers of tonsils, base of tongue, and back of throat (oropharyngeal cancer) in both men and women

HPV infections can also cause anogenital warts.

HPV vaccine can prevent over 90% of cancers caused by HPV.

HPV is spread through intimate skin-to-skin or sexual contact. HPV infections are so common that nearly all people will get at least one type of HPV at some time in their lives. Most HPV infections go away on their own within 2 years. But sometimes HPV infections will last longer and can cause cancers later in life.

### 2. HPV vaccine

HPV vaccine is routinely recommended for adolescents at 11 or 12 years of age to ensure they are protected before they are exposed to the virus. HPV vaccine may be given beginning at age 9 years and vaccination is recommended for everyone through 26 years of age.

HPV vaccine may be given to adults 27 through 45 years of age, based on discussions between the patient and health care provider.

Most children who get the first dose before 15 years of age need 2 doses of HPV vaccine. People who get the first dose at or after 15 years of age and younger people with certain immunocompromising conditions need 3 doses. Your health care provider can give you more information.

HPV vaccine may be given at the same time as other vaccines.

# 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of HPV vaccine, or has any severe, lifethreatening allergies
- Is pregnant—HPV vaccine is not recommended until after pregnancy

In some cases, your health care provider may decide to postpone HPV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting HPV vaccine.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given can happen after HPV vaccination.
- Fever or headache can happen after HPV vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

### 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

### 6. The National Vaccine Injury **Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at www.cdc.gov/vaccines.

# MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

MMR vaccine can prevent measles, mumps, and rubella.

- MEASLES (M) causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- MUMPS (M) causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- RUBELLA (R) causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

### 2. MMR vaccine

**Children** need 2 doses of MMR vaccine, usually:

- First dose at age 12 through 15 months
- Second dose at age 4 through 6 years

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. These children should still get 2 additional doses at the recommended ages for long-lasting protection.

**Older children, adolescents**, and **adults** also need 1 or 2 doses of MMR vaccine if they are not already

immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

A third dose of MMR might be recommended for certain people in mumps outbreak situations.

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of MMR or MMRV vaccine, or has any severe, life-threatening allergies
- Is pregnant or thinks they might be pregnant pregnant people should not get MMR vaccine
- Has a weakened immune system, or has a parent, brother, or sister with a history of hereditary or congenital immune system problems
- Has ever had a condition that makes him or her bruise or bleed easily
- Has recently had a blood transfusion or received other blood products
- Has tuberculosis
- Has gotten any other vaccines in the past 4 weeks

In some cases, your health care provider may decide to postpone MMR vaccination until a future visit.



### Case 1:21-cv-01857-TNM Document 31-1 Filed 11/15/21 Page 113 of 131

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting MMR vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Sore arm from the injection or redness where the shot is given, fever, and a mild rash can happen after MMR vaccination.
- Swelling of the glands in the cheeks or neck or temporary pain and stiffness in the joints (mostly in teenage or adult women) sometimes occur after MMR vaccination.
- More serious reactions happen rarely. These can include seizures (often associated with fever) or temporary low platelet count that can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

### 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

### 6. The National Vaccine Injury **Compensation Program**

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at <a href="https://www.cdc.gov/vaccines">www.cdc.gov/vaccines</a>.

# Varicella (Chickenpox) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

Varicella vaccine can prevent varicella.

Varicella, also called "chickenpox," causes an itchy rash that usually lasts about a week. It can also cause fever, tiredness, loss of appetite, and headache. It can lead to skin infections, pneumonia, inflammation of the blood vessels, swelling of the brain and/or spinal cord covering, and infections of the bloodstream, bone, or joints. Some people who get chickenpox get a painful rash called "shingles" (also known as herpes zoster) years later.

Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant people, and people with a weakened immune system. Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox.

Most people who are vaccinated with 2 doses of varicella vaccine will be protected for life.

### 2. Varicella vaccine

**Children** need 2 doses of varicella vaccine, usually:

- First dose: age 12 through 15 months
- Second dose: age 4 through 6 years

Older children, adolescents, and adults also need 2 doses of varicella vaccine if they are not already immune to chickenpox.

Varicella vaccine may be given at the same time as other vaccines. Also, a child between 12 months and 12 years of age might receive varicella vaccine together with MMR (measles, mumps, and rubella) vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

# 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of varicella vaccine, or has any severe, lifethreatening allergies
- Is pregnant or thinks they might be pregnant pregnant people should not get varicella vaccine
- Has a weakened immune system, or has a parent, brother, or sister with a history of hereditary or congenital immune system problems
- Is taking salicylates (such as aspirin)
- Has recently had a blood transfusion or received other blood products
- Has tuberculosis
- Has gotten any other vaccines in the past 4 weeks

In some cases, your health care provider may decide to postpone varicella vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting varicella vaccine.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

- Sore arm from the injection, redness or rash where the shot is given, or fever can happen after varicella vaccination.
- More serious reactions happen very rarely. These can include pneumonia, infection of the brain and/ or spinal cord covering, or seizures that are often associated with fever.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get varicella vaccine.

It is possible for a vaccinated person to develop a rash. If this happens, the varicella vaccine virus could be spread to an unprotected person. Anyone who gets a rash should stay away from infants and people with a weakened immune system until the rash goes away. Talk with your health care provider to learn more.

Some people who are vaccinated against chickenpox get shingles (herpes zoster) years later. This is much less common after vaccination than after chickenpox disease.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

# 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

# 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="https://www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at <a href="https://www.cdc.gov/vaccines">www.cdc.gov/vaccines</a>.

# DTaP (Diphtheria, Tetanus, Pertussis) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

DTaP vaccine can prevent diphtheria, tetanus, and pertussis.

Diphtheria and pertussis spread from person to person. Tetanus enters the body through cuts or wounds.

- **DIPHTHERIA** (**D**) can lead to difficulty breathing, heart failure, paralysis, or death.
- TETANUS (T) causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- PERTUSSIS (aP), also known as "whooping cough," can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious especially in babies and young children, causing pneumonia, convulsions, brain damage, or death. In teens and adults, it can cause weight loss, loss of bladder control, passing out, and rib fractures from severe coughing.

### 2. DTaP vaccine

DTaP is only for children younger than 7 years old. Different vaccines against tetanus, diphtheria, and pertussis (Tdap and Td) are available for older children, adolescents, and adults.

It is recommended that children receive 5 doses of DTaP, usually at the following ages:

- 2 months
- 4 months
- 6 months
- 15-18 months
- 4−6 years

DTaP may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

DTaP may be given at the same time as other vaccines.

## 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of any vaccine that protects against tetanus, diphtheria, or pertussis, or has any severe, lifethreatening allergies
- Has had a coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)
- Has seizures or another nervous system problem
- Has ever had Guillain-Barré Syndrome (also called "GBS")
- Has had severe pain or swelling after a previous dose of any vaccine that protects against tetanus or diphtheria

In some cases, your child's health care provider may decide to postpone DTaP vaccination until a future visit.

Children with minor illnesses, such as a cold, may be vaccinated. Children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.

Your child's health care provider can give you more information.



#### 4. Risks of a vaccine reaction

- Soreness or swelling where the shot was given, fever, fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

# 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

## 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC's website at <a href="www.cdc.gov/vaccines">www.cdc.gov/vaccines</a>.

# Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, thousands of people in the United States die from flu, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flurelated visits to the doctor each year.

## 2. Live, attenuated influenza vaccine

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called "LAIV") is a nasal spray vaccine that may be given to non-pregnant people 2 **through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine does not cause flu.

Influenza vaccine may be given at the same time as other vaccines.

# 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Is younger than 2 years or older than 49 years of age
- Is **pregnant**. Live, attenuated influenza vaccine is not recommended for pregnant people
- Has had an allergic reaction after a previous dose of influenza vaccine, or has any severe, life-threatening allergies
- Is a child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin- or salicylate-containing products
- Has a weakened immune system
- Is a child 2 through 4 years old who has asthma or a history of wheezing in the past 12 months
- Is 5 years or older and has asthma
- Has taken influenza antiviral medication in the last
   3 weeks
- Cares for severely immunocompromised people who require a protected environment
- Has other underlying medical conditions that can put people at higher risk of serious flu complications (such as lung disease, heart disease, kidney disease



like diabetes, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders)

- Does not have a spleen, or has a non-functioning spleen
- Has a cochlear implant
- Has a cerebrospinal fluid leak (a leak of the fluid that surrounds the brain to the nose, throat, ear, or some other location in the head)
- Has had Guillain-Barré Syndrome within 6 weeks after a previous dose of influenza vaccine

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing, and headache can happen after LAIV vaccination.
- Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

# 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

# 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

### 7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
- Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's website at www.cdc.gov/flu.

8/6/2021

# Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

### 1. Why get vaccinated?

Pneumococcal conjugate vaccine (PCV13) can prevent pneumococcal disease.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions, adults 65 years or older, and cigarette smokers are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

### 2. PCV13

PCV13 protects against 13 types of bacteria that cause pneumococcal disease.

**Infants and young children** usually need 4 doses of pneumococcal conjugate vaccine, at ages 2, 4, 6, and 12–15 months. **Older children (through age 59 months)** may be vaccinated if they did not receive the recommended doses.

A dose of PCV13 is also recommended for **adults** and children 6 years or older with certain medical conditions if they did not already receive PCV13.

This vaccine may be given to healthy **adults 65 years or older** who did not already receive PCV13, based on discussions between the patient and health care provider.

# 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

 Has had an allergic reaction after a previous dose of PCV13, to an earlier pneumococcal conjugate vaccine known as PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), or has any severe, life-threatening allergies

In some cases, your health care provider may decide to postpone PCV13 vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PCV13.

Your health care provider can give you more information.

### 4. Risks of a vaccine reaction

• Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, and chills can happen after PCV13 vaccination.

Young children may be at increased risk for seizures caused by fever after PCV13 if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

# 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

# 6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at <a href="www.hrsa.gov/vaccinecompensation">www.hrsa.gov/vaccinecompensation</a> or call 1-800-338-2382 to learn about the program and about filing a claim.

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
- Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's website at www.cdc.gov/vaccines.



# EXHIBIT 18

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA)
AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND
OLDER

#### FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably.<sup>1</sup>

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- a 2-dose primary series to individuals 12 through 15 years;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19

<sup>&</sup>lt;sup>1</sup> When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine.
   Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a 2-dose primary series to individuals 12 years of age and older;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:
  - 65 years of age and older
  - o 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine.
   Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see <a href="https://www.cvdvaccine.com">www.cvdvaccine.com</a>.

### WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

### WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

2

Revised: 29 October 2021

### WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine when prepared according to their respective instructions for use, can be used interchangeably.

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

### WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- · are breastfeeding
- have received another COVID-19 vaccine
- · have ever fainted in association with an injection

### **HOW IS THE VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

### **Booster Dose:**

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - o 18 through 64 years of age at high risk of severe COVID-19

3

- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals
  who have completed primary vaccination with a different authorized
  COVID-19 vaccine. Please check with your healthcare provider regarding
  eligibility for and timing of the booster dose.

The vaccine may not protect everyone.

Revised: 29 October 2021

### WHO SHOULD NOT GET THE VACCINE?

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

#### WHAT ARE THE INGREDIENTS IN THE VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:

mRNA and lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

• potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains the following additional ingredients: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

#### HAS THE VACCINE BEEN USED BEFORE?

Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is authorized for use in individuals 12 years and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

### WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

#### WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

### WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

5

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: <a href="https://www.cdc.gov/vsafe">www.cdc.gov/vsafe</a>.

### WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

# ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

# CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

### WHAT IF I AM IMMUNOCOMPROMISED?

If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are

immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

### WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

#### WILL THE VACCINE GIVE ME COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

#### **KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

### **ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	
	1-877-829-2619 (1-877-VAX-CO19)

#### **HOW CAN I LEARN MORE?**

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at <a href="https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization">https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</a>.
- Contact your local or state public health department.

### WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

### CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a

COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

### WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

### WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit <a href="https://www.hrsa.gov/cicp/">www.hrsa.gov/cicp/</a> or call 1-855-266-2427.

### WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

8 Revised: 29 October 2021

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



Manufactured by Pfizer Inc., New York, NY 10017

### BIONTECH Manufactured for

Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany

LAB-1451-11.2

Revised: 29 October 2021



Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode date: 09/30/2021

9

### **CERTIFICATE OF SERVICE**

On this 15th day of November, 2021, a true and accurate copy of the foregoing Amended Verified Complaint for Declaratory and Injunctive Relief was served on counsel for all parties through the District Court's Electronic Case Filing system (CM-ECF).

/s Rolf G. S. Hazelhurst