West Virginia E-Filing Notice

CC-41-2025-C-230

Judge: Todd Kirby

To: John Bryan
jhb@johnbryanlaw.com

NOTICE OF FILING

IN THE CIRCUIT COURT OF RALEIGH COUNTY, WEST VIRGINIA
Miranda Guzman v. State Department of Education
CC-41-2025-C-230

The following complaintwas FILED on 6/24/2025 10:49:08 AM

Notice Date: 6/24/2025 10:49:08 AM

Brianne Steele
CLERK OF THE CIRCUIT COURT
Raleigh County
222 Main Street
BECKLEY, WV 25801

(304) 255-9135
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COVER SHEET

E-FILED | 6/24/2025 10:49 AM
CC-41-2025-C-230
Raleigh County Circuit Clerk
Brianne Steele

GENERAL INFORMATION

IN THE CIRCUIT COURT OF RALEIGH COUNTY WEST VIRGINIA

Miranda Guzman v. State Department of Education

First Plaintiff: ☐ Business ☑ Individual ☐ Government ☐ Other

First Defendant: ☐ Business ☐ Individual ☑ Government ☐ Other

Judge: Todd Kirby

COMPLAINT INFORMATION

Case Type: Civil

Complaint Type: Other

Origin: ☑ Initial Filing ☐ Appeal from Municipal Court ☐ Appeal from Magistrate Court

Jury Trial Requested: ☐ Yes ☑ No **Case will be ready for trial by:** _____

Mediation Requested: ☐ Yes ☑ No

Substantial Hardship Requested: ☐ Yes ☑ No

☐ Do you or any of your clients or witnesses in this case require special accommodations due to a disability?

- ☐ Wheelchair accessible hearing room and other facilities
- ☐ Interpreter or other auxiliary aid for the hearing impaired
- ☐ Reader or other auxiliary aid for the visually impaired
- ☐ Spokesperson or other auxiliary aid for the speech impaired
- ☐ Other: _____

☐ I am proceeding without an attorney

☑ I have an attorney: John Bryan, PO Box 366 , Union, WV 24983

SERVED PARTIES (only first 10 parties are listed)

Name: State Department of Education
Address: Nancy J. White 1900 Kanawha Boulevard East, Charleston WV 25305
Days to Answer: 30 **Type of Service:** Filer - Private Process Server

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Name: State Department of Education
Address: Victor Gabriel 1900 Kanawha Boulevard East, Charleston WV 25305
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Days to Answer: 30 **Type of Service:** Filer - Private Process Server

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Name: State Department of Education
Address: Gregory Wooten 1900 Kanawha Boulevard East, Charleston WV 25305
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Name: State Department of Education
Address: Cathy Justice 1900 Kanawha Boulevard East, Charleston WV 25305
Days to Answer: 30 **Type of Service:** Filer - Private Process Server

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Name: State Department of Education
Address: Michelle Blatt 1900 Kanawha Boulevard East, Charleston WV 25305
Days to Answer: 30 **Type of Service:** Filer - Private Process Server

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IN THE CIRCUIT COURT OF RALEIGH COUNTY, WEST VIRGINIA
FOURTEENTH JUDICIAL CIRCUIT

MIRANDA GUZMAN, *individually and on behalf of her minor child* A.G.,

Plaintiff,

v.

WEST VIRGINIA BOARD OF EDUCATION; NANCY J. WHITE, *in her official capacity as President of the Board of Education*; VICTOR GABRIEL, F. SCOTT ROTRUCK, L. PAUL HARDESTY, ROBERT W. DUNLEVEY, CHRISTOPHER STANSBURY, DEBORAH SULLIVAN, GREGORY WOOTEN, AND CATHY JUSTICE, *all in their official capacities as members of the West Virginia Board of Education;* MICHELE BLATT, *in her official capacity as State Superintendent of Schools*; RALEIGH COUNTY BOARD OF EDUCATION; LARRY FORD, RICHARD SNUFFER, CHARLOTTE HUTCHENS, MARIE HAMRICK, and MARSHA SMITH, *all in their official capacities as members of the Raleigh County Board of Education; and* SERENA L. STARCHER, *in her official capacity as Superintendent, Raleigh County Board of Education,*

Defendants.

Civil Action No.: _____

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This case evokes unpleasant memories from our country's past because Defendant school officials are essentially standing in the schoolhouse door defiantly interfering with controlling law and blocking Plaintiff—a widow—from sending her child, A.G., to school.

2. West Virginia's Supreme Court of Appeals has held that "[t]he mandatory requirements of 'a thorough and efficient system of free schools' found in . . . the West Virginia Constitution, make education a fundamental, constitutional right in this State." *Pauley v. Kelly*, 162 W. Va. 672, 707 (1979); *see also State v. Beaver*, No. 22-616, 2022 W. Va. LEXIS 700, *36 (W. Va. 2022) ("Both the State Constitution and [West Virginia courts] have established that education is a fundamental right"); *see also Goss v. Lopez,* 419 U.S. 565, 95 (1975) (holding when state law creates a right to public education, that right becomes protected by the Due Process Clause of the Fourteenth Amendment).

3. But despite the fundamental right to receive an education in this State, A.G. has nevertheless been excluded from West Virginia's educational system because of Plaintiff's religious beliefs and is unable to access the practical and social benefits of a formal education that her secular peers enjoy.

4. This is because in West Virginia it is unlawful for any child to attend "any of the schools of the state or a state-regulated childcare center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough" and "[n]o person shall be allowed to enter school without at least one dose of each required vaccine." W. Va. Code § 16-3-4 (c) and (e) ("the **Compulsory Vaccination Law**" or "**CVL**"). The State Health Officer and other public health officials within the West Virginia

Department of Health regulate whether schoolchildren are following the Compulsory Vaccination Law. *See generally* W. Va. Code § 16-3-4.

5. West Virginia's interest in mandating that schoolchildren are vaccinated, however, certainly is not absolute, as evidenced by the fact that the State permits discretionary secular medical exemptions from the Compulsory Vaccination Law. *See id.* at § 16-3-4 (h) (providing that public health officials may grant a medical exemption "upon sufficient medical evidence that immunization is contraindicated or there exists a specific precaution to a particular vaccine.").

6. Similar to language in the U.S. Constitution that vests in the President unitary executive authority to enforce federal law, the West Virginia Constitution vests solely in the Governor "chief executive power" to generally enforce State law, entrusting the Governor to "take care that the laws be faithfully executed." W. Va. Const. art. VII, § 5 (1872).

7. Faithfully executing his duty to uphold the law, on January 14, 2025, Governor Patrick Morrisey issued Executive Order 7-25 on January 14, 2025 ("**Executive Order**") pursuant to his exclusive chief executive power under the State Constitution's Take Care Clause to enforce West Virginia law, including the West Virginia Equal Protection for Religion Act enacted by the Legislature in 2023, W.V. Code 35-1A-1 ("**EPRA**"), other applicable sections of the West Virginia Constitution, precedent of the West Virginia Supreme Court, and certain litigation and rulings in federal court including in *Perry v. Marteny*, NDWV, 2:24-cv-00018-TSK. A true and accurate copy of the Executive Order is attached hereto as **Exhibit 1.**

8. To enforce the EPRA, Governor Morrisey's Executive Order directed the State Health Officer and other officials in the West Virginia Department of Health to establish a religious exemption process so parents could request that their children be exempt from the Compulsory Vaccination Law based on their religious beliefs.

9. In response, West Virginia Department of Health officials properly implemented Governor Morrisey's lawful Executive Order and began to issue certificates of exemption from mandatory vaccination to children so they could attend school.

10. A.G. received a religious exemption certificate from the State Health Department, exempting her from the CVL's mandatory vaccination scheme because the CVL substantially burdened Plaintiff's exercise of religion including her religious beliefs to not vaccinate her child. Attached as **Exhibit 2** is a true and correct copy of A.G.'s religious exemption certificate.

11. Plaintiff then enrolled A.G. in Clear Fork District Elementary School, a PK-5 elementary school in Raleigh County, for the upcoming 2025-26 school year

12. But thereafter, Defendants West Virginia Board of Education, by and through its members Nancy White, Victor Gabriel, F. Scott Rotruck, L. Paul Hardesty, Robert W. Dunlevey, Christopher Stansbury, Deborah Sullivan, Gregory Wooten, and Cathy Justice; and its Superintendent Michele Blatt, (collectively the "**State Board Defendants**"), decided to issue a directive to school districts in the State advising them to *not* honor Governor Morrisey's Executive Order, and to *not* permit unvaccinated children—like A.G.—to attend school despite them receiving a valid religious exemption certificate from the State Health Officer.

13. The Raleigh County Board of Education, by and through its school board, composed of Defendants Larry Ford, Richard Snuffer, Charlotte Hutchens, Marie Hamrick, and Marsha Smith, and its Superintendent, Serena Starcher (collectively the "**Local Board Defendants**"), is following this illegal directive of the State Board Defendants and disregarding the Governor's Executive Order, excluding unvaccinated children with a valid religious exemption certificate like A.G. from attending school.

14. Specifically, on June 17, 2025, Local Board Defendant and County Superintendent Serena Starcher emailed Plaintiff to advise that A.G.'s valid religious exemption certificate would not be accepted because Raleigh County Schools will "accept medical exemptions only."

15. As a consequence of Defendants denying A.G.'s valid religious exemption from the CVL authorized by the West Virginia Department of Health, stopping her from enrolling in the Raleigh County Schools unless she takes mandatory vaccines under the CVL's schedule that violate Plaintiff's religious beliefs, and disregarding Governor Morrisey's Executive Order, the CVL and Defendants' enforcement of it violates the EPRA, substantially burdening Plaintiff's and her child's exercise of their religious beliefs to not vaccinate.

16. Although forty-five states allow schoolchildren *both* secular and religious exemptions from compulsory vaccines, West Virginia is a radical outlier from the rest of the country in that its CVL *only* allows secular medical exemptions and disallows religious exemptions.[1]

17. Defendants' enforcement of the CVL against Plaintiff, and defiance of Governor Morrisey's Executive Order enforcing the EPRA, are particularly troubling because the overwhelming majority of West Virginians are religious.

18. The straightforward legal issue presented in this Complaint is whether Defendants' actions in enforcing the CVL violate the EPRA.

19. Defendants' enforcement of the CVL against Plaintiff violates the EPRA for at least two reasons. First, it substantially burdens Plaintiff's religious beliefs to not vaccinate A.G. and is

[1] Forty-five states allow school-age children to be exempt from vaccinations for religious reasons and at least two others have provisions grandfathering in children with a prior religious exemption. *See* NATIONAL CONFERENCE OF STATE LEGISLATURES, *States with Religious and Philosophical Exemptions from School Immunization Requirements,* https://www.ncsl.org/health/state-non-medical-exemptions-from-school-immunization-requirements (last visited June 21, 2025).

not the least restrictive means of furthering any purported compelling State interest because it fails to provide a religious exemption option along with the secular medical exemption and other exceptions that it already allows. *See* W. Va. Code 35-1A-1(a)(1). Second, and as a separate and distinct violation of the EPRA, it treats Plaintiff's religious conduct more restrictively than conduct of reasonably comparable risk. *See* W. Va. Code 35-1A-1(a)(2).

PARTIES

20. Plaintiff Miranda Guzman is a widow who resides in the unincorporated community of Clear Creek, West Virginia in Raleigh County ("**Plaintiff**" or "**Ms. Guzman**"). Plaintiff maintains profound religious objections to injecting her four-year-old child, A.G., with the vaccinations required under the CVL's schedule. Defendants prohibit A.G. from attending any Raleigh County Schools unless she receives all CVL-mandated vaccines.

21. Plaintiff obtained a religious exemption certificate from the West Virginia Department of Health exempting A.G. from the CVL's vaccination requirements for the 2025-26 school year. The West Virginia Department of Health also issued a copy of A.G.'s religious exemption certificate to Clear Fork District Elementary School, a public school within the Raleigh County Schools. *See* **Exhibit 2**.

22. Defendant West Virginia Board of Education, pursuant to W. Va. Code §18-2-5, "[s]ubject to and in conformity with the Constitution and laws of this state," has the power to make and enforce rules in certain designated areas involving the general supervision of public schools. These areas of limited authority subject to the West Virginia Constitution and general laws of the State are carried out by and through its members Nancy White, Victor Gabriel, F. Scott Rotruck, L. Paul Hardesty, Robert W. Dunlevey, Christopher Stansbury, Deborah Sullivan, Gregory Wooten, Cathy Justice, and Superintendent Michele Blatt. All are sued in their official capacities.

23. Defendant, Raleigh County Board of Education, pursuant to W. Va. Code §18-5-1, by and through its school board, composed of Defendants Larry Ford, Richard Snuffer, Charlotte Hutchens, Marie Hamrick, and Marsha Smith, and Superintendent Serena Starcher, are all sued in their official capacities. The Local Board Defendants pursuant to W. Va. Code §§ 18-4-10, 18-5-1, 18-5-5, and 18-5-34 have authority and control in certain areas over Raleigh County Schools.

JURISDICTION AND VENUE

24. Pursuant to W. Va. Code § 51-2-2, this Court has jurisdiction over this matter, because it is a matter arising in equity that seeks injunctive and declaratory relief in accordance with the EPRA, W. Va. Code § 35-1A-1(b)(1).

25. Venue is proper in this Circuit and Raleigh County, pursuant to W. Va. Code § 14-2-2, because Plaintiff resides in this County. Venue is also proper under W. Va. Code § 56-1-1, because the Local Board Defendants reside in this County.

FACTS

A. West Virginia Constitution's Take Care Clause First Enacted in 1872 Authorizes the Governor as Chief Executive to Enforce State Laws

26. In April of 1872, West Virginia Governor John J. Jacob by written Proclamation enshrined into law the West Virginia Constitution.[2]

27. Embodied in the West Virginia Constitution of 1872 that still remains in effect today is W. Va. Const. art. VII, § 5 (1872), regarding the Executive Branch and the Governor's authorized State powers.[3]

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[2] *See* https://www.wvlegislature.gov/legisdocs/publications/acts/Acts_1872_const_conv.pdf (last visited June 21, 2025).

[3] *Id.*; *see also* https://www.wvlegislature.gov/wvcode/wv_con.cfm#articleV (last visited June 21, 2025).

28. It says, "The chief executive power shall be vested in the governor, who shall take care that the laws be faithfully executed." W. Va. Const. art. VII, § 5 (1872).

29. Further, the Preamble to the State Constitution says, "Since through Divine Providence we enjoy the blessings of civil, political and religious liberty, we, the people of West Virginia, in and through the provisions of this Constitution, reaffirm our faith in and constant reliance upon God and seek diligently to promote, preserve and perpetuate good government in the state of West Virginia for the common welfare, freedom and security of ourselves and our posterity." W. Va. Const. pmbl. (1872).

30. An expansive and broad religious freedom clause guarantee in the State Constitution also declares in relevant part that no "man [shall] be enforced, restrained, molested or burthened, in his body or goods, or otherwise suffer, on account of his religious opinions or beliefs, but all men shall be free to profess and by argument, to maintain their opinions in matters of religion." W. Va. Const. art. III, § 15 (1872).

B. Governor Morrisey's Executive Order Enforced the EPRA, Correcting the CVL's Glaring Defect of Not Allowing Families Religious Exemptions

31. As the State's Chief Executive responsible for enforcing West Virginia law, including the EPRA, Governor Morrisey's Executive Order was properly directed to public health officials requesting they implement a religious exemption process for families because the CVL, without such a process, violates the EPRA. *See* **Exhibit 1**.

32. For example, West Virginia's scheme of allowing discretionary medical exemptions from vaccines while simultaneously adopting a de facto "no religious exemption" policy significantly undermines the State's public health goals. *See* W. Va. Code § 16-3-4 (h); *see also Bosarge v. Edney*, 669 F. Supp. 3d 598, 625 (S.D. Miss. 2023) (holding that Mississippi's

mandatory vaccination statutory scheme, which allowed medical exemptions while excluding religious exemptions, violated the First Amendment).

33. And West Virginia is among the most religious states in America.[4]

34. According to the Pew Research Center, 77% of West Virginians say that "they believe in God with absolute certainty."[5]

35. Religious exemptions have long been the norm when it comes to school vaccination laws. Forty-five states (plus the District of Columbia) currently offer religious exemptions from their mandatory school vaccination laws.[6]

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[4] *See* PEW RESEARCH CENTER, *How religious is you state*? *Available* at https://www.pewresearch.org/fact-tank/2016/02/29/how-religious-is-your-state/?state=west-virginia (last visited June 21, 2025).

[5] *See* PEW RESEARCH CENTER, *Religious Landscape Study*, *available* at https://www.pewresearch.org/religious-landscape-study/database/west-virginia/ (last visited June 21, 2025).

[6] *See* Ala. Code § 16-30-3; Alaska Admin. Code tit. 7, § 57.550; Ariz. Rev. Stat. Ann. §§ 15-872(G), -873(A)(1); Ark. Code Ann. § 6-18-702(d)(4)(A); Colo. Rev. Stat. §§ 25-4-902, -903(b)(V); Del. Code Ann. tit. 14, § 131(a)(6); D.C. Code §§ 38-501, -506(1); Fla. Stat. § 1003.22(1); Ga. Code Ann. § 20-2-771(e); Haw. Rev. Stat. §§ 302A-1154, -1156(2); Idaho Code §§ 39-4801, -4802(2); 105 Ill. Comp. Stat. § 5/27-8.1(6); Ind. Code § 21-40-6; Iowa Code § 139A.8(4)(a)(2); Kan. Stat. Ann. § 72-6262(b)((2); Ky. Rev. Stat. Ann. § 214.034(2); La. Stat. Ann. §§ 17:170(E), 40:31.16(D); Md. Code Ann., Educ. § 7-403(b)(1); Mass. Gen Laws ch. 76, § 15; Mich. Comp. Laws §§ 333.9208, .9215(2); Minn. Stat. § 121A-15; Mo. Rev. Stat. §§ 167.181(3), 210.003; Mont. Code Ann. §§ 20-5-403, -405(1)(a); Neb. Rev. Stat. §§ 79-217, 221(1); Nev. Rev. Stat. §§ 392.435, .437; N.H. Rev. Stat. Ann. § 141-C:20-a, :20-c; N.J. Stat. Ann. § 26:1A-9.1; N.M. Stat. Ann. § 24-5-1, -3(A); N.C. Gen. Stat. §§ 130A-155, -157; N.D. Cent. Code § 23-07-17.1(3); Ohio Rev. Code Ann. § 3313.671(B)(4); Okla. Stat. tit. 70, §§ 1210.191, .192; Or. Rev. Stat. § 433.267(1)(c)(A); 28 Pa. Cons. Stat. §§ 23-83, -84; 16 R.I. Gen. Laws § 16-38-2(a); S.C. Code Ann. § 44-29-180(D); S.D. Codified Laws § 13-28-7.1; Tenn. Code Ann. § 49-6-5001(b)(2); Tex. Educ. Code Ann. § 38.001(c)(1)(B); Utah Code Ann. § 53G-9-303(3); Vt. Stat. Ann. tit. 18, §§ 1121, 1122(3)(A); Va. Code Ann. §§ 22.1-271.2(C), 32.1-46(D)(1); Wash. Rev. Code § 28A.210.080, .090(1)(c); Wis. Stat. § 252.04(3); Wyo. Stat. Ann. § 21-4-309(a). Mississippi now offers a religious exemption after a federal court issued a permanent injunction following a free exercise challenge requiring Mississippi to provide a religious exemption process. *See Bosarge v. Edney*, 669 F. Supp. 3d 598, 625 (S.D. Miss. 2023).

36. Until Governor Morrisey's Executive Order enforcing the EPRA, West Virginia was a radical outlier in prohibiting a religious exemption option from mandatory vaccines, and the *only state* in the country to have *never* offered families a religious exemption option. Only five states do not currently allow religious exemptions, and for most of them, this is a relatively recent development. California, Maine, Connecticut, and New York historically allowed religious exemptions, but those options were recently removed by the legislatures of those states.[7]

37. Because infectious diseases spread not only in school settings and impact adults and schoolchildren alike, and most of the vaccines required to attend school under the CVL do not in any event prevent transmission, the CVL can never credibly fulfill its contagious disease mitigation goals.

38. Even assuming all vaccines required by the CVL prevent transmission, which they do not, universal vaccination is not the only disease prevention tactic that can be deployed. States with a religious exemption process deploy a variety of alternative tactics, such as quarantine in the event of an outbreak, temporary exclusion from school, and other measures to help control disease.

39. Moreover, West Virginia could also do what other surrounding states do in the event of a disease outbreak and keep unvaccinated children home when there is an outbreak.

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[7] *See, e.g.*, Cal. Health & Safety Code § 120325 et seq. (religious exemption eliminated in 2016); N.Y. Pub. Health Law § 2164(1) (religious exemption removed in 2019); Conn. Gen. Stat. § 10-204a (religious exemption eliminated in 2021); Me. Stat. tit. 20-A, § 6355 (religious exemption eliminated in 2019). Notably, West Virginia is the only state that has never offered a religious exemption option. W. Va. Code § 16-3-4.

40. Notably, the states contiguous to West Virginia that allow for religious exemptions from childhood vaccination laws all implement the less restrictive alternative of quarantining, if an outbreak of an infectious disease were ever to occur.[8]

41. West Virginia's CVL also does not require any of the least restrictive countermeasures for children with medical exemptions like other states, or for unvaccinated teachers and staff working in the school system including in the Raleigh County Schools.

42. Indeed, if vaccination is effective against transmission of disease, as Defendants claim is the justification for the CVL, then a handful of religious exemptions for in-person students would present absolutely no risk to the remaining vaccinated students who attend school in person, particularly assuming as true Defendants' anticipated position that the mandated vaccines under the CVL's schedule are effective and work as intended.

43. The overwhelming majority of states have for decades recognized the compelling interest in respecting their citizens' religious freedoms and have allowed for a religious exemption

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[8] *See, e.g.*, 28 Pa. Code § 27.77(e) (Pennsylvania: "Whenever one of the diseases … has been identified within a child care group setting, the [health] Department … may order the exclusion from the child care group setting …which is determined to be at high-risk of transmission of that disease, of an individual susceptible to that disease in accordance with public health standards …"); Kentucky Exemption Form ("In the event that the county health department or state health department declares an outbreak of a vaccine-preventable disease for which proof of immunity for a child cannot be provided, he or she may not be allowed to attend childcare or school for up to three (3) weeks, or until the risk period ends.") *available* at https://www.chfs.ky.gov/agencies/dph/dehp/imm/EPID230a.pdf; Md. Code Regs. 10.06.04.05(B) (Maryland: "The exemption allowed under … this regulation does not apply when the Secretary declares an emergency or epidemic of disease"); Oh. Rev. Code § 3313.671(C) (Ohio: "a school may deny admission to a pupil otherwise exempted from the chicken pox immunization requirement if … a chicken pox epidemic exists in the school's population. The denial of admission shall cease when the director notifies the principal … that the epidemic no longer exists"); 12 Va. Admin Code 5-110-80(A)(3) (Virginia: "Upon the identification of an outbreak, potential epidemic, or epidemic of a vaccine-preventable disease in a public or private school, the commissioner has the authority to require the exclusion from such school of all children who are not immunized against that disease.").

option from mandatory childhood vaccination requirements, further demonstrating childhood vaccination requirements are more than capable of allowing for religious exemptions without a problem.

44. Recently, the Honorable Thomas S. Kleeh, Chief Judge of the U.S. Northern District Court of West Virginia, issued a preliminary injunction and Order in favor of a student challenging the CVL under the First Amendment's Free Exercise Clause, holding that State officials had "failed to demonstrate W. Va. Code § 16-3-4 is narrowly tailored to achieve the identified compelling state interest." *See* **Exhibit 3** at 58, a true copy of the Order is attached.

45. But Defendants continue to stand alone on an island by enforcing the antiquated CVL that was first enacted in 1937, which glaringly has never offered a religious exemption option to families in the State like Plaintiff and her child A.G.

C. The CVL Has Other Numerous Defects That Undermine the State's Public Health Goals

46. By way of background, vaccination for some of the diseases required by the CVL have been combined into single shot, for example, the measles, mumps, and rubella ("**MMR**") vaccine.

47. That said, most of the injections required under the CVL provide, at best, personal protection.

48. For example, the tetanus, diphtheria, and pertussis vaccines ("**DTaP**" licensed for children up to age 6 and "**Tdap**" licensed for children 10 years of age and older) do not prevent infection or transmission of the target diseases. These vaccines potentially provide only a temporary level of personal protection by lessening the chances a recipient will experience the symptoms of these infections.

49. Tetanus is not contagious from person to person. As such, the tetanus vaccine does not prevent infection and transmission of a communicable disease but rather can only provide personal protection for the recipient.[9]

50. Likewise, the pertussis vaccine at best provides only some degree of potential personal protection for a limited duration of time.[10]

51. The same is true of the diphtheria vaccine—it at best provides some potential degree of personal protection.[11]

52. The meningococcal vaccine also does not contribute to herd immunity but at best provides an undefined potential personal benefit to the vaccine recipient. "Rates of meningococcal disease have declined in the United States since the 1990s and remain low today. Much of the decline occurred before the routine use of MenACWY vaccines. … [D]ata suggest MenACWY

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[9] *See* Centers for Disease Control and Prevention Pink Book, *available* at https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-21-tetanus.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html ("Tetanus is not contagious from person to person.") (last visited June 23, 2025).

[10] *See e.g.*, https://pubmed.ncbi.nlm.nih.gov/31333640/ ("Natural infection evokes both mucosal and systemic immune responses, while aPVs [acellular pertussis vaccine, the exclusive pertussis vaccine used in the United States] induce only a systemic immune response. … Mucosal immunity is essential to prevent colonization and transmission of B. pertussis organisms. Consequently, preventive measures such as aPVs that do not induce a valid mucosal response **can prevent disease but cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. As such, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect**.") (emphasis added) (last visited June 21, 2025).

[11] *See e.g.*, https://pubmed.ncbi.nlm.nih.gov/5026197/ (Diphtheria vaccine only creates antibodies to a toxin released by the diphtheria bacteria and does not generate any antibodies to the diphtheria bacteria itself, hence "**Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection**.") (emphasis added) (last visited June 21, 2025).

vaccines **have provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity).**"[12]

53. Contrary to the common conceptions, the currently mandated polio vaccine (and the only one available in the United States) also does not prevent infection and transmission of the targeted pathogen. It too is a personal protection vaccine at best. That is because the "inactivated polio vaccine (IPV) is the only polio vaccine that has been given in the United States since 2000." "IPV… protects people from polio disease but does not stop transmission of the virus."[13]

54. Like COVID-19 vaccines, these vaccines in the CVL's schedule do not result in "herd immunity." And West Virginia does not require COVID-19 vaccines as a condition of entering school. *See* W.Va. Code §§ 16-3-4b, 16-3-4c.

55. Since these products potentially reduce symptoms, but do not prevent infection and transmission, those vaccinated with these products are more likely to asymptomatically spread these pathogens due to a false sense of security and misunderstanding of the limitations of these products.

56. Further, hepatitis B is not transmitted through activities in a school setting, as confirmed by federal health authorities. In response to a FOIA request, the CDC stated, "A search of our [CDC] records failed to reveal any documents" of "transmission of Hepatitis B in an

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[12] *See* CDC, Meningococcal Vaccination: *What Everyone Should Know*, *available* at https://www.cdc.gov/vaccines/vpd/mening/public/index.html (emphasis added) (last visited June 21, 2025).

[13] *See* CDC webpage, *Polio Disease and Poliovirus Containment*, *available* at https://www.cdc.gov/orr/polioviruscontainment/diseaseandvirus.htm, which links to the CDC et al., *Polio Global Eradication Initiative* webpage, *available* at https://polioeradication.org/about-polio/the-vaccines/ipv/, which further explains: "IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces … **IPV does not stop transmission of the virus**." (emphases added) (last visited June 21, 2025).

elementary, middle or high school setting." *See* CDC FOIA Response Regarding Hep B Vaccine, a true and correct copy attached hereto as **Exhibit 4**.

57. Thus, four of the six injections required under the CVL are incapable of preventing infection and transmission of target pathogens in the school setting and are, at best, personal protection vaccines.[14]

58. The only remaining vaccines required under the CVL are the MMR and varicella injections.

59. Unlike those who have been previously infected with a target pathogen (nearly 100% of whom become immune), many of the students who have received all required doses pursuant to the CVL will not seroconvert and hence are akin to children who did not receive these products.

60. For example, numerous studies estimate anywhere from 2 to 10% of those vaccinated with two doses of measles vaccine fail to develop protective humoral immunity and for those who do develop some level of protective immunity, studies find that those antibody levels wane over time.[15] After two doses of rubella vaccine, an estimated 9% of children do not seroconvert.[16] The efficacy for the mumps vaccine has been shown to be far worse than that of both measles and rubella. Hence, these children who do not seroconvert or whose immunity has waned are no different than a child who never received these products.

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[14] Ten vaccines are required under the CVL, *see* W. Va Code § 16-3-4 (c) and (e), but because they are injected in combination vaccines, a total of six distinct products with multiple doses for several of the vaccines (e.g., MMR, DTaP, varicella, etc.) are required.

[15] *See, e.g.*, https://pubmed.ncbi.nlm.nih.gov/23256739/; https://pubmed.ncbi.nlm.nih.gov/17339511/.

[16] *See* https://pmc.ncbi.nlm.nih.gov/articles/PMC5576672/; https://pubmed.ncbi.nlm.nih.gov/25891446/; https://pubmed.ncbi.nlm.nih.gov/34556367/; https://pubmed.ncbi.nlm.nih.gov/27895276/.

61. The same is true for the varicella vaccine (i.e., the chickenpox).

62. The CVL does not require children to be tested to see if they show immunity to these pathogens before they are enrolled at school despite the fact that these products do not provide even measurable protection to a percent of children directly after injection (and this is putting aside the fact that efficacy wants over time which occurs for all of these products).

63. In addition, the varicella vaccine is a live virus vaccine, meaning there is, albeit modified, live chicken pox virus in each dose. Those vaccinated with this live virus can infect others with the chicken pox virus for up to six weeks after receipt of the live vaccine. This is why its package insert, approved by the FDA, explains "that transmission of varicella vaccine virus (Oka/Merck) resulting in varicella infection including disseminated disease may occur between vaccine recipients (who develop or do not develop a varicella-like rash) and contacts susceptible to varicella including healthy as well as high-risk individuals" and that "[d]ue to concern for transmission of vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals for up to six weeks following vaccination" including "[i]mmunocomposed individuals [and] [p]regnant women … [and] [n]ewborn infants of mothers without documented history of varicella."[17]

64. Nevertheless, even in light of these scientific findings from the FDA, the CVL does not exclude those vaccinated with this product from West Virigina schools for six weeks after vaccination to prevent transmission.

65. In practice, West Virginia officials and Defendants do not strictly follow the CVL and liberally allow unvaccinated children to remain in school.

[17] *See* https://www.fda.gov/media/76008/download?attachment (last visited June 21, 2025).

66. Indeed, the State Board Defendants and Local Board Defendants allow numerous children who do not have all required vaccinations to remain enrolled in school and to attend in-person classes, provided they do not request a religious exemption from the CVL before enrolling.

67. For example, in response to requests under the West Virginia Freedom of Information Act, W. Va Code § 29B-1-1, et seq., ("**WVFOIA**"), Local Board Defendant Superintendent Starcher on behalf of Raleigh County Schools responded and confirmed on May 24, 2024, that, in the 2023-24 school year, sixteen children who did not have all required vaccinations were enrolled in in-person classes for more than thirty days (one medical exemption and fifteen students with no exemptions). No student received a religious exemption from Raleigh County Schools during this period. Attached as **Exhibit 5** is a true and correct copy of the Raleigh WVFOIA response.

68. Similarly, the Fayette County Board of Education responded that, in the 2023-24 school year, 440 children who did not have all required vaccinations were enrolled in in-person classes for more than thirty days. Attached as **Exhibit 6** is a true and correct copy of the Fayette WVFOIA response.

69. And the Monongalia County School District reported 147 children who did not have all required vaccinations but who were enrolled in in-person classes for more than thirty days. Attached as **Exhibit 7** is a true and correct copy of the Monongalia WVFOIA response.

70. These are just three examples of school districts which permit unvaccinated students to attend in-person classes. Many more students who are out of compliance with the CVL are permitted to attend in-person classes in school districts throughout the State, so long as they do not request a religious exemption.

71. Official federal government records also indicate considerable non-compliance rates for West Virginia kindergarteners attending in-person classes. For example, according to CDC records for the 2022-23 school year, as many as 4.4% of West Virginia kindergarteners fail to comply with the CVL.[18]

72. These involve instances of school districts and children that are willfully out of compliance with the CVL, yet the students are permitted to continue their educations in-person, while Defendants prevent Plaintiff from sending A.G. to school with a religious exemption.

73. West Virginia's lackadaisical approach to its vaccination requirements in school settings is further demonstrated by the fact that teachers and others working in West Virginia's educational system are not subject to the vaccination requirements of the CVL. Many, if not most, teachers, administrators, and staff working in the West Virginia school system have never been required to receive the full battery of injections required by the CVL's vaccine schedule.

74. This is because, as of 1986, when many of the adults in the school system were themselves in school, there were only three routine vaccines in the U.S. It was only after 1986, the year Congress gave pharmaceutical companies immunity from liability for injuries caused by childhood vaccines, that the explosion in the childhood vaccine schedule occurred. *See* 42 U.S.C. §§ 300aa-11. And in the years following this immunity from liability protection, West Virginia then required the recombinant Hep-b vaccine, the varicella vaccine, the pertussis vaccine, and the conjugate meningococcal vaccine for school.

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[18] *See* CENTERS FOR DISEASE CONTROL, *Vaccination Coverage and Selected Vaccines and Exemption Rates Among Children in Kindergarten – United States*, 2022-23 School Year, available at https://www.cdc.gov/mmwr/volumes/72/wr/mm7245a2.htm#:~:text=National%20coverage%20remained%20near%2093.22%20school%20year%20(2.6%25) (detailing percentages of religious and medical exemption rates, along with non-compliance rates, for U.S. kindergarteners in the 2022-23 school year, and detailing a non-compliance rate in West Virginia of approximately 4.4%) (last visited June 21, 2025)).

75. Most adults in the State today, who comprise over 80% of the State's population,[19] were never subject to most of the State's school vaccine requirements.

76. The State has shown through action and inaction that its infectious disease related goals can be accomplished while allowing exceptions to the CVL.

77. Defendants liberally allow for non-vaccination for secular reasons throughout the State, including in school settings.

78. The State permits teachers and staff who are not fully up to date with the required vaccines to roam freely throughout campuses across the state and intermingle with schoolchildren without showing proof of vaccination.

79. Defendants also permit the public, including countless numbers of West Virginia citizens who remain unvaccinated or partially unvaccinated for any reason they choose, including secular reasons, to freely access school campuses throughout the state without vaccination-based entry restrictions including at events in which there are large crowds gathered in close proximity, such as high school and college basketball and football games.

80. These examples demonstrate the CVL's numerous defects that undermine the State's purported public health goals, including that Defendants allow several secular exemptions from mandatory vaccination.

[19] *See* UNITED STATES CENSUS BUREAU, *QuickFacts, West Virginia*, available at https://www.census.gov/quickfacts/fact/table/WV,US/PST045223 (last visited June 21, 2025).

D. The State Board Defendants and Local Board Defendants Take Action Against Plaintiff to Regulate Vaccines and Exemptions in Schools Under the CVL

81. Just over a week ago, the State Board Defendants voted to disregard Governor Morrisey's Executive Order that provided a religious exemption option from the CVL.

82. After the vote, the State Board Defendants released a public statement and said, "The WVBE directed the State Superintendent of Schools to notify all school districts to follow the law that has been in effect since 1937 [the CVL]. This is in line with the Action of the West Virginia Legislature during the 2025 Regular Session, which did not vote in favor of religious exemptions for vaccines."[20]

83. Notably, in their public statement the State Board Defendants did not say specifically what provision of the CVL, W. Va. Code § 16-3-4, they were relying on to regulate exemptions from the CVL and thus disregard the Governor's Executive Order.

84. Nevertheless, the Local Board Defendants followed the State Board Defendants' directive and are not honoring Plaintiff's religious exemption certificate for A.G. that she received from the State Public Health Officer.

85. On June 17, 2025, Plaintiff Ms. Guzman emailed the Raleigh County Schools to inquire about enrolling A.G. for the upcoming 2025-26 school year and said:

> She has been accepted at CFDE For the upcoming school year 25–26 in preschool with a religious exemption. I am super excited about [] going to school, but I have been very confused and concerned with the latest news that I have heard from the state Board of Education and I want to know if Raleigh County will be accepting the religious exemption or not.

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[20] *See* https://www.wtrf.com/news/west-virginia-board-of-education-votes-to-continue-mandatory-vaccines-for-schools/ (last visited June 21, 2025).

86. That same day, Local Board Defendant Superintendent Starcher responded to Plaintiff's email and said:

> Ms. Guzman,
>
> Thank you for your email. Raleigh County Schools will follow direction provided by the West Virginia Board of Education at its most recent meeting. As such, Raleigh County Schools will follow the law and accept medical exemptions only.
>
> Thank you.
>
> Serena Starcher
> Superintendent

87. Thus, at the direction of the State Board Defendants, Local Board Defendants have taken official government action and have excluded Plaintiff's child A.G. from enrolling in Clear Fork District Elementary School by not honoring her religious exemption certificate issued by the State Department of Health because they only accept medical exemptions from the CVL.

88. The Local Board Defendants have also issued to all Raleigh County School principals a written directive effective immediately to disregard any previous communication regarding vaccination requirements under the CVL, and that only medical exemptions are permitted. Attached as **Exhibit 8** is a true and correct copy of this written directive.

89. Defendants have taken the position that they are the exclusive government enforcers of the CVL, including regulating secular and religious exemptions.

E. The CVL Substantially Burdens Plaintiff's Religious Beliefs

90. Plaintiff has sincere religious beliefs against vaccinating her child A.G., beliefs which are substantially burdened by the CVL and Defendants' enforcement of the CVL.

91. For religious reasons, A.G. has never received any of the mandated vaccines on the CVL's schedule.

92. Plaintiff is a Christian and has been for decades.

93. Plaintiff possesses multiple religious objections to vaccinating A.G., based on her Christian beliefs, including the following four examples.

94. ***First,*** Ms. Guzman maintains profound religious objections to the vaccines' use of aborted fetal cells. As a Christian, Plaintiff has maintained objections to abortion going back to at least her teenage years in the 1990s. Her religious objections further solidified when she was working as a neo-natal ICU nurse in the early 2000s. In the 2008 timeframe, Plaintiff treated a newborn child who had serious medical conditions, rendering the newborn incompatible with life. The family was advised that child would likely not make it through delivery, and would not live if delivered and were therefore advised of the benefits of terminating the child's life pre-birth. The family, however, decided to keep the child because of their religious beliefs against abortion. The child was born alive, and Ms. Guzman observed as the family spent precious time with the baby girl, which would not have occurred had they listened to the medical advice to terminate the pregnancy. This profound experience, and others like it, cemented Ms. Guzman's religious objections to the practice of abortion.

95. Plaintiff learned that vaccines required under the CVL were designed and developed through use of aborted children's body parts. As a Christian who sincerely believes that the Bible prohibits abortion, Plaintiff views this prohibition to include declining any injection of a substance into her child that was made from the use of aborted children. She sincerely believes that the taking of an unborn life is tantamount to murder, and to be connected to that sin through vaccinating A.G. with vaccines, including but not limited to those that contain aborted fetal tissue from children whose lives were ended to advance medical research, would entail profound and potentially eternal consequences.

96. Religious objections, like Plaintiff's, to vaccination based on fetal cell involvement in the development and production of vaccines on the CVL's childhood schedule are not attenuated or foundationless religious objections. Abortion and fetal cell research in the development of childhood vaccines is well-documented.

97. For example, in just one study, over seventy-five normally developing babies were aborted, and while keeping the fetuses alive for harvesting their body parts, had nearly every body part chopped up into little cubes to culture viruses on, including their tongues, livers, intestines, pituitary glands, kidneys, and hearts. *See* attached as **Exhibit 9** from the Wistar Institute of Anatomy and Biology, Cytological Virological and Chromosomal Studies of Cell Strains from Aborted Human Fetuses (May 1966) (detailing aborted pre-born and normally developing children in support of vaccination research and development).

98. In sworn testimony, Dr. Stanley Plotkin—who is commonly referred to as the "Godfather" of vaccines, and one of the lead researchers on the aforementioned study—candidly admitted he worked with the chopped-up pituitary glands, kidneys, spleens, and hearts of seventy-six healthy, normally developing babies, whose tissue needed to remain alive to be used to culture viruses, whose mutilated bodies were utilized in furtherance of his research. *See* attached as **Exhibit 10** a true and correct copy of excerpts of the Deposition of Stanley Plotkin, Jan. 11, 2018, at pdf pp. 9-12 of 17.[21]

99. Additionally, many of the CVL-required vaccines contain genetic and cellular material derived from aborted fetuses, materials that would be injected directly into A.G.'s body were Plaintiff to comply with West Virginia's mandatory vaccination requirements. *See, e.g.*, FDA

[21] *See also* excerpt of deposition video of Dr. Stanley Plotkin discussing this study, available at https://www.sirillp.com/plotkin-abortion/ (last visited July 5, 2024).

Package Insert for M-M-R II Vaccine, attached hereto as **Exhibit 11**, at pdf p. 8 of 12 (stating the Measles, Mumps, and Rubella ("MMR") combination vaccine contains strains of "human diploid lung fibroblasts" cultured from a fetal cell line); *see also* FDA Package Insert for VARIVAX vaccine, attached hereto as **Exhibit 12**, at pdf pp. 9-10 of 16 (stating the Varicella vaccine was propagated in "human diploid cell cultures" and "contains residual components of [a fetal cell line] including DNA and protein").

100. To vaccinate A.G. would force Plaintiff into participating in an action with illicit connections to the termination of an innocent life, and into activity that condones abortion.

101. After learning that many vaccines have been researched, tested, and developed through the use of aborted fetal cell lines, and that several vaccines required under the CVL contain human genetic material derived from aborted pre-born children, Plaintiff has never vaccinated A.G. Plaintiff cannot in good conscience knowingly inject A.G. with anything that would make her complicit in the sin of abortion.

102. ***Second***, Plaintiff also possesses religious objections to vaccination based on the belief that she must not preemptively tinker with A.G.'s God-given natural immune system. Plaintiff takes a natural approach to treating illness, believing that God has created humans with well-functioning immune systems that were designed by God to counteract threats. While Plaintiff does not object to all medication in general, she only seeks out medication when an intervention is clearly necessary.

103. This is because Plaintiff sincerely believes that God designed her child's immune system with special care and with the well-designed ability to counteract disease (even though it is not fail-proof), and that to preemptively alter that immune system would demonstrate a lack of faith in God. Accordingly, because of these beliefs, Plaintiff does not seek medical attention unless

she or A.G. are sick, and additionally, only in cases where, after focused prayer, she is certain their God-given immune systems are incapable of eliminating that sickness without assistance. To do otherwise would be to violate her religious beliefs and faith in God.

104. ***Third***, Plaintiff believes that one's physical body is the temple of God's Holy Spirit because the scriptures state that one's body is God's temple. As such, Plaintiff is careful to observe the Bible's instruction to guard one's physical body. Consequently, Plaintiff does not have tattoos and does not consume alcohol because she believes she must keep her body spiritually clean. In Plaintiff's system of beliefs, she believes the vaccines required under the CVL are spiritually impure and that to inject them into A.G. would defile the temple of God's Holy Spirit.

105. ***Fourth***, Plaintiff has engaged in thoughtful prayer regarding whether to vaccinate A.G. and has come under firm spiritual conviction that she must not; she is confident that conviction came from the Holy Spirit. Through her spiritual journey, Plaintiff has learned the importance of seeking God's direction for both large and small decisions. For example, in 2013 Plaintiff and her husband were living in Virgina, in her dream home. Her husband passed away, and it made the most practical sense to stay in Virginia to raise her children in the already established home. However, after engaging in focused prayer regarding what to do next, Plaintiff knows she received firm direction from the Holy Spirit to move to West Virginia to be closer to family to raise her children.

106. When Plaintiff is under conviction from the Holy Spirit, she is careful to obey, knowing that to do otherwise will entail eternal consequences.

107. Plaintiff sought guidance from the Holy Spirit through prayer, and gained what she is certain is firm direction from the Holy Spirit that she must not vaccinate A.G.

108. After much thought and prayer, Plaintiff is certain that vaccinating A.G. would be to disobey the Holy Spirit's leading.

109. Plaintiff's religious objections to vaccination detailed above have been substantially burdened by Defendants through their directives, including as they relate to the CVL and excluding A.G. from attending the Raleigh County Schools.

110. Because A.G. is unvaccinated, and lacks secular reasons for being unvaccinated, she is not permitted by Defendants to enroll in Clear Fork District Elementary School.

111. If Plaintiff's child faced medical repercussions from vaccinating, they could seek an exemption pursuant to the CVL but the fact that they seek spiritual and religious repercussions is meaningless under the CVL.

112. Plaintiff is a widow, and she is the sole provider for her family. Plaintiff has been receiving survivor benefits since her husband's death in 2013, and these benefits will terminate in 2027.

113. Plaintiff is a registered nurse and will soon need to re-enter the workforce to provide for her family, which she will be unable to do because she has to keep A.G. at home because of the CVL and Defendants' enforcement of the CVL against her, including not honoring A.G.'s valid religious exemption, in defiance of Governor Morrisey's Executive Order and in violation of the EPRA.

114. Defendants have made it virtually impossible in Plaintiff's specific case to educate her child, provide for her family, and simultaneously uphold her religious convictions.

115. Plaintiff has been severely burdened and negatively impacted on multiple fronts by the decision to exercise her sincerely held religious beliefs in conflict with the CVL's mandatory vaccination requirements.

116. A.G. has been categorically excluded from West Virginia's educational system, including the irrational and punitive decision by the State Board Defendants and Local Board Defendants to exclude A.G. from the Raleigh County Schools.

117. Notwithstanding the CVL and Defendants' prohibition on her attending Clear Fork District Elementary School, A.G. regularly socializes with other children her age.

118. For example, A.G. frequently has playdates with cousins, who also live in Clear Creek, and with friends, and A.G. plays with and learns alongside children at Sunday school. A.G. interacts with West Virginia children outside of a school setting on a daily basis.

119. A.G. has playdates with friends and cousins, who attend public school at Fairdale. A.G. has participated in organized gymnastics and competition cheer, both of which entail hours' long sessions with large numbers of children A.G.'s age. A.G. has signed up for a dance camp in July and will be interacting with large numbers of children A.G.'s age.

120. August 26, 2025, is the first day for student instruction in the 2025-26 school year for Raleigh County Schools.[22]

121. Therefore, Plaintiff needs and therefore respectfully requests relief from this Court at least thirty days before that date or on or before **July 25, 2025**, to properly enroll A.G. in school.

[22] *See* https://boe.rale.k12.wv.us/article/2149605 (last visited June 20, 2025).

COUNT I
(VIOLATION OF EQUAL PROTECTION FOR RELIGION ACT W. Va. Code § 35-1A-1)

The CVL Substantially Burdens Plaintiff's Religious Beliefs to Not Vaccinate A.G. and Is Not the Least Restrictive Means of Furthering a Compelling State Interest

122. Plaintiff incorporates the allegations in the foregoing paragraphs as if set forth fully herein.

123. The EPRA, W. Va. Code § 35-1A-1, provides in relevant part: "(a) Notwithstanding any other provision of law, no state action may: (1) Substantially burden a person's exercise of religion unless applying the burden to that person's exercise of religion in a particular situation is essential to further a compelling governmental interest; and is the least restrictive means of furthering that compelling governmental interest; nor (2) Treat religious conduct more restrictively than any conduct of reasonably comparable risk; nor (3) Treat religious conduct more restrictively than comparable conduct because of alleged economic need or benefit."

124. It also provides that "(b) (1) A person whose exercise of religion has been substantially burdened, or is likely to be substantially burdened, in violation of this article may assert such violation or impending violation, including against the state or its political subdivisions, as a claim or as a defense in any judicial or administrative proceeding: Provided, That relief is limited to injunctive or declaratory relief and reimbursement of costs and reasonable attorney fees."

125. Defendants' State actions enforcing the CVL against Plaintiff, including refusing to recognize religious exemptions from the CVL while simultaneously recognizing medical exemptions and allowing other exceptions and non-compliance, refusing to honor A.G.'s valid religious exemption from the State Health Department, and not following Governor Morrisey's Executive Order 7-25, also substantially burden Plaintiff's exercise of her religion to not vaccinate

A.G., and do so in a manner that is not essential to further a compelling State interest and is not the least restrictive means of furthering any alleged compelling State interest, which violate W. Va. Code § 35-1A-1(a)(1).

126. Defendants' State actions enforcing the CVL against Plaintiff, including refusing to recognize religious exemptions from the CVL, refusing to honor A.G.'s valid religious exemption from the State Health Department, and not following Governor Morrisey's Executive Order 7-25, treat Plaintiff's religious conduct to not vaccinate A.G. more restrictively than any conduct of reasonably comparable risk, such as the State allowing other students medical exemptions and other exceptions including non-compliance from the CVL, which violate W. Va. Code § 35-1A-1(a)(2).

127. Courts are instructed to not inquire into the validity or plausibility of a person's beliefs; instead, the task is to determine whether "the beliefs professed [] are sincerely held and whether they are, in [a believer's] own scheme of things, religious." *United States v. Seeger*, 380 U.S. 163, 185 (1965). The "guarantee of free exercise is not limited to beliefs which are shared by all of the members of a religious sect." *Thomas v. Review Bd. of Ind. Emp't Sec. Div.*, 450 U.S. 707, 715-16 (1981).

128. Plaintiff's sincerely held religious beliefs that prohibit her from vaccinating her minor child, A.G., have been substantially burdened by Defendants. Plaintiff's attempts to enroll A.G. in the Raleigh County Schools with a religious exemption from the CVL were rejected.

129. As such, Defendants have pitted Plaintiff's religious integrity against educating A.G. even though West Virginia has created a system of public education whereby it guarantees an education to every student. *See, e.g., Pauley*, 162 W. Va. at 707 (holding that "[t]he mandatory requirements of 'a thorough and efficient system of free schools' found in . . . the West Virginia

Constitution, make education a fundamental, constitutional right in this State."); *see also State v. Beaver*, No. 22-616, at *36 ("Both the State Constitution and [West Virginia courts] have established that education is a fundamental right").

130. Nevertheless, despite West Virginia's guarantee of a free public-school education, Plaintiff's child, A.G., cannot obtain a formal education because of her mother's religious convictions, not in public school, private school, or even in a virtual academy.

131. But West Virginia families with secular, medical motivations for declining compulsory vaccination can be exempted from the CVL's mandatory requirements. Those exempt children, unlike Plaintiff's child, A.G., are then free to attend class in person while unvaccinated.

132. Defendants have made a value judgment that secular (i.e., medical) motivations for opting out of compulsory vaccination under the CVL are permitted, but that religious motivations are not. In other words, under the CVL's scheme that Defendants are enforcing against Plaintiff, medical motivations are superior to religious motivations. That alone violates the EPRA.

133. Whatever interest Defendants may have in promoting childhood vaccination in schools, their interest is not so extraordinary or compelling as to allow an exemption from the CVL for secular reasons, while simultaneously forbidding an exemption for religious reasons.

134. Further, Defendants liberally allow functional exemptions through non-enforcement of the CVL as the WVFOIA examples and exhibits clearly show, and do not prohibit unvaccinated children from visiting public libraries or museums, or from interacting with their peers in any other way. Nor do Defendants require that teachers, staff members, or school visitors provide proof of vaccination upon entry into a particular school. Defendants also allow unvaccinated students to be educated in learning pods in unlimited numbers.

135. These activities in which West Virginia permits non-vaccination for secular reasons each, in isolation, pose a purported greater threat to its purported infectious disease-related goals than would permitting A.G. to be educated with a religious exemption from the CVL.

136. It is axiomatic that a law cannot be regarded as protecting an interest of the highest order when it leaves appreciable damage to that purportedly vital interest unprohibited (e.g., here, granting medical exemptions for students physically attending school, permitting functional exemptions through lax enforcement of the CVL, and by allowing unvaccinated adults to work in the educational system).

137. And Defendants cannot rely on a broad policy goal in defending the CVL but must demonstrate a compelling State interest in denying a religious exemption to Plaintiff specifically. Defendants must further show that specifically denying Plaintiff a religious exemption in her particular situation is the least restrictive means of furthering a compelling State interest.

138. Defendants cannot meet these stringent requirements.

139. For the reasons detailed throughout, the CVL is not essential to achieving a compelling State interest in Plaintiff's particular situation, is not the least restrictive means of furthering a compelling interest, is not narrowly tailored, is overinclusive and substantially underinclusive, and therefore fails to adhere to the EPRA on these additional grounds.

140. West Virginia's CVL cannot withstand heightened scrutiny because it is both over-inclusive and underinclusive relative to the State interests it purportedly attempts to achieve. Instead of regulating with the precision and refinement necessary to avoid conflict with burdening its citizens' free exercise rights, West Virginia has taken the extraordinary position of eliminating *every* possibility for its citizens' religious observance in the mandatory vaccination arena.

141. West Virginia's compulsory vaccination scheme is underinclusive because it only applies to children in a school setting. The vaccine mandate does not apply to non-school attending children (who regularly interact with their peers) nor to adults in the State, who comprise over 80% of West Virginia's population.

142. The CVL is also underinclusive because children possessing a religious exemption in schools would pose no greater threat than their secular peers with a medical exemption. Moreover, the vaccination requirements do not apply to adults who are employed in West Virginia's school system, or to school visitors.

143. Further, the existence of a religious exemption for attending school would have an immaterial impact on the number of individuals vaccinated in West Virginia. Nor would the existence of a religious exemption option from the CVL materially impact the overall percentage of vaccinated school children.

144. Given that West Virginia boasts one of the highest vaccination rates in the country, allowing a religious exemption for a handful of students like A.G., just as secular medical exemptions are permitted, would constitute an actual attempt at narrow tailoring and provide the least restrictive means to achieving a compelling State interest. These children already live in West Virgina and regularly interact with the communities in which they live in, they are just not permitted to attend school.

145. Because West Virginia's CVL is simultaneously too narrow and too broad to fulfill the State interests it purportedly attempts to accomplish and considering that forty-five other states have religious exemption options, the regulation lacks the narrow tailoring necessary to survive the heightened review that is required under EPRA.

146. Collectively, the aggregation of individual secular behaviors the State permits—medical exemptions, students who are permitted to attend school on a daily basis while willfully out of compliance with the CVL, teachers and staff who are not subject to the law, the learning pod option for unvaccinated children, and members of the general public who have not received vaccines required under the law but who regularly intermingle on school campuses and mass gatherings throughout the state——pose a dramatically greater impingement to West Virginia's stated goals than would permitting Plaintiff's child A.G. to attend school with a religious exemption. Again, Plaintiff's child is already part of the community in every possible manner; A.G. is just not permitted to attend school.

147. Further, this aggregation of individual behaviors that Defendants permit poses a significantly greater impingement to Defendants' purported goals than would permitting a religious exemption option for A.G. to be exempt from the CVL.

148. Childhood vaccination schemes, including in West Virginia, are clearly amenable to exemptions. That cannot be reasonably undisputed.

149. West Virginia's CVL violates the EPRA because it is not essential to further a sufficiently "compelling" State interest for purposes of EPRA's exacting standards in Plaintiff's particular situation, nor is it the least restrictive means of furthering any compelling State interest Defendants allege because it does not offer Plaintiff a religious exemption option for A.G. to attend school in Raleigh County.

150. Here, the option for a religious exemption mechanism can be seamlessly implemented, like it has been in forty-five other states and how medical exemptions have been implemented in West Virginia, without endangering ordered State governance and preservation of the CVL.

151. These states have demonstrated that their goals undergirding vaccination requirements can be satisfied while simultaneously respecting families' religious freedoms.

152. The CVL is also overbroad because it captures more conduct than necessary to achieve its goals.

153. First, the CVL fails to include a reasonable religious exemption option for the miniscule fraction of families who, like Plaintiff, hold sincere religious beliefs against vaccinating their children. Thus, their religion is substantially burdened by the CVL, and there is no less restrictive alternative that would not force them to violate their religious beliefs available for them to educate their children.

154. Second, assuming the required vaccines provide the protection that Defendants claim and considering that the overwhelming majority of West Virginia families have vaccinated their children in compliance with the CVL, Defendants do not meaningfully advance their goals in the least restrictive manner by forcing Plaintiff to violate her sincerely held religious beliefs by injecting A.G. with the required vaccines as a condition of education in the Raleigh County Schools. Stated another way, while the State may have a compelling interest in the abstract, that does not mean that it has one "in each marginal percentage point by which" it achieves its general goals. *Brown v. Entm't Merchs. Ass'n*, 564 U.S. 786, 803 n.9 (2011).

155. West Virginia's CVL also violates the EPRA because it permits, from a risk perspective, "comparable" secular activity that fatally undermines the State's purported infectious disease related goals.

156. *First*, West Virginia has granted medical exemptions from the CVL, and these medical exemptions are for children who attend school in-person. Unvaccinated schoolchildren with a medical exemption are permitted to attend school and intermingle and socialize with other

children on a daily basis. A single child with a medical exemption who attends in-person instruction in the Raleigh County Schools and elsewhere in the State presents the same hypothetical purported risk that a child, like A.G., with a religious exemption does, accepting that all of Defendants' claims about these products are true.

157. *Second*, West Virginia permits scores of unvaccinated children to continue their education, despite non-compliance with the CVL, and these children intermingle and socialize in person with their peers on a daily basis. These children have not presented a medical or religious reason for non-compliance with the CVL as the various WVFOIA exhibits show. A single child out of compliance with the law permitted to continue attending school presents the same purported threat to West Virginia's public health goals as would permitting A.G. to attend school with a religious exemption, accepting that all of Defendants' claims about these products are true.

158. *Third*, West Virginia permits adults working in the school system—teachers, administrators, lunch staff, bus drivers, etc.—to altogether disregard the CVL's vaccination requirements. Most adults working in the system have never been required to receive the full schedule of vaccines required under the CVL. A single adult working in person in the school system who has not received the vaccines required by the CVL presents the same purported threat to West Virginia's public health goals than permitting A.G. to attend school with a religious exemption, accepting that all of Defendants' claims about these products are true.

159. *Fourth*, West Virginia does not place restrictions on unvaccinated children or adults outside of the school setting, or outside of school hours. For example, under Defendants' logic, one unvaccinated child or adult attending a crowded University of West Virginia Mountaineers' basketball game at WVU Coliseum presents less of a threat to West Virginia's public health goals

than permitting unvaccinated children with a religious exemption, like A.G., to pursue their education in the Raleigh County Schools.

160. *Fifth*, even if the State's infectious disease related goals could logically be restricted to children, and exclusively in a school setting during school hours, West Virginia permits unvaccinated children to be educated in unlimited numbers in "learning pods," a school setting where children intermingle on a daily basis. Under W. Va. Code § 18-8-1, the government permits unvaccinated children—whatever their reasons for declining vaccination—to be educated in these learning pods. This too presents a considerably greater threat to West Virginia's claimed public health goals than permitting A.G. to attend school with a religious exemption.

INJUNCTIVE RELIEF ALLEGATIONS

161. Plaintiff incorporates the allegations in the foregoing paragraphs as if set forth fully herein.

162. Plaintiff alleges that, as applied, the CVL violates and substantially burdens her religious liberties and rights under the EPRA to not vaccinate A.G. as a condition of enrolling A.G. as a student in the Raleigh County Schools.

163. Plaintiff is being and will continue to be irreparably harmed unless this Court enjoins Defendants from enforcing the CVL against Plaintiff.

164. Plaintiff has no plain, speedy, and adequate remedy at law to prevent Defendants from enforcing the CVL against Plaintiff.

165. If not enjoined by this Court, Defendants will continue to implement and enforce the CVL in violation of Plaintiff's rights under the EPRA.

166. Accordingly, injunctive relief is appropriate.

DECLARATORY RELIEF ALLEGATIONS

167. Plaintiff incorporates the allegations in the foregoing paragraphs as if set forth fully herein.

168. Plaintiff is entitled to a declaratory judgment pursuant to W.Va. Code §55-13-1. An actual and substantial controversy exists between Plaintiff and Defendants as to their legal rights and duties with respect to whether West Virginia's CVL, which allows for secular but not religious exemptions, violates the EPRA.

169. The case is presently justiciable because the CVL and absence of any religious exemption to it applies to Plaintiff, who is currently harmed by having her child, A.G., excluded from the Raleigh County Schools.

170. Declaratory relief is therefore appropriate to resolve this controversy.

NO NOTICE REQUIRED UNDER W. VA. CODE § 55-17-3

171. Plaintiff incorporates the allegations in the foregoing paragraphs as if set forth fully herein.

172. Notice is not required under W. Va. Code § 55-17-3 because Plaintiff has been, and continues to be, irreparably harmed by Defendants' enforcement of the CVL against Plaintiff and A.G.

173. Generally, under W. Va. Code § 55-17-3, at least thirty days prior to the institution of an action against a governmental agency, the complaining party or parties shall provide the chief officer of the governmental agency and the Attorney General written notice of the action. This requirement, however, "do[es] not apply in actions seeking injunctive relief where the court finds that irreparable harm would have occurred if the institution of the action was delayed by the provisions of this subsection." W. Va. Code § 55-17-3 (a)(1).

174. If the First Amendment and the federal Religious Freedom Restoration Act ("**RFRA**"), 42 U.S.C. § 2000bb, provide any guidance, violation of Plaintiff's religious freedom under the EPRA constitutes irreparable injury as a matter of law. *See Elrod v. Burns*, 427 U.S. 347, 373, 96 S. Ct. 2673, 49 L. Ed. 2d 547 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); *see also Korte v. Sebelius*, 735 F.3d 654, 666 (7th Cir. 2013) (concluding the First Amendment's irreparable harm analysis would extend to RFRA, a law that the people's representatives passed to protect against the violation of free-exercise rights); *Kikumura v. Hurley,* 242 F.3d 950, 963 (10th Cir. 2001) ("[C]ourts have held that a plaintiff satisfies the irreparable harm analysis by alleging a violation of RFRA.").

175. Plaintiff is suffering and will continue to suffer additional irreparable harm absent prompt injunctive relief. A.G. is categorically evicted from the State's educational system, even though West Virginia's Constitution combined with the Fourteenth Amendment guarantees a free public-school education. *Pauley v. Kelly*, 162 W. Va. 672, 707 (1979); *see also State v. Beaver*, No. 22-616, 2022 W. Va. LEXIS 700, *36 (W. Va. 2022) ("Both the State Constitution and [West Virginia courts] have established that education is a fundamental right"); *see also Goss v. Lopez,* 419 U.S. 565, 95 (1975) (holding when state law creates a right to public education, that right becomes protected by the Due Process Clause of the Fourteenth Amendment).

176. Plaintiff will be forced to homeschool A.G. and forego her nursing career, or alternative career(s), and is thus precluded from providing for her family. After Defendants defied Governor Morrisey's Executive Order and rejected the order to honor the religious exemption issued by the Department of Health for A.G. to attend Clear Fork District Elementary School,

Plaintiff is left in indefinite limbo, including making plans to earn needed finances for her family, while not knowing whether A.G. will be able to attend school.

177. Plaintiff's injuries—past, ongoing, and imminent—cannot be remedied by a later-issued, or significantly delayed, order from this Court.

PRAYER FOR RELIEF

178. Pursuant to W.Va. Code §55-13-1 and W.Va. Code § 35-1A-1, it is appropriate and proper that a declaratory judgment be issued by this Court, declaring that the CVL violates the EPRA as applied to Plaintiff.

179. Pursuant to W.Va. Code §55-13-1 and W.Va. Code § 35-1A-1 and W.Va. Civ. R. Civ. P. 65, it is appropriate and hereby respectfully requested that the Court issue a preliminary injunction on or before **July 25, 2025**, and thereafter at the Court's discretion a permanent injunction, prohibiting Defendants from enforcing the CVL against Plaintiff.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court enter judgment against Defendants and provide Plaintiff with the following relief:

A. Declare the "no religious accommodation" policy to the CVL, as applied by Defendants, violative of W.Va. Code § 35-1A-1;

B. Issue a preliminary and permanent injunction prohibiting Defendants, their agents, servants, employees and any other persons acting on their behalf from implementing and enforcing W. Va Code § 16-3-4 against Plaintiff without providing a religious exemption or honoring one provided by the State Department of Health, based on application of the EPRA, W.Va. Code § 35-1A-1;

C. Grant Plaintiff's reasonable attorneys' fees and costs under W.Va. Code § 35-1A-1 and any other applicable authority; and

D. For any such other and further relief as the Court deems equitable and just under the circumstances.

Dated: June 24, 2025

Respectfully submitted,

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Attorneys for Plaintiff
**pro hac vice* to be submitted

VERIFICATION

I, Miranda Guzman, a citizen of the United States and of the state of West Virginia, have read the foregoing Verified Complaint and know the contents thereof as to myself and that the same is true to my own knowledge and as to all other matters on information and belief and I believe them to be true. Specifically, without limitation and based on my personal knowledge, the factual allegations that pertain to me and my family in paragraphs 1, 3, 10, 11, 13, 14, 15, 20, 21, 25, 84 through 121, 161 through 164, and 175-177 are true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on June 23, 2025, in Clear Creek, West Virginia.

06 / 23 / 2025

Miranda Guzman

Miranda Guzman

Exhibit 1

STATE OF WEST VIRGINIA

EXECUTIVE DEPARTMENT

At Charleston

EXECUTIVE ORDER NO. 7-25

By the Governor

WHEREAS, the Constitution of West Virginia recognizes that all people "are, by nature, equally free and independent," and "have certain inherent rights" of which they cannot justly be deprived or divested, W. Va. Const. Art. III, § 1 (1872); and

WHEREAS, the Constitutions of both the United States and West Virginia acknowledge the "free exercise" of religion, U.S. Const. Amend. I, cl. 2, and freedom "to profess and by argument, maintain" religious opinions, W. Va. Const. art. III, § 15, as among these inherent rights; and

WHEREAS, the Constitution of West Virginia also recognizes that no person can be justly "enforced, restrained, molested or burthened, in his body or goods, or otherwise suffer, on account of his religious opinions or beliefs," and that a person's religious beliefs should "in nowise, affect, diminish or enlarge their civil capacities," W. Va. Const. art. III, § 15; and

WHEREAS, the Constitution of West Virginia further directs the Legislature to "provide, by general law, for a thorough and efficient system of free schools," W. Va. Const. art. XII, § 1;

WHEREAS, the Supreme Court of Appeals of West Virginia found that directive makes "education a fundamental, constitutional right in this State," *State v. Beaver*, 248 W. Va. 177, 196, 887 S.E.2d 610, 629 (2022); and

WHEREAS, Chapter 16, Article 3, Section 4 of the West Virginia Code establishes compulsory vaccination requirements for admission to public schools and state-regulated child care centers; and

WHEREAS, that compulsory vaccination law prevents any child from attending "the schools of the state or a state-regulated child care center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough," W. Va. Code § 16-3-4(c) (2015); and

WHEREAS, the law authorizes the Commissioner of the Bureau for Public Health to "grant . . . exemptions to the compulsory immunization requirements of this section, on a statewide basis, upon sufficient medical evidence that immunization is contraindicated or there exists a specific precaution to a particular vaccine," W. Va. Code § 16-3-4(h); and

WHEREAS, in isolation, West Virginia Code Section 16-3-4 does not expressly provide for a religious or conscientious based exemption to compulsory school vaccination; and

WHEREAS, the only other states that do not allow any type of non-medical exemption for school immunization are California, New York, Connecticut, and Maine, NATIONAL CONFERENCE OF STATE LEGISLATURES, STATE NON-MEDICAL EXEMPTIONS FROM SCHOOL IMMUNIZATION REQUIREMENTS (Aug. 13, 2024), https://www.ncsl.org/health/state-non-medical-exemptions-from-school-immunization-requirements; and

WHEREAS, more recently, the Legislature enacted the Equal Protection for Religion Act of 2023, W. Va. Acts 2023, c. 295 (May 29, 2023), *codified in* W. Va. Code § 35-1A-1 (2023); and

WHEREAS, that law mandates that "no state action may" "[s]ubstantially burden a person's exercise of religion unless" it "is essential to further a compelling governmental interest" and "is the least restrictive means of" achieving that interest, W. Va. Code § 35-1A-1(a)(1); and

WHEREAS, the Legislature directed the Equal Protection for Religion Act to apply "[n]otwithstanding any other provision of law," W. Va. Code § 35-1A-1(a); and

WHEREAS, a number of citizens of West Virginia have religious and moral objections to one or more of the vaccines on the compulsory immunization list; and

WHEREAS, compulsory immunization forces those West Virginians to choose between their religious belief and their children's fundamental right to public education; and

WHEREAS, even after the enactment of the Equal Protection for Religion Act of 2023, the compulsory immunization law is still being used to bar West Virginians with religious and moral objections to vaccines from sending their children to state schools; and

WHEREAS, forcing those West Virginians to vaccinate their children despite their religious and moral objections substantially burdens the free exercise of religion in violation of

the inherent religious liberties guaranteed by the Constitutions of the United States and West Virginia; and

WHEREAS, the Constitution of West Virginia vests "chief executive powers" of the State in the Governor and entrusts the Governor to "take care that the laws be faithfully executed." W. Va. Const. art. VII, § 5 (1872).

NOW, THEREFORE, I, PATRICK MORRISEY, by virtue of the authority vested in me as the Governor of the State of West Virginia, do hereby **DIRECT** and **ORDER**:

1. The Commissioner of the Bureau for Public Health and the State Health Officer to:
    a. Establish a process for objections to compulsory school immunization from persons who desire to send their children to a state school or state-regulated child care center but object on religious or conscientious grounds to one or more vaccine required by the compulsory immunization law;
        i. For purposes of this process, a writing signed by the objector shall be sufficient proof to establish the objection;
2. When—as directed by the Equal Protection for Religion Act of 2023, W. Va. Code § 35-1A-1 (2023)—the compulsory immunizations requirements violate a religious and moral objection, the Commissioner of the Bureau for Public Health, the State Health Officer, and all officials and employees of the State under their authority shall—consistent with the Equal Protection for Religion Act of 2023, W. Va. Code § 35-1A-1 (2023)—take no action to enforce the compulsory school immunization requirements against the particular objector or his or her child.
3. By February 1, 2025, the Bureau for Public Health and the State Health Officer shall
    a. Submit a plan the Office of the Governor, including a proposal for any necessary legislation and rules, to enable and facilitate a statewide exemption to the compulsory school immunization in Chapter 16, Article 3, Section 4 of the West Virginia Code for objections based on religious and moral beliefs; and
    b. Report to the Office of the Governor on the number of people who have filed written objections to the compulsory school immunization requirements.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of West Virginia to be affixed.

DONE at the Capitol in the City of Charleston, State of West Virginia, this Fourteenth Day of January, in the Year of our Lord, Two Thousand Twenty-Five in the One Hundred Sixty-Second Year of the State.

GOVERNOR

SECRETARY OF STATE

Exhibit 2

West Virginia Department of HEALTH

Arvin Singh, EdD, MBA, MPH, MS, FACHE
Secretary of Health

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH
BUREAU FOR PUBLIC HEALTH
Commissioner's Office

Justin J. Davis
Acting Commissioner

May 22, 2025

Miranda Guzman
[redacted]

Re: Religious Exemption Request

Dear Miranda Guzman:

The Bureau for Public Health has received your written request for a religious exemption from compulsory vaccination for your child, [redacted] (DOB: [redacted] dated May 21, 2025. In accordance with Executive Order 7-25, your request is hereby granted for the 2025-2026 school year. The Bureau for Public Health will not enforce the compulsory school immunization requirements against you or your child, [redacted]

The Bureau of Public Health is also providing a copy of this exemption letter to Clear Fork Elementary School. Consistent with the Governor's May 9, 2025, guidance, a student who has received a religious exemption under Executive Order 7-25 should be allowed to attend public school without being compelled to be immunized.

Very truly yours,

Justin J. Davis
Acting Commissioner

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

KRYSTLE PERRY and ANTHONY PERRY, individually and on behalf of their minor child K.P.,

Plaintiffs,

v. **Civil Action No. 2:24-CV-18**

STACY MARTENEY et al,

Defendants.

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS [ECF NO. 29], GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION [ECF NO. 7] AND DENYING DEFENDANT'S MOTION TO STAY [ECF NO. 22]

Pending before the Court are Defendants Stacy Marteney, Christine Miller, and the Upshur County Board of Education's Motion to Dismiss [ECF No. 29], Plaintiffs' Motion for Preliminary Injunction and Expedited Consideration [ECF No. 7] as well as Defendant Matthew Christiansen's Motion to Stay [ECF No. 22]. The motions are fully briefed and, after oral argument on August 12, 2024 at the Clarksburg point of holding court, are ripe for decision. For the reasons and to the extent set forth herein, Plaintiffs' Motion for Preliminary Injunction [ECF No. 7] is **GRANTED**, Defendants' Motion to Dismiss [ECF No. 29] is **GRANTED IN PART** and **DENIED IN PART** and Defendant's Motion to Stay [ECF No. 22] is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs, Krystle and Anthony Perry, individually and on behalf of their minor child, K.P., filed their Complaint on July 5, 2024. ECF No. 1. Therein, they claim their respective First Amendment rights have been infringed by West Virginia's mandatory vaccination law, W. Va. Code § 16-3-4. Specifically, they claim the mandatory vaccinations provided for under state law run counter to their sincerely held religious beliefs and, with Defendants' refusal to enroll K.P. in virtual school, they seek relief under 42 U.S.C. § 1983 including injunctive relief and attorneys' fees. In their pending motion, Plaintiffs request the Court enjoin Defendants from enforcing the challenged statute against K.P. as it pertains to her efforts to enroll in virtual schooling for the 2024-2025 academic year.

Defendants argue against any injunction and, via separate motion, urge the Court to stay this matter under the Pullman abstention doctrine. In addition, the Upshur County Defendants urge the Court to dismiss Plaintiffs' Complaint for multiple reasons including Eleventh Amendment immunity and failure to join indispensable parties.

II. FINDINGS OF FACTS

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, the Court makes the following findings of fact in support of the injunction entered with this Order.[1]

Plaintiffs filed the instant civil action, individually and on behalf of their minor child, K.P., against the School Board Parties — the Upshur County Board of Education, Superintendent Christine Miller, and Virtual School Coordinator Stacey Marteney; Dr. Matthew Christiansen, as the State Health Officer and Commissioner of the Bureau of Public Health; and Mr. Doug Cipoletti,[2] as Executive Director of the West Virginia Virtual Academy, on July 5, 2024. See generally Compl., ECF No. 1.

From August 2022 through January 2024, K.P., Plaintiffs' minor daughter, was enrolled in an online learning program but was not physically present in a classroom with other children. Id. ¶¶ 2 and 70. K.P. was enrolled in Upshur County Virtual School for approximately 16 months. Id. ¶ 75.[3]

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[1] The Court offered each party the opportunity to call witnesses and present any other evidence they believed the Court should consider at the August 12, 2024 hearing. The parties declined the invitation noting the written record was sufficient.

[2] Mr. Cipoletti has been replaced by Bryan Hoylman as a Defendant. ECF No. 20.

[3] The Complaint alleges K.P. was enrolled in the West Virginia Virtual Academy; however, she was actually enrolled as a student with the Upshur County Virtual School – a separate program offered exclusively through Upshur County. The parties agreed at the April 12, 2024, hearing this was the case.

Regarding the mandatory immunization of school children, West Virginia Code § 16-3-4 prohibits K.P. from attending school in West Virginia unless she receives all the vaccines required under the statute absent medical exemption. Id. ¶ 1. In West Virginia, it is unlawful for any child to attend "any of the schools of the state or a state-regulated childcare center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough" and "[n]o person shall be allowed to enter school without at least one dose of each required vaccine." Id. ¶ 18; see also W. Va. Code § 16-3-4. Similarly, no child may be "admitted or received in any of the schools of the state" unless they have received the required vaccinations. ECF No. 1 at ¶ 99; see also W. Va. Code § 16-3-4. K.P. has not received all the vaccines listed in the statute. ECF No. 1 at ¶ 6. Plaintiffs allege that they possess deeply held religious beliefs that forbid them from fully vaccinating K.P., as required under W. Va. Code § 16-3-4. Id. ¶ 11.[4]

On December 18, 2023, the Superintendent of the West Virginia Department of Education sent the Superintendent's Update email, which included a directive to county school systems across the

[4] No dispute has been raised as to this allegation and the Court accepts it as true for purposes of this motion.

state, informing them that all full-time virtual students were "required to be fully immunized according to W. Va. Code § 16-3-4 exactly as they would be when enrolling for in-person instruction" and that the school boards were to "review the enrollment records of [their] full-time virtual students and . . . correct any non-compliance enrollment occurrences."

On June 14, 2023, the West Virginia State Board of Education authorized an immediate intervention of the Upshur County School system. As a result of the Special Circumstance Review, it was the recommendation of the West Virginia Department of Education that extraordinary circumstances existed in the county that constituted major impediments to the provision of education programs and services for students, and that the Upshur County school system be issued Non-approval status. It was further recommended that since these extraordinary circumstances had been documented and existed, delaying the intervention by the State Board into Upshur County Schools for any period of time would not have been in the best interest of the students and staff in Upshur County in accordance with W. Va. Code § 18-2E-5. The State Board made findings related to preliminary investigations and broadly delegated the county's statutory authority to the State Board. See also W. Va. Code § 18-2E-5. Among the State Board's findings was that "the authority of the Upshur County Board of Education

shall be limited in areas that compromise the delivery of a thorough and efficient education to its students as designated by the WVBE . . .". In addition, the State Board appointed Stephen L. Wotring as interim Superintendent and granted the Deputy State Superintendent the authority to hire a county superintendent to replace the interim. The State Board "limited the authority of the Upshur County Board of Education as to finances, personnel, federal programs and any other areas designated by the WVBE. . ." On June 14, 2023, the State Board commenced its immediate intervention. In January 2024, following the State Board's takeover, K.P. withdrew from Upshur County Virtual School because she elected not to receive the required vaccinations due to religious beliefs.

Plaintiffs' eight-year-old child, K.P., was enrolled in the Upshur County Virtual School for 17 months, from August of 2022 to January of 2024. ECF No. 1 at ¶ 134. Defendant Miller is the duly empaneled Superintendent of the Upshur County School system and directs Defendant Marteney's actions, including enrollment and dis-enrollment of students in the virtual school. Id. ¶ 94. In December 2023, Defendant Marteney, the Virtual Learning Coordinator for the Upshur School District, informed Plaintiffs that K.P. would not be enrolled in the Upshur County Virtual School if she did not receive all vaccines required under W. Va. Code §

16-3-4. Id. ¶ 75. Plaintiffs thereafter requested a religious exemption for K.P. so she could continue her education in the virtual school without receiving any additional vaccine doses. Defendants rejected that request. Id. ¶ 183; see also ECF No. 1-7 (denial of Plaintiffs' religious exemption request).

In their verified Complaint, Plaintiffs allege, and submit competent evidence via their verifications, Defendant Marteney is "tasked with implementing and enforcing, and does implement and enforce, the mandatory vaccination requirements of W. Va. Code § 16-3-4 against school-aged children desiring to attend the Virtual Academy, and she enforced the [statute] against the Plaintiffs and excluded K.P. from the Virtual Academy" after Plaintiffs requested a religious exemption. ECF No. 1 ¶ 92. Defendant Miller is also tasked, under W. Va. Code § 18-4-10, with implementing and enforcing all procedures of state law, including enforcing W. Va. Code § 16-3-4 against K.P., which necessarily extended to oversight of the denial of her religious exemption request and exclusion from the virtual school. Id. ¶ 94.

West Virginia Governor Jim Justice vetoed a bill passed by the West Virginia Legislature during the 2024 regular session that would have allowed for exemptions from vaccination requirements for students enrolled only in virtual public schools. Id. ¶ 143. Currently, the only exemption to the compulsory immunization of

school children is a medical exemption. Id. ¶¶ 144 and 170; see also W. Va. Code § 16-3-4.

In their Complaint, Plaintiffs seek a declaration by this Court related to the constitutionality of W. Va. Code § 16-3-4, specifically the lack of religious exemption thereto. Id. Plaintiffs allege violations of their First Amendment Free Exercise Rights. Id. at Count I. Additionally, Plaintiffs seek to enjoin the Upshur County Board from implementing and enforcing W. Va. Code § 16-3-4 as it relates to K.P. Id.

Given the issues presented in the myriad of motions pending, a review of certain West Virginia statutes as it pertains to the parties and their duties under law is necessary.

As a statutory corporation, a West Virginia county school board only has those powers expressly granted by state law or which arise by necessary implication from expressly granted powers. See, e.g., Shinn v. Bd. of Educ., 20 S.E. 604 (W. Va. 1894) ("The board of education of a school district is a corporation created by statute with functions of a public nature expressly given and no other; and it can exercise no power not expressly conferred or fairly arising from necessary implication, and in no other mode than that prescribed or authorized by statute."); Honaker v. Bd. of Educ., 24 S.E. 544 (W. Va. 1896). Regarding boards of education, the Supreme Court of Appeals of West Virginia has

observed "the rule of law applies of strict construction and a consequent limitation of the rights which may be exercised by them and the duties which they can legally perform." Herald v. Bd. of Educ., 65 S.E. 102 (W. Va. 1909).

Historically and currently, a board of education is a "creature of statute" with no powers other than those expressly given to it or that arise by necessary implication. See, e.g., State v. Rouzer, 32 S.E.2d 865 (W. Va. 1945); Dooley v. Board of Education, 93 S.E. 766 (W. Va. 1917). Thus, the Board may only act in the mode prescribed or authorized by statute. Id. In addition, the Board is a political subdivision of the State of West Virginia, maintains a corporate character, and is charged with the control and management of the schools and the district pursuant to West Virginia Code §§ 18-5-1, 18-5-5, and 18-5-13.

A county superintendent of schools has statutory duties enumerated by the West Virginia Legislature. Specifically, a county superintendent shall:

> (1) Act as the chief executive officer of the county board as may be delineated in his or her contract or other written agreement with the county board, and, under the direction of the state board, execute all its education policies;
>
> *****

> (10) Exercise all other authority granted by this chapter or required by the county board or state board; []

W. Va. Code § 18-4-10.

With respect to compulsory immunization of school children, West Virginia Code § 16-3-4 provides:

> (a) Whenever a resident birth occurs, the commissioner shall promptly provide parents of the newborn child with information on immunizations mandated by this state or required for admission to a public, private and parochial school in this state or a state-regulated child care center.
>
> (b) Except as hereinafter provided, a child entering school or a state- regulated child care center in this state must be immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough.
>
> (c) No child or person may be admitted or received in any of the schools of the state or a state-regulated child care center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio,, rubella, tetanus and whooping cough or produces a certificate from the commissioner granting the child or person an exemption from the compulsory immunization requirements of this section.
>
> (d) Any school or state-regulated child care center personnel having information concerning any person who attempts to be enrolled in a school or state-regulated child care center without having been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough shall report the names of all such persons to the commissioner.

(e) Persons may be provisionally enrolled under minimum criteria established by the commissioner so that the person's immunization may be completed while missing a minimum amount of school. No person shall be allowed to enter school without at least one dose of each required vaccine.

(f) County health departments shall furnish the biologicals for this immunization for children of parents or guardians who attest that they cannot afford or otherwise access vaccines elsewhere.

(g) Health officers and physicians who provide vaccinations must present the person vaccinated with a certificate free of charge showing that they have been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough, or he or she may give the certificate to any person or child whom he or she knows to have been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough.

(h) The commissioner is authorized to grant, renew, condition, deny, suspend or revoke exemptions to the compulsory immunization requirements of this section, on a statewide basis, upon sufficient medical evidence that immunization is contraindicated or there exists a specific precaution to a particular vaccine.

(1) A request for an exemption to the compulsory immunization requirements of this section must be accompanied by the certification of a licensed physician stating that the physical condition of the child is such that immunization is contraindicated or there exists a specific precaution to a particular vaccine.

> (2) The commissioner is authorized to appoint and employ an Immunization Officer to make determinations on request for an exemption to the compulsory immunization requirements of this section, on a statewide basis, and delegate to the Immunization Officer the authority granted to the commissioner by this subsection.
>
> (3) A person appointed and employed as the Immunization Officer must be a physician licensed under the laws of this state to practice medicine.
>
> (4) The Immunization Officer's decision on a request for an exemption to the compulsory immunization requirements of this section may be appealed to the State Health Officer.
>
> (5) The final determination of the State Health Officer is subject to a right of appeal pursuant to the provisions of article five, chapter twenty-nine a of this code.
>
> (i) A physician who provides any person with a false certificate of immunization against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio,, rubella, tetanus and whooping cough is guilty of a misdemeanor and, upon conviction, shall be fined not less than $25 nor more than $100.

W. Va. Code § 16-3-4.

Effective September 14, 2015, the State Board of Education promulgated a legislative rule related to "Health Promotion and Disease Prevention," known as Policy 2423. 126 W. Va. C.S.R. § 51. Specifically, this legislative rule includes provisions related to statewide immunization tracking, state-declared health promotion through up-to-date immunizations, disease prevention measures

through immunizations, and required vaccinations for students. See 126 W. Va. C.S.R. 51 at §§ 4.23, 5.1, 6.1, 6.2, 6.3, 6.4, 7.1.

III. ANALYSIS

A. Subject Matter Jurisdiction and Ex Parte Young

In Count I of the Complaint, Plaintiffs allege the Upshur County Defendants (the Upshur County Board of Education, Defendant Marteney, and Defendant Miller) and Defendant Christiansen have and continue to violate their respective First Amendment rights and seek redress, specifically injunctive relief and attorneys' fees pursuant to 42 U.S.C. § 1988, under 42 U.S.C. § 1983. ECF No. 1. That claim vests this Court with jurisdiction per 28 U.S.C. § 1331–federal question jurisdiction.[5]

Defendants argue, however, the Eleventh Amendment prohibits Plaintiffs from pursuing their claims in this Court. Plaintiffs

[5] During the August 12, 2024 oral argument, the parties alluded to the limitations on federal court jurisdiction under Article III of the United States Constitution. Of course, "[f]ederal courts are not courts of general jurisdiction; they have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto." Bender v. Williamsport Area Sch. Dist., 475 U.S. 534, 541 (1986). The parties cannot conjure subject-matter jurisdiction, nor can a defect in subject-matter jurisdiction be waived. See United States v. Cotton, 535 U.S. 625, 630 (2002). Thus, questions of subject-matter jurisdiction may be raised at any point during the proceedings and may (or, more precisely, must) be raised sua sponte by the court. See Bender, 475 U.S. at 541 ("[E]very federal appellate court has a special obligation to satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review, even though the parties are prepared to concede it.") (internal quotation marks omitted).

contend the relief sought does not run afoul of constitutional immunity. The Court, being mindful of the Fourth Circuit's direction in Sonda v. West Virginia Oil and Gas Conservation Comm'n, 92 F.4th 213 (4th Cir. 2024),[6] considers the issue of jurisdiction first.

The Eleventh Amendment to the United States Constitution provides that "[t]he Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. Const. amend. XI. The Supreme Court of the United States has interpreted this Amendment to mean that a state may not "be sued as defendant in any court in this country without [its] consent . . .." Hans v. Louisiana, 134 U.S. 1, 17 (1890) (quoting Cunningham v. R.R. Co., 109 U.S. 446, 451 (1883)); see also Doyle v. Hogan, 1 F.4th 249, 254 (4th Cir. 2021) (citing Va. Off. For Protection & Advocacy v. Stewart, 563 U.S. 247 (2011) ("In general, States may not be haled into federal court without their consent.")). The question of Eleventh Amendment immunity is a jurisdictional

[6] As discussed infra, Defendants urge the Court to exercise its discretion and decline Plaintiffs' invitation to adjudicate their First Amendment claims or, at least, stay this case invoking Pullman abstention. Sonda is much discussed in the briefs and herein on that issue. However, the Fourth Circuit made clear in Sonda that subject matter jurisdiction must be considered initially. See id. at 219-220.

one. See Suarez Corp. Industries v. McGraw, 202 F.3d 676, 683 n.12 (4th Cir. 2000) (citation omitted).

1. Dr. Christiansen as A State Entity

The threshold (but not necessarily dispositive) issue is whether any of the defendants are considered "the state" under the Eleventh Amendment. The Court addresses each Defendant in turn starting with the more obvious question of Defendant Dr. Christiansen. He serves as State Health Officer and Commissioner for the West Virginia Department of Health and Human Resources. ECF No. 1 at ¶ 95. Under the challenged statute, W. Va. Code § 16-3-4, Dr. Christiansen is charged with implementing the mandatory vaccination requirements for school-aged children, while also granting medical exemptions for the same. Id.[7] He is only named as a defendant in his official capacity. Id. An "official capacity suit" is merely another way to assert a claim against the state itself. See Panico v. City of Westover, Civil Action No. 21-CV-96, 2022 WL 989120, at *6 (N.D.W. Va. March 31, 2022) (citing Kentucky v. Graham, 473 U.S. 159, 165-66 (1985)). Thus, Dr. Christiansen is considered a state official for Eleventh Amendment purposes.

[7] Plaintiffs allege Defendant Christiansen is charged with "enforcing" W. Va. Code § 16-3-4. For the reasons discussed herein, the Court disagrees with that interpretation of his duties under that statute.

2. Upshur County Defendants as State Entities

The Upshur County Defendants present a more complicated assessment. Typically, "counties [and therefore their employees] are not arms of the state and thus do not fall within the ambit of the Eleventh Amendment." Workman v. Mingo County Schools, 667 F. Supp. 2d 679, 685 (S.D.W. Va. 2009). However, as discussed above, the State Board of Education has assumed control of the Upshur County Board of Education. It has also, under its statutory authority, appointed the individual defendants, Virtual Learning Coordinator Stacy Marteney and Superintendent Christine Miller, to their positions. The parties have thoroughly addressed the complicating factor the State takeover presents here. At the August 12, 2024 oral argument, Plaintiffs offered to dismiss the Upshur County Board of Education as a defendant noting it an unnecessary party to secure the injunctive relief sought here and to avoid any Eleventh Amendment immunity entanglements. No party did or has objected. The Court, having no objection of its own, hereby **DISMISSES** the Upshur County Board of Education as a party-defendant at Plaintiffs' request.

Two inquiries can bring a local government body within the protection of Eleventh Amendment immunity. First, "if the State treasury will be called upon to pay a judgment against a governmental entity, then Eleventh Amendment immunity applies to

that entity." Cash v. Granville Cty Bd. of Educ., 242 F.3d 219, 223 (4th Cir. 2001). Because Plaintiffs in this matter seek only declaratory and prospective injunctive relief, the first factor does not apply.

The second inquiry, often referred to as the "sovereign dignity" inquiry, considers whether the government entity and the State are "sufficiently close to make the entity an arm of the State." Id. at 224. In determining whether a government entity is an "arm of the state," the Court must consider:

> (1) the degree of control that the State exercises over the entity or the degree of autonomy from the State that the entity enjoys;
>
> (2) the scope of the entity's concerns—whether local or statewide—with which the entity is involved; and
>
> (3) the manner in which State law treats the entity.

Id. In Cash, the Fourth Circuit concluded that because, under North Carolina law, the local school board had nearly full autonomy to act, including the power to hire and fire administrators, because its concerns were generally local, and because the State treats local school boards as local entities, the local school board in Cash was not an arm of the State.

This Court has the benefit of Judge Goodwin's analysis in Workman. There, Judge Goodwin applied the sovereign dignity test

to the entity defendant Mingo County Board of Education, concluding that it was an arm of the State entitled to sovereign immunity. Workman, 667 F. Supp.2d at 687. The court reached this conclusion primarily because the Mingo Board had been taken over by the State Board of Education under W. Va. Code § 18-2E-5(p)(4)(C). Under that provision, the court reasoned that because the Mingo Board "ha[d] little to no rights of autonomy and self-control," and because the State Board was effectively "empowered to manage the schools in Mingo County and accordingly control the Mingo Board," the Mingo Board—after takeover—was an arm of the State entitled to state sovereign immunity. As a result, the court concluded that all claims against the Mingo Board were barred in federal court and dismissed it as a defendant.

Here, the State Board of Education has used the same statute to take over the Upshur County Board of Education. See ECF No. 40-2. Through its takeover order, the State Board has removed the county superintendent and all employees who served at the pleasure of the county superintendent. Id. at ¶ 6; 9. The State Board further limited the Upshur Board's authority "in areas that comprise the delivery of a thorough and efficient education to its students as designated by the WVBE by rule," including delegating decision-making authority to the Deputy State Superintendent. Id. at ¶ 5. Although the provisions of the takeover law are now

somewhat different, the level of control possessed by the State Board remains the same. Accordingly, the Upshur Board is, in the circumstances presented, an arm of the state entitled to state sovereign immunity. That entity has already been voluntarily dismissed. See supra.

However, the County Superintendent and Virtual Learning Coordinator remain parties in their official capacities. ECF No. 1. ¶¶ 92 and 94. The County Superintendent, Defendant Miller, was hired by the Deputy State Superintendent, see ECF No. 40-2 at ¶ 7-8, and operates under the authority of the State Board of Education via the takeover order. Moreover, because the Deputy State Superintendent was empowered to fill all administrative positions in the Upshur County Schools, see ECF No. 40-2 at ¶ 10, both the County Superintendent and the Upshur County Virtual Learning Coordinator would be considered "state officials" for Eleventh Amendment purposes. See Workman, 667 F. Supp. 2d at 688. "Even though the language of the Eleventh Amendment preserves sovereign immunity of only the **States** of the Union, it is settled that this protection extends also to 'state agents and state instrumentalities,' or stated otherwise, to 'arms of the State' and State officials." Cash, 242 F.3d at 222 (emphasis in the original) (cleaned up).

3. Ex parte Young

Plaintiffs contend quite correctly this does not end the inquiry, however. In Ex parte Young, the Supreme Court observed that "a suit against individuals, for the purpose of preventing them, as officers of a state, from **enforcing** an unconstitutional enactment, to the injury of the rights of the plaintiff, is not a suit against the state within the meaning of the [Eleventh] Amendment." 209 U.S. 123, 154 (1908) (emphasis added) (citation omitted).

> If the act which [a state officer] seeks to enforce [is] a violation of the Federal Constitution, the officer, in proceeding under such enactment, comes into conflict with the superior authority of that Constitution, and he is in that case stripped of his official or representative character and is subjected in his person to the consequences of his individual conduct. The state has no power to impart to him any immunity from responsibility to the supreme authority of the United States.

Id. at 159–60. Accordingly, "federal courts may exercise jurisdiction over claims against state officials by persons at risk of or suffering from violations by those officials of federally protected rights, if (1) the violation for which relief is sought is an ongoing one, and (2) the relief sought is only prospective." Republic of Paraguay v. Allen, 134 F.3d 622, 627 (4th Cir. 1998).

Nevertheless, "[i]n making an officer of the state a party defendant in a suit to enjoin the enforcement of an act alleged to be unconstitutional, it is plain that such officer must have some connection with the enforcement of the act[.]" Ex parte Young, 209 U.S. at 157; see also Doyle, 1 F.4th at 254. Otherwise, a plaintiff "is merely making him a party as a representative of the State, and thereby attempting to make the State a party." Id. The Fourth Circuit has further explained that "Ex parte Young requires a 'special relation' between the state officer and the challenged statute to avoid the Eleventh Amendment's bar." Waste Mgmt. Holdings, Inc. v. Gilmore, 252 F.3d 316, 331 (4th Cir. 2001); Doyle, 1 F.4th at 254. Moreover, a general authority to enforce the laws of a state is not a close enough relation. Id. "Instead, the officer sued must be able to enforce, if he [or she] so chooses, the specific law the plaintiff challenges." Doyle, 1 F.4th at 255. Overall, "[t]he exception is narrow: it applies only to prospective relief, [and] it does not permit judgments against state officers declaring that they violated federal law in the past. . .." P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc., 506 U.S. 139, 146 (1993).

a. Dr. Christiansen Remains Immune

The Court first examines Ex parte Young with respect to Dr. Christiansen, named only in his official capacity as State Health

Officer and Commissioner of the Bureau of Public Health. ECF No. 1. The relief sought is largely limited to prospective enforcement of the West Virginia mandatory vaccine law, W. Va. Code § 16-3-4, as it pertains to Plaintiffs. Dr. Christiansen's legal authority under the challenged statute is limited to (1) providing parents of newborn children with information on mandated vaccinations, W. Va. Code § 16-3-4(a); (2) providing medical exemptions, W.Va. Code § 16-3-4(c), (h); (3) developing a minimal criteria for the provisional enrollment of a student who has "at least one dose of each required vaccine," "so that the [student's] immunization may be completed while missing a minimum amount of school," W. Va. Code § 16-3-4(e); and (4) appointing and employing an Immunization Officer, W. Va. Code § 16-3-4(h)(2). As Plaintiffs vociferously protest, West Virginia law does not provide Dr. Christiansen or anyone else authority to grant any other exemptions including exemption for religious objections.

Dr. Christiansen is irrelevant to fashioning the remedy requested in the Complaint. Dr. Christiansen cannot force Upshur County officials – even while that county's schools are under State control - to re-enroll the Plaintiff. The State Health Officer does not have the authority to mandate that any student be enrolled, or unenrolled in a school. In short, the State Health Officer has no control over the State Superintendent, the County

Board of Education, or any individual school. See W. Va. Code §§ 16-1-5 (designating that the State Health Officer may also serve as the Commissioner of the Bureau for Public Health); 16-1-6 (enumerating powers of the Commissioner of the Bureau for Public Health). In short, Dr. Christiansen lacks the legal ability to remedy the alleged constitutional violation as Plaintiffs expressly seek in their Prayer for Relief. See ECF No. 1, at ¶¶ 283-84. No "special relation" or even "some connection" exists between Defendant Christiansen and the relief sought here. See Doyle, 1 F.4th at 254. Accordingly, this Court lacks jurisdiction over Dr. Christiansen as he remains vested with immunity from suit in this Court under the Eleventh Amendment and must be dismissed.[8]

[8] Dr. Christiansen also argues Plaintiffs lack standing to seek even injunctive relief against him in his official capacity. Although not raised via Rule 12(b)(1) motion, "federal courts are under an independent obligation to examine their own jurisdiction, and standing is perhaps the most important of [the jurisdictional] doctrines." FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231 (1990) (internal quotations and citations omitted), holding modified by City of Littleton, Colo. v. Z.J. Gifts D-4, L.L.C., 541 U.S. 774 (2004). For the same reasons the Court finds Dr. Christiansen is cloaked in Eleventh Amendment immunity here, the Court concludes Plaintiffs have not established either the requisite "causal connection" between their claimed injury and Dr. Christiansen's conduct or that Dr. Christiansen could, even under this Court's command, redress that injury. See Friends for Ferrell Parkway, LLC v. Stasko, 282 F.3d 315 (4th Cir. 2002). Plaintiffs' lack of standing with respect to their claims against Dr. Christiansen requires his dismissal on this separate, independent basis.

b. Upshur County Individual Defendants Are Not Immune

With respect to Defendants Marteney and Miller, the Court ultimately reaches a different decision, however. Again, although the Eleventh Amendment technically bars a party from suing a state or its agency to seek injunctive relief,[9] a plaintiff may bring the suit against a state officer in his or her official capacity seeking prospective injunctive relief, thereby effecting the same result. Seminole Tribe v. Florida, 517 U.S. 44, 71 n.14 (1996) ("An individual can bring suit against a state officer in order to ensure that the officer's conduct is in compliance with federal law."). It remains a narrow exception to constitutional sovereign immunity. "Young's applicability has been tailored to conform as precisely as possible to those specific situations in which it is necessary to permit the federal courts to vindicate federal rights and hold state officials responsible to the supreme authority of the United States." Papasan v. Allain, 478 U.S. 265, 277 (1986); Griffin v. Cnty. School Bd. of Prince Edward Cnty., 377 U.S. 218, 228 (1964) (noting "suits against state and county officials" to enjoin unconstitutional action are permitted under Ex parte Young). In such cases, citizens can bring suits against a state officer, in his official capacity, where he has a "special

[9] See Cory v. White, 457 U.S. 85, 91 (1982) ("Thus, the Eleventh Amendment by its terms clearly applies to a suit seeking an injunction.").

relation" to the challenged act. Id. at 157; see also Quern v. Jordan, 440 U.S. 332, 346-49 (1979); Edelman v. Jordan, 415 U.S. 651, 665-69 (1974).

To meet the "special relation" requirement, the challenged official must have "proximity to and responsibility for the challenged state action," thus ensuring "that a federal injunction will be effective with respect to the underlying claim." South Carolina Wildlife Federation v. Limehouse, 549 F.3d 324, 332-33 (4th Cir. 2008). This test does not require the challenged statute specify the official's role, but where there are express obligations, the officer's duty is made clearer. See Ex parte Young, 209 U.S. at 157. Ultimately, the "important and material fact" is that "the state officer, by virtue of his office, has some connection with the enforcement of the act." Id.

Defendant Miller ("Superintendent Miller") is the duly appointed Superintendent of the Upshur County School System and has been sued only in her official capacity as Superintendent. Her duties are outlined in W. Va. Code § 18-4-10 and include enforcement of all policies and procedures by state law, including, as is relevant here, enforcement of W. Va. Code § 16-3-4 against Plaintiffs. Again, Superintendent Miller was appointed by the State Department of Education, and is subject, at present, to their oversight rather than that of the local board. See ECF 40-2.

Among other things, statutory authority renders Superintendent Miller the "chief executive officer" of the board and empowers her to "under the direction of the state board, execute all its education policies." W. Va. Code § 18-4-10(1) and (10).

Defendant Marteney works as the Virtual Learning Coordinator for Upshur School Schools, the system through which Plaintiffs enrolled, and attempted to re-enroll, K.P. into the Upshur County Virtual School. ECF No. ¶ 92. Marteney is sued solely in her official capacity. Id. Ms. Marteney is tasked with implementing and enforcing, and does implement and enforce, the mandatory vaccination requirements of W. Va. Code § 16-3-4 and cited this statute when refusing to re-enroll K.P. in the county's virtual school. Id. Plaintiffs allege Marteney was primarily responsible for the decision made subject of the Complaint. Id. ¶¶ 75-79.

In fact, the challenged statute, specifically W. Va. Code §16-3-4(c) and (d) charges the schools and school boards to enforce the mandatory vaccine requirement. Those sections provide:

> (c) No child or person may be **admitted** or received **in any of the schools of the state** or a state-regulated child care center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio,, rubella, tetanus and whooping cough or produces a certificate from the commissioner granting the child or person an exemption from the compulsory immunization requirements of this section.

> (d) Any **school** or state-regulated child care center personnel having information concerning any person who attempts to be **enrolled in a school** or state-regulated child care center without having been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough shall report the names of all such persons to the commissioner.

Id. (emphasis added).

This Court once again finds Judge Goodwin's analysis in Workman compelling on this particular issue. There, the plaintiffs asserted claims against the Mingo County Board of Education, which had likewise been taken over by the State Board of Education, and others challenging the constitutionality of W. Va. Code § 16-3-4. See Workman, 667 F. Supp.2d at 681-684. Judge Goodwin found the official capacity claims against the individual defendants including the State Superintendent of Schools and the Superintendent of Mingo County Schools survived Eleventh Amendment immunity challenges under Ex parte Young such that he "must address the merits of [plaintiff's] claims." Id. at 688. In doing so, he highlighted the fact that the county superintendent (post-state take over) "was hired by a state officer, to enact state policy." Id. "Local officers, depending on the particular circumstances,

may be entitled to Eleventh Amendment protection as agents of the state." Id. (citation omitted).[10]

The same result is appropriate here.[11] Both Defendants Marteney and Miller were installed after the State Board of Education assumed control of the Upshur County Board of Education and its operations. In their respective roles of Virtual Learning Coordinator and County Superintendent, they have the authority to admit and enroll students, or not to do so, in accordance with state law including W. Va. Code § 16-3-4. The Court, at this preliminary injunction stage, concludes both Defendants Marteney and Miller have the requisite degree of "some connection" to the West Virginia mandatory vaccine statute. Thus, considering the prospective injunctive relief sought, this Court has jurisdiction

[10] In affirming Judge Goodwin's grant of summary judgment to defendants, the Fourth Circuit did not substantively address plaintiffs' assignment of error on subject matter jurisdiction including the Eleventh Amendment. See Workman v. Mingo County Board of Education, 419 Fed. Appx. 348 (4th Cir. 2011).

[11] The Upshur County Defendants inexplicably urge this Court to follow Judge Goodwin's lead in Workman and find the individual defendants "agents of the state" for Eleventh Amendment purposes but to plot a different path on application of Ex parte Young. ECF No. 45 at 17. They argue Defendants Marteney and Miller were only hired to "enact state policy" which ostensibly includes W. Va. Code § 16-3-4. The Court rejects the inconsistent argument instead concluding those assigned duties establish "some connection" to the challenged statute triggering Ex parte Young.

over Plaintiffs' claims against those specific Defendants pursuant to Ex parte Young.[12]

B. Pullman Abstention

Defendant Dr. Christiansen first raised the issue of abstention in his Motion to Stay. He has now been dismissed which arguably renders that relief moot. However, the Upshur County Defendants argued in support of abstention or, alternatively, a stay. The Court therefore considers whether either is appropriate here. First, the Court must – and does – determine it has jurisdiction over this matter. See Sonda, 92 F.3d at 219 (noting a court's "independent obligation to satisfy itself of its jurisdiction."). Plaintiffs' claims arise under federal law, i.e., 42 U.S.C. § 1983, vesting original jurisdiction here. See 18 U.S.C. § 1331. Defendants make no argument or suggestion to the contrary.[13]

"The generally applicable rule is that a federal court, whose jurisdiction has been invoked, must exercise that jurisdiction and

[12] The Upshur County Defendants do argue that some "state treasure" may be implicated calling into question Ex parte Young's application. The Court finds that argument unavailing upon review of Plaintiffs' Complaint. The only monetary recovery sought is for attorney's fees under 42 U.S.C. § 1988. Such relief does not vitiate jurisdiction here. See Hutto v. Finney, 437 U.S. 678 (1978); Missouri v. Jenkins, 491 U.S. 274 (1989); Kentucky v. Graham, 473 U.S. 159 (1985).

[13] The Court rejects the remaining Defendants Eleventh Amendment immunity argument. See supra.

address the matter before it." Sonda, 92 F.3d at 219. Both the Supreme Court and the Fourth Circuit have repeatedly instructed district courts this is their "strict duty." Martin v. Stewart, 499 F.3d 360, 363 (4th Cir. 2007) (quoting Quackenbush v. Allstate Ins. Co., 517 U.S. 706, 716 (1996)). Indeed, the Supreme Court has emphasized that this duty is a "virtually unflagging obligation." Deakins v. Monaghan, 484 U.S. 193, 203 (1988) (quoting Colo. River Water Conservation Dist. v. United States, 424 U.S. 800, 813 (1976)). Federal courts have "no more right to decline the exercise of jurisdiction which is given, than to usurp that which is not given." Cohens v. Virginia, 19 U.S. 264, 404 (1821) (Marshall, C.J.).

However, "an extraordinary and narrow exception" to this duty exists when abstention is justified by the relevant circumstances, as for example, under the abstention doctrine articulated in Pullman. See Quackenbush, 517 U.S. at 728 (cleaned up). Defendants ask the Court to abstain from deciding the issues presented or stay this matter pending state court resolution of the purported state law issues implicated. The Pullman exception may be applied when "there is (1) an unclear issue of state law presented for decision (2) the resolution of which may moot or present in a different posture the federal constitutional issue such that the state law issue is potentially dispositive." Wise

v. Circosta, 978 F.3d 93, 101 (4th Cir. 2020) (en banc) (quoting Educ. Servs., Inc. v. Md. State Bd. for Higher Educ., 710 F.2d 170, 174 (4th Cir. 1983)).

Defendants argue abstention is appropriate here considering the 2023 enactment of the Equal Protection for Religion Act ("EPRA") in West Virginia. That statute, found at W. Va. Code § 35-1A-1, largely codifies the traditional strict scrutiny standard deployed in constitutional question litigation. Specifically, the EPRA prohibits the state from "substantially burden[ing] a person's exercise of religion unless applying the burden to that person's exercise of religion in a particular situation is essential to further a compelling governmental interest; and is the least restrictive means of furthering that compelling governmental interest . . . ." W. Va. Code § 35-1A-1(a)(1). The EPRA, however, also creates a "claim" for violation of this standard for "injunctive or declaratory relief and reimbursement of costs and reasonable attorney fees." W. Va. Code § 35-1A-1(b)(1).

Plaintiffs, however, assert no EPRA claim here. See generally Compl., ECF No. 1. In fact, they have repeatedly disclaimed any such cause of action here. This strikes the Court as significant as to whether exercising its discretion under Pullman is even an option. The first step in a Pullman analysis is to determine if

there is "an unclear issue of state law **presented for decision**." Wise, 978 F.3d at 101 (emphasis added). The Fourth Circuit has further noted the ambiguous state law claim must be "in issue" and "not duplicative" of the asserted claims. Educational Services, Inc. v. Maryland State Board for Higher Education, 710 F.2d 170, 174 (1983). Simply, neither of these prerequisites are satisfied here.

Again, Plaintiffs have expressly disavowed an EPRA claim. It is therefore not "presented" or "in issue" directly. Moreover, it is difficult to discern what ambiguity exists in the EPRA which would justify this Court pausing consideration of Plaintiffs' claims given the presence of jurisdiction. The statute codifies strict scrutiny and enables a state law challenge to any state effort to burden religious observance. Nothing about the statute is unclear as it is, contrary to Educational Services' holding, duplicative of Plaintiffs' claims before this Court.

Defendants also tepidly point to the mandatory vaccine statute as a potential basis for triggering Pullman abstention. Like EPRA, nothing in W. Va. Code § 16-3-4 presents as ambiguous. The mandatory vaccine statute specifically lists the required vaccines and declares only those medically exempted are excused from compliance. Again, nothing in either statute at the forefront of Plaintiffs' claims is ambiguous such that deference to the West

Virginia state courts is advisable. "[W]hen a statute is not ambiguous, there is no need to abstain even if state courts have never interpreted the statute." City of Houston, Tex. v. Hill, 482 U.S. 451, 469 (1987).[14]

Defendants rely heavily upon Judge Bailey's reasoned decision in West Virginia Parents for Religious Freedom v. Christiansen, 685 F. Supp.3d 371 (N.D.W. Va. 2023) where His Honor elected to invoke Pullman abstention. There, the plaintiffs asserted a constitutional challenge to the same statute, W. Va. Code § 16-3-4, but sought wider relief including mounting a facial challenge, in addition to an as-applied challenge, to the statute. After the State of West Virginia submitted its amicus curiae brief arguing the EPRA was "directly relevant" to the issues before the Court, Judge Bailey granted the defendant's motion for summary judgment to the extent it urged Pullman abstention was the proper course of action.

Respectfully, this Court has a different interpretation of the issues presented in this specific case. Plaintiffs have undertaken a different tact in this case: different parties,

[14] As noted, the EPRA merely codifies the strict scrutiny standard. As the Court discusses supra, there is little ambiguity about the impact strict scrutiny analysis has on Plaintiffs' as-applied challenge to the mandatory vaccine statute either. "[S]trict scrutiny, in practice, is virtually impossible to satisfy . . ..". Washington Post v. McManus, 944 F.3d 506, 520 (4th Cir. 2019)

different facts (a student only seeking ability to enroll virtually), and a different constitutional challenge (as-applied challenge only). Plaintiffs eschewed any reference to the EPRA and, instead, Defendants ask the Court to impose that statute and potential claim here over Plaintiffs' objection. Also, here, the Court does not have the benefit of the "State's" position in this as-applied challenge as Judge Bailey had – despite notice being afforded. ECF No. 40-1. The EPRA, although not presented here, is duplicative of Plaintiffs' First Amendment challenge.

In summary, the Court does not find the Pullman factors to be satisfied; therefore, it would be inappropriate to abstain where jurisdiction is otherwise established. See Sonda, 92 F.4th at 219-220.

C. Rule 19 Motion to Dismiss

Defendants Marteney and Miller also move to dismiss Plaintiffs' Complaint for failure to join an indispensable party arguing the State Board of Education and State Superintendent should have been named as party-defendants. ECF No. 29. Specifically, Defendants argue they are powerless to "consider a religious exemption" to W. Va. Code § 16-3-4 and, in addition, the state takeover renders them largely unable to do much of anything

other than follow direction from the State Board and State Superintendent.[15]

"Courts are loathe to dismiss cases based on nonjoinder of a party, so dismissal will be ordered only when the resulting defect cannot be remedied and prejudice or inefficiency will certainly result." Owens-Illinois, Inc. v. Meade, 186 F.3d 435, 441 (4th Cir. 1999) (citation omitted). Therefore, before dismissing, courts conduct an in-depth, two-step inquiry to assure non-joinder is in fact fatal to the claim. See National Union Fire Ins. Co. of Pittsburgh, PA v. Rite Aid of South Carolina, Inc., 210 F.3d 246, 249 (4th Cir. 2000) ("Federal Rule of Civil Procedure 19 sets forth a two-step inquiry for a district court to determine whether a party should be joined in an action."). First, courts consider whether a party is necessary "because of its relationship to the matter under consideration." Owens-Illinois, Inc., 186 F.3d at 440. Next, "[i]f a party is necessary, it will be ordered into the action." Id. Only when a party cannot be joined will the court "determine whether the proceeding can continue in its absence, or whether it is indispensable pursuant to Fed. R. Civ. P. 19(b) and the action must be dismissed." Id.; see also

[15] Defendants Marteney and Miller likewise argue Defendant Christiansen is indispensable as the "chief enforcer" of W. Va. Code § 16-3-4, the singular statute made subject of Plaintiffs' as-applied challenge here. The Court, for reasons set forth previously, rejects this argument.

Teamsters Local Union No. 171 v. Keal Driveaway Co., 173 F.3d 915, 917–18 (4th Cir. 1999).

Federal Rule of Civil Procedure 19(a) identifies persons that are to be joined "if feasible," including a person who is subject to service of process and whose joinder will not deprive the court of subject-matter jurisdiction, if:

> (A) in that person's absence, the court cannot accord complete relief among existing parties, or
>
> (B) that person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may:
>
> (i) as a practical matter impair or impede the person's ability to protect that interest; or
>
> (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest.

Fed. R. Civ. P. 19(a).

In determining whether a party is indispensable, Rule 19 specifies the following factors for the Court to consider:

> (1) the extent to which a judgment rendered in the person's absence might prejudice that person or the existing parties;
>
> (2) the extent to which any prejudice could be lessened or avoided by:
>
> (A) protective provisions in the judgment;
>
> (B) shaping the relief; or
>
> (C) other measures;

> (3) whether a judgment rendered in the person's absence would be adequate; and
>
> (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.

Fed. R. Civ. P. 19(b)(1)-(4).

The Upshur County Defendants argue both the West Virginia Department of Education and the West Virginia State Superintendent of Schools are indispensable parties here based on their respective duties imposed under state law. Plaintiffs contend the named (and remaining) defendants, if enjoined, can afford them complete relief.

1. No other party is necessary to afford Plaintiffs complete relief.

The Court agrees with Plaintiffs here. If the Court enjoins Defendants Marteney and Miller and – even - those acting in concert with them "from enforcing W. Va. Code § 16-3-4 against Plaintiffs, unless the government provides an option for Plaintiffs to request a religious exemption to the Virtual Academy" (ECF No. 1 at ¶ 55), Plaintiffs would obtain complete relief against the existing parties to the suit, and that relief would be sufficient to remedy the constitutional violations alleged. See Dixon v. Edwards, 290 F.3d 699, 713 (4th Cir. 2002) (holding that a party was not necessary where the "injunction entered by the district court in fact gave [the plaintiff] complete relief.").

Defendants Marteney and Miller's assertion that complete relief cannot be provided without the State Department of Education and the State Superintendent as parties to the suit is unpersuasive. Defendants claim the State Board and the State Superintendent are tasked generally with "interpreting" and "enforcing" the laws touching on public schools, including the mandatory vaccination law, and that they consequently have an "interest" in this litigation. See ECF No. 30 at 14. Defendants Marteney and Miller then imply they will potentially be subject to "incurring inconsistent obligations" if the Court grants injunctive relief, and the State Department of Education and the State Superintendent then interpret the mandatory vaccination statute contrary to the Court's directives and require them to violate a federal court order.

Other courts have held that inclusion of sufficient officials to effect relief satisfies the Rule 19 requirements of joining necessary parties, even if perhaps other parties have some interest in the matter – rejecting the contentions of Defendants here. See Fitzgerald v. Wildcat, 687 F. Supp. 3d 756, 784-785 (W.D. Va. 2023) (holding that inclusion of sufficient officials in their official capacities to afford relief meets the necessary party requirement); see also Salt River Project Agr. Imp. & Power Dist. v. Lee, 672 F.3d 1176, 1180 (9th Cir. 2012). Again, the Supreme

Court has explained that official-capacity suits "generally represent only another way of pleading an action against an entity of which an officer is an agent." Kentucky v. Graham, 473 U.S. 159, 165 (1985). Thus, they are not "suit[s] against the official personally, for the real party in interest is the entity." Id. at 166.

Here, the County Superintendent is acting under the authority and agent of the State Board due to the takeover of the local district. And her inclusion in her official capacity is sufficient to impute their interests in all events. Moreover, the State Board and State Superintendent are unable to merely replace Superintendent Miller to avoid the requirements of an injunction, because the official capacity suit against her and any injunction entered against her in her official capacity will flow to any successor in office. See Fed. R. Civ. P. 25(d).

In Robertson v. Jackson, 972 F.2d 529 (4th Cir. 1992), the official primarily responsible for enforcement of the challenged action argued that other officials should be made a party. However, the Fourth Circuit found no error in not joining the additional officials to the action because the official before the Court was sufficient to provide the relief ordered. Id. at 535. The court noted "no evidence has been presented to suggest he cannot do so with the authority he enjoys under Virginia law."

Id. "The potentiality that the Commissioner may, at some future time, be unable to cause a particular local agency to comply with federal requirements does not relieve him of his responsibility under federal law to attempt fully to ensure compliance." Id.

Later, the Fourth Circuit followed the same path in Staley v. Darlington County Sch. Dist., 84 F.3d 707 (4th Cir. 1996). There the Fourth Circuit found that joinder of the state board, despite their general supervision over local school districts, was not necessary under Rule 19. The Court reasoned including the local officials who engaged in segregation was sufficient to fashion and award the desegregation injunctive relief orders entered by the court.

The same reasoning applies here. The Fourth Circuit in Stanley concluded the state board was not necessary because "the [School] District has failed to provide a single example of how the State has impeded the district's compliance with the court's order and federal law since 1970." Id. at 714. There, the court ultimately found no error by not forcing the Plaintiffs to include the state board because it was not necessary to afford relief. Id. ("The federal rules, however, do not authorize a defendant to compel an unwilling plaintiff to assert a claim against a second defendant.").

In terms of joinder of the State Board of Education, the Fourth Circuit in Jackson observed that "[w]e do not address the question of whether we should refuse to entertain the claim of necessary parties, because we do not believe that either the State Board or the local agencies are parties that must be joined to grant complete relief." Id. at 536. To that end, "[t]he district court's order, requiring the Commissioner to bring about full compliance with federal timely processing and program access requirements, cannot be considered either 'partial' or 'hollow' relief." Id. (citing Fed. R. Civ. P. 19(a)(1) advisory committee's note; and 3A J. Moore, J. Lucas & G. Grotheer, Moore's Federal Practice, P 19.071[1] (2d ed. 1991) (joinder is not necessary "where, although certain forms of relief are unavailable due to a party's absence, meaningful relief can still be provided")). "Neither the State Board nor the local agencies has been shown to be an impediment to the achievement of full compliance with the federal regulations." Id.

The analysis in Robertson is equally applicable here. There is no evidence that inclusion of the State Board of Education, or of the State Superintendent, is necessary to effect remedial relief. Enjoining Defendants Miller and Marteney is sufficient to effect K.P.'s re-enrollment. Defendants' arguments to the contrary are unavailing. See, e.g., Luce v. Lexington Cnty. Health

Servs. Dist., 3:22-03998-MGL, 2023 WL 8809994, at *6 (D.S.C. September 20, 2023) (determining that state official was not a necessary party and inclusion of local officials in official capacity was sufficient). The specific claim and relief sought here ultimately informs the Court's decision. "An 'as applied' challenge contends that a law's application to a particular person under particular circumstances deprives that person of a constitutional right. Thus, a successful 'as applied' challenge precludes the enforcement of a statute against a plaintiff alone." Marcellus v. Virginia State Bd. of Elections, 168 F. Supp. 3d 865, 872 n.8 (E.D. Va. 2016), aff'd, 849 F.3d 169 (4th Cir. 2017) (citing Fed. Election Comm'n v. Wisconsin Right to Life, Inc., 551 U.S. 449, 481 (2007)). The remaining Defendants – Ms. Marteney and Mr. Miller – are sufficient to permit the Court to fashion a full and proper remedy if warranted.

2. There is no prejudice to the State parties and no inconsistent obligations imposed on Defendants Marteney and Miller.

Defendants also argue prejudice if the State Board and/or State Superintendent are not present to defend their interests and potential inconsistent obligations if this case proceeds as postured. The Court disagrees.

First, the nature of the Board and Superintendent's duty under the challenged statute is minimal. The enforcement mechanism of

W. Va. Code § 16-3-4 lies with the local school system. See W. Va. Code § 16-3-4(c) ("No child or person may be admitted or received in any of the schools of the state . . . "). Other than generalized supervision responsibility, see W. Va. Code § 18-2-5, the State Board and Superintendent have no direct connection to the mandatory vaccination statute. The state takeover of Upshur County schools makes no significant difference here. The duly appointed County Superintendent and Virtual Learning Coordinator are charged with county-level administration. Therefore, outside of an interest in enforcing the law generally, those entities have no real interest to defend here.

Defendants Marteney and Miller are also not, realistically, exposed to "incurring inconsistent obligations" under Rule 19(a)(1)(B)(ii) if the Court grants injunctive relief. There is no legitimate scenario where any entity, including the State Board or State Superintendent, would direct the remaining Defendants to ignore or act in contravention of an order from this Court. Judge Chambers of the Southern District of West Virginia dismissed a similar argument in Nelson v. Warner, 446 F. Supp. 3d 119, 126 (S.D.W. Va. 2020) - albeit in a facial challenge. Regardless, this Court is satisfied it has jurisdiction over the remaining Defendants and Plaintiffs' claims thereby ensuring compliance with any ultimate resolution and judgment. Moreover, because this is

an as-applied challenge, injunctive relief would only extend to Defendants Marteney and Miller with respect to K.P. and her enrollment in the Upshur County Virtual School.

"Dismissal of a case is a drastic remedy, however, which should be employed only sparingly." Teamsters Local Union No. 171, 173 F.3d at 918. In determining whether to dismiss a complaint, a court must proceed pragmatically, "examin[ing] the facts of the particular controversy to determine the potential for prejudice to all parties, including those not before it." Id. Having done so, the Court concludes no necessary parties, and certainly no indispensable parties, are absent. Defendants' motion on this ground is therefore **DENIED**.

D. Preliminary Injunction Standard

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Dewhurst v. Century Aluminum Co., 649 F.3d 287, 290 (4th Cir. 2011) (quoting Winter v. Nat. Res. Def. Counsel, Inc., 555 U.S. 7 (2008)); see Peterson v. Nat'l Telecomms. & Info. Admin., 505 F. Supp.2d 313, 317 (E.D. Va. 2006) (quoting Direx Israel Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 811 (4th Cir. 1992)) (recognizing that "[a] preliminary injunction is an extraordinary remedy involving the exercise of a very far-reaching

power, which is to be applied only in the limited circumstances which clearly demand it").

In order to justify the extraordinary remedy that a preliminary injunction provides, the movant has the burden of demonstrating the following: (1) "that he is likely to succeed on the merits"; (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief"; (3) "that the balance of equities tips in his favor"; and (4) "that an injunction is in the public interest." Dewhurst, 649 F.3d at 290 (internal quotation marks and citations omitted); see Direx Israel, 952 F.2d at 812 (indicating that the moving party bears the burden of demonstrating the propriety of a preliminary injunction). In Dewhurst, the United States Court of Appeals for the Fourth Circuit emphasized the fact that controlling precedent from the Supreme Court mandates that a plaintiff "clearly show" that he is likely to succeed on the merits. Dewhurst, 649 F.3d at 290 (quoting Winter, 555 U.S. at 22) (emphasis added).

The demanding standard outlined in Dewhurst becomes even more exacting when, as here, a plaintiff seeks a preliminary injunction that mandates action, as opposed to the typical form of preliminary injunctive relief seeking to preserve the status quo pending trial. See East Tenn. Nat. Gas Co. v. Sage, 361 F.3d 808, 828 (4th Cir. 2004) (quoting Wetzel v. Edwards, 635 F.2d 283, 286 (4th Cir.

1980)) (noting that "mandatory preliminary injunctions do not preserve the status quo and normally should be granted only in those circumstances when the exigencies of the situation demands such relief"). Preliminary injunctions are ordinarily intended to "protect the status quo and to prevent irreparable harm during the pendency of the lawsuit or alternately to preserve the court's ability to render a meaningful judgment on the merits." In re Microsoft Corp. Antitrust Litig., 333 F.3d 517, 525 (4th Cir. 2003). In Microsoft, the Fourth Circuit elaborated that such "[m]andatory preliminary injunctive relief in any circumstance is disfavored, and warranted only in the most extraordinary circumstances." Id. (citation omitted). The court further noted that the "application of th[e] exacting standard of review [for preliminary injunctions] is even more searching" when the movant requests relief that "is mandatory rather than prohibitory in nature." Id.

With this framework in mind, the Court turns to the substance of Plaintiffs' claims against Defendants.

E. The Free Exercise Clause

The First Amendment provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." U.S. Const. amend. I. The "Free Exercise" component of the First Amendment applies to states through the

Fourteenth Amendment, rendering "the legislatures of the states as incompetent as Congress to enact such laws." Cantwell v. Connecticut, 310 U.S. 296, 303 (1940).

The Supreme Court has held that "religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection." Fulton v. City of Philadelphia, 593 U.S. 522 (2021) (quotation omitted). In considering whether a plaintiff's rights under the Free Exercise Clause are infringed, a court must determine whether the plaintiff's religious exercise has been burdened and whether the burden the government has imposed is constitutionally permissible. Id. A plaintiff bears the burden of showing an infringement of his or her rights under the Free Exercise Clause, and if he or she does so, "the focus then shifts to the defendant to show that its actions were nonetheless justified and tailored consistent with the demands of [Supreme Court] case law." Kennedy v. Bremerton Sch. Dist., 597 U.S. 507, 142 S. Ct. 2407, 2421 (2022).

To establish a Free Exercise violation, a plaintiff may show that "a government entity has burdened his [or her] sincere religious practice pursuant to a policy that is not neutral or generally applicable." Id. at 2422 (quotation omitted). As with many constitutional challenges, the key issue here is the level of scrutiny the Court must apply. When a religiously neutral and

generally applicable law incidentally burdens Free Exercise rights, courts will sustain the law against constitutional challenge if it is rationally related to a legitimate governmental interest. See Fulton v. City of Philadelphia, 593 U.S. 522, 533 (2021) (citing Employment Division v. Smith, 494 U.S. 872, 878-82 (1990)). When a law is not neutral or generally applicable, however, the statute may survive only if it is narrowly tailored to achieve a compelling governmental interest. Id. at 1881 (citing Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 546 (1993)).

In determining whether a law is neutral or generally applicable, "[a] law is not generally applicable if it invites the government to consider the particular reasons for a person's conduct by providing a mechanism for individualized exemptions." Fulton, 593 U.S. at 533 (quotation omitted). Under that rule, if a state reserves the authority to "grant exemptions based on the circumstances underlying each application," it must provide a compelling reason to exclude "religious hardship" from its scheme. Id. (quoting Smith, 494 U.S. at 884). A law also fails to be generally applicable "if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way." Id.

A policy is not neutral if it is "specifically directed at religious practice," meaning that it either "discriminates on its face" or "religious exercise is otherwise its object." Kennedy, 597 U.S. at 526 (quotations omitted). "Government fails to act neutrally when it proceeds in a manner intolerant of religious beliefs or restricts practices because of their religious nature." Fulton, 593 U.S. at 533 (citing Masterpiece Cakeshop, Ltd. V. Colo. Civ. Rights Comm'n, 584 U.S. 617, 138 S. Ct. 1719, 1730-32 (2018)). "Failing either the neutrality or general applicability test is sufficient to trigger strict scrutiny." Kennedy, 597 U.S. at 526.

1. West Virginia's Mandatory Vaccine Program is not generally applicable.

Plaintiffs contend the West Virginia mandatory vaccination statute institutes a discretionary exemption to the compulsory vaccination schedule that permits families with medical objections to seek medical exemptions but prohibits families with religious objections from seeking an exemption for religious reasons.

Defendants argued the contrary of course. They do concede general applicability may be absent when a law provides "a mechanism for individualized exemptions," because it creates the risk that administrators will use their discretion to effectively create exemptions on a case-by-case basis, exempting individuals from complying with the law for secular reasons, but not religious reasons. Smith, 494 U.S. at 884 (citations omitted). Defendants

note, in Smith, the Court considered an exemption that was granted for "good cause" as an example of such "individualized exception." 494 U.S. at 884. Similarly, they argue, in Fulton, a city official was able to create exemptions in his or her "sole discretion," which was violative of the general applicability framework. Fulton, 593 U.S. at 523.

Defendants rely heavily on the First Circuit's decision in Does 1-6 v. Mills, 16 F.4th 20 (1st Cir. 2021), in urging the Court to find W. Va. Code § 16-3-4 generally applicable. In Does 1-6, the First Circuit assessed a challenge to Maine's state regulation mandating healthcare workers receive a COVID-19 vaccination. See id. at 24. Among the many issues raised, the court had to determine which level of scrutiny applied to the healthcare workers' constitutional claims and specifically if the state regulations were generally applicable under Smith. See id. at 29-30. The court ultimately concluded the regulatory scheme was generally applicable subjecting the Maine vaccination rule to something less stringent than strict scrutiny. "The emergency rule does not require the state government to exercise discretion in evaluating individual requests for exemptions." Id. at 30.

That conclusion stands to reason because no state official approval or review of the exemption is required under Maine's compulsory vaccination rules. No "request" is actually made.

Instead, a "medical exemption is available to an employee who provides a written statement from a licensed physician, nurse practitioner or physician assistant that, in the physician's, nurse practitioner's or physician assistant's professional judgment, immunization against one or more diseases may be medically inadvisable." Me. Rev. Stat. Ann. tit. 22, § 802. Nor is there any administrative appeal to a Maine state, county, or local government agency for an adverse decision or the like. An employer is only required to keep the physician's certification "in the permanent health record for that employee for a minimum of six years after termination." Code Me. R. tit. 10-144 Ch. 264, § 3. Maine's statutory and regulatory scheme is sufficiently different from West Virginia's mandatory vaccination statute to make Does 1-6 readily distinguishable on the generally applicable issue.[16]

Although W. Va. Code 16-3-4 does not tend toward the unbridled discretion found in Fulton ("sole discretion") or Smith ("good cause"), the Court finds the medical exemption provided in West Virginia law, as applied to K.P., to be sufficiently discretionary

[16] The Court likewise finds Defendants' other points of authority - Miller v. McDonald, No. 1:23-CV-00484 EAW, 2024 WL 1040777 (W.D.N.Y. Mar. 11, 2024) and Royce v. Bonta, No. 3:23-CV-02012-H-BLM, 2024 WL 1269485 (S.D. Cal. Mar. 25, 2024) - on this question unavailing as well. The Court finds the other cited authority that predates Fulton unpersuasive. See, e.g., ECF No. 21 at p.12.

to fall outside the "generally applicable" field. The statute provides the health commissioner "is authorized to grant . . . exemptions to the compulsory immunization requirements . . . on a statewide basis, upon sufficient medical evidence that immunization is contraindicated or there exists a specific precaution to a particular vaccine." W. Va. Code § 16-3-4(h). The statute is silent as to an exemption for any family who may have religious objections. As alleged in the Complaint, Defendants communicated the same to Plaintiffs when they requested a religious exemption for K.P.

At the first level of the medical exemption process, a physician must complete a form, the Request for Medical Exemption from Compulsory Immunization Form,[17] requesting an exemption and justifying the request. If and when the medical exemption form is signed by a physician, it is then forwarded to the State's Immunization Officer for personalized review. See ECF No. 1-2, Dr. Alvin Moss Declaration, ¶¶ 5-12. According to the West Virginia Office of Epidemiology and Prevention Services, the Immunization Officer will review the evidence obtained from the child's

[17] The form can be located at https://oeps.wv.gov/immunizations/Documents/Childcare,%20School%20and%20College%20Requirements/WV%20Medical%20Exemption%20Request%20Form-05-03-2024.pdf (last visited October 15, 2024). It provides several lines for the physician to discuss medical diagnoses and any "further information you feel is relevant to this request."

physician. If the evidence or information is incomplete, the Immunization Officer will make a request for additional evidence. If all the evidence received by the Immunization Officer, including **all medical opinion(s)**, is consistent and there is sufficient evidence to determine whether to grant an exemption, the Immunization Officer will make a determination or decision based on that evidence. If the exemption is approved, that student is permitted to attend school without having received the mandated vaccines. If the Immunization Officer denies the medical exemption, the decision can be appealed to the State Health Officer, who reviews the appeal on a case-by-case basis and determines whether to uphold or reverse the State Immunization Officer's decision. See W. Va. Code § 16-3-4(h)(4).

In practice, based on the record currently before the Court, there is significant individualized discretion in this process. First, the Exemption Request form requires diagnosis information and "any other relevant information" from a practicing physician. The Immunization Officer then considers evidence including "medical opinions" in determining whether to approve the request. Plaintiffs also provide testimony from Dr. Alvin Moss, a West Virginia physician, who has evaluated schoolchildren and determined in his discretion whether their health conditions qualify them for a medical exemption under West Virginia Code §

16-3-4(h). See ECF No. 1-2, ¶¶ 12-17. Dr. Moss further details the inherent case-by-case discretion associated with evaluating these requests. Id. at ¶¶ 8-12. The criteria by which medical exemptions are evaluated are not objective and are subject to the opinion of each government official who evaluates the exemption request and differing outcomes can and are reached depending on the evaluator of the request. Id. Moreover, the implementing regulations for the medical exemption provide for consideration of "evidence from medical sources, such as medical history, **opinions**, and statements about treatment the child has received." W. Va. C.S.R. § 64-95-17.2.a.2 (emphasis added).

As Dr. Moss's Declaration makes clear, the practice of medicine including in the area of contraindication for vaccines involves discretion and judgment. Reasonable minds, of course, may differ. The process set forth in W. Va. Code § 16-3-4 involves multiple layers of medical judgment and review. Initially, a practicing physician offers his or her opinions. Then, the government becomes involved reviewing and passing judgment on the treating physician's recommendation. This review requires discretion and judgment to be exercised – not the simple task of checking objective boxes. Ultimately, the Court concludes this process is sufficiently similar to the standards at issue in Fulton

and Smith to consider W. Va. Code § 16-3-4 short of general applicability.

The Court therefore concludes W. Va. Code 16-3-4 is not a generally applicable statute under Fulton.[18] Thus, Plaintiffs' as-applied challenge triggers strict scrutiny.

2. Defendants fail to satisfy strict scrutiny.

Where strict scrutiny applies, government policy survives "only if it advances interests of the highest order and is narrowly tailored to achieve those interests," meaning that "so long as the government can achieve its interests in a manner that does not burden religion, it must do so." Fulton, 593 U.S. at 541 (quotation omitted). When considering the governmental interests at issue, a court must not rely on "broadly formulated interests"; instead, it "must scrutinize the asserted harm of granting specific exemptions to particular religious claimants." Id. (quotation omitted). The relevant question is not whether the government has a compelling interest in enforcing its policies generally, but instead whether the government has such an interest in denying a religious exemption to a particular plaintiff. Id.

The parties debate the impact of the Fourth Circuit's decision in Workman here. That case, decided over 13 years ago, addressed

[18] The Court need not – and for purposes of resolving the pending motions, does not – reach the question of whether W. Va. Code § 16-3-4 is neutral.

the same statute challenged here, W. Va. Code 16-3-4. Workman, 419 Fed. Appx. 348 (4th Cir. 2011).[19] Ultimately, the Fourth Circuit affirmed Judge Goodwin's summary judgment finding for the defendants noting the mandatory vaccination statute served a compelling state interest. Id. at 353. "[T]he state's wish to prevent the spread of communicable diseases clearly constitutes a compelling interest." Id.: see also Does 1-6 v. Mills, 16 F.4th 20, 32 (1st Cir. 2021) ("Few interests are more compelling than protecting public health against a deadly virus.").[20]

Notably, however, the Workman court did not address whether the statue was sufficiently narrow in its tailoring.[21] The court

[19] Plaintiffs make much of Workman being an unpublished decision. Although "unpublished opinions are not binding precedent in this circuit," Rule 32.1 permits citation to the decision which occurred after January 1, 2007. Even if unpublished, this Court affords serious and significant consideration to any pronouncement of the Fourth Circuit and has done so here. Considering the recent developments in the law and for all the reasons articulated herein, the Court reaches a different conclusion.

[20] Plaintiffs argue the efficacy and purpose of some of the mandated vaccines should inform the Court's decision here. The Court finds it unnecessary to delve into those matters to resolve the pending motions. Moreover, the Court does not believe it proper to adjudicate such important questions without the benefit of a fully developed factual record.

[21] Defendants also point the Court to the Supreme Court of Appeals of West Virginia's decision in D.J. v. Mercer County Board of Education, No. 13-0237, 2013 WL 6152363 (W. Va. November 22, 2013). There, the court considered a challenge to the State's vaccination requirements under the West Virginia Constitution's equal protection and due process clauses. It does not appear a Free Exercise challenge was mounted. Although not binding here, the Court always gives careful consideration to the State's highest

relied on the oft-cited combination of Jacobson v. Massachusetts, 197 U.S. 11 (1905) and Prince v. Massachusetts, 321 U.S. 158 (1944). The Jacobson decision was certainly prevalent in the litigation surrounding various COVID-era executive orders and the like. There, the Supreme Court found compulsory vaccination against smallpox a valid exercise of the state's police power without infringing any federal constitutional rights. See Workman, 419 Fed. Appx. at 353. Of course, since Workman and the even further removed time of Jacobson, the Supreme Court has wrestled with Free Exercise Clause challenges to the exercise of that "police power" during the COVID pandemic. This Court now has the benefit of that analysis and guidance in assessing Plaintiffs' claims here.

As discussed above, if strict scrutiny applies, Defendants must satisfy the stringent strict scrutiny standard – and both prongs of it. "[H]istorically, strict scrutiny requires the State to further 'interests of the highest order' by means 'narrowly tailored in pursuit of those interests.'" Tandon v. Newsom, 593 U.S. 61, 64-65 (2021) (quoting Church of Lukumi Babaly Aye, Inc.,

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court's analysis particularly on matters of State law such as those presented here. However, the Supreme Court of Appeals did not consider the "narrowly tailored" prong of the strict scrutiny analysis despite acknowledging its application and the compelling interest of protecting the health and safety of the public. Id. at *4. The Court, therefore, finds little guidance in that decision when resolving Plaintiffs' claims here.

508 U.S. at 546). "That standard is not watered down; it really means what it says." Id. (internal quotations and citations omitted). At this stage of these proceedings, considering Workman and the other authority Defendants cite, the Court finds Defendants have carried their burden to show a compelling state interest in preventing the spread of infectious disease. See, e.g., D.J. v. Mercer County Board of Education, 2013 WL 6152363, at *4 ("[T]he protection of the health and safety of the public is one of the most important roles of the state."); Does 1-6, 16 F.4th at 32 ("Few interests are more compelling than protecting public health against a deadly virus.").

However, the Court finds Defendants have failed to demonstrate W. Va. Code § 16-3-4 is narrowly tailored to achieve the identified compelling state interest. As an initial matter, and as Plaintiffs note, 45 other states have religious or philosophical exemption options to their vaccine mandates. Thus, it is readily apparent the approach West Virginia has taken is broader than other states, rendering any suggestion W. Va. Code § 16-3-4 is narrowly tailored to advance the identified compelling interest of stemming infectious disease spread unpersuasive.[22]

[22] As discussed supra, Governor Justice's veto message touted the broad sweep of West Virginia's vaccination requirements and its relative success rate in advancing the state's compelling interest in curbing the spread of contagious disease.

In addition, West Virginia has also provided carve outs for other students removed from physical school structures from the mandatory vaccination statute. Specifically, children are exempted from compulsory school attendance requirements, and are excluded from "any other provision of law relating to education," if they participate in learning pods or microschools. W. Va. Code § 18-8-1(n)(8). Under West Virginia law, a "learning pod" means "a voluntary association of parents choosing to group their children together to participate in their elementary or secondary academic studies as an alternative to enrolling in a public school, private school, homeschool, or microschool, including participation in an activity or service provided to the children in exchange for payment." W. Va. Code § 18-8-1(n)(1)(A). A "microschool" "means a school initiated by one or more teachers or an entity created to operate a school that charges tuition for the students who enroll and is an alternative to enrolling in a public school, private school, homeschool, or learning pod." W. Va. Code § 18-8-1(n)(1)(B).

Unlike students enrolled in virtual school such as K.P., West Virginia pupils advancing their education in either an otherwise permissible learning pod or microschool are excluded from the requirements of W. Va. Code § 16-3-4. There is no statutory requirement that either learning pods or microschools adhere to or

teach any religious curriculum or belief system. These students, like virtual students, rarely, if ever, physically attend class or school. It therefore strains reason to find W. Va. Code § 16-3-4 is sufficiently tailored to advance the State's interest within constitutional confines when similarly situated secular students are excused from the statute's reach. "The principle that government, in pursuit of legitimate interests, cannot in a selective manner impose burdens only on conduct motivated by religious belief is essential to the protection of the rights guaranteed by the Free Exercise Clause." Church of Lukumi Babaly Aye, Inc., 508 U.S. at 543.

In determining there exists a narrower path to advance the State's compelling interest, the Court also considers recent legislative activity demonstrating the possibility. During the 2024 Regular Legislative Session, the West Virginia Legislature passed House Bill 5105 which sought to amend the challenged statute here, W. Va. Code § 16-3-4, by, inter alia, creating an exemption to the mandatory vaccine requirement for full-time virtual public school students. Governor Justice vetoed this legislation citing feedback primarily from the medical community and West Virginia's

success in combating the spread of the diseases listed in W. Va. Code § 16-3-4(b) – the compelling interest here.[23]

However, House Bill 5105 bolsters Plaintiffs' argument that a more narrowly tailored approach is possible to advance that interest which, to withstand strict scrutiny, the Constitution requires. "If a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative." United States v. Playboy Ent. Grp., Inc., 529 U.S. 803, 813 (2000) (citation omitted) (assessing Free Speech claim under the First Amendment). Many other states have deployed a less restrictive measure to advance the identified compelling interest. The West Virginia Legislature has indicated it is possible as well. At

[23] Respectfully, the political machinations of the legislative process assist the Court only in assessing if a more narrowly tailored approach is available. The merits of the arguments over House Bill 5105 are better left to other branches of government. Legislative enactments, of course, must remain within the Constitution's framework. As the Supreme Court summarized,

> The very purpose of a Bill of Rights was to withdraw certain subjects from the vicissitudes of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts. One's right to life, liberty, and property, to free speech, a free press, freedom of worship and assembly, and other fundamental rights may not be submitted to vote; they depend on the outcome of no elections.

W. Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 638 (1943).

this point, Defendants have failed to sustain their burden on this issue.

Having found W. Va. Code § 16-3-4 is subject to strict scrutiny in deciding Plaintiffs' Free Exercise challenge, the Court finds Plaintiffs are likely to succeed on the merits in that the mandatory vaccine statute is not sufficiently narrowly tailored to satisfy Constitutional safeguards. The Court, therefore, must assess the remaining Winter factors.

3. Plaintiffs will suffer Irreparable Harm.

Plaintiffs must also demonstrate irreparable harm for injunctive relief to issue. See Hyman v. City of Salem, 396 F. Supp.2d 666, 670 (N.D.W. Va. 2019) (citation omitted). "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976). The Supreme Court has been clear and has reiterated in recent years that a plaintiff may be "irreparably harmed by the loss of free exercise rights 'for even minimal periods of time.'" Tandon, 593 U.S. at 64 (quoting Roman Cath. Diocese of Brooklyn v. Cuomo, 592 U.S. 14, 19 (2020)). The Fourth Circuit has echoed the same. "[T]he denial of a constitutional right . . . constitutes irreparable harm for purposes of equitable jurisdiction." Ross v. Meese, 818 F.2d 1132, 1135 (4th Cir. 1987);

see also Recht v. Justice, No. 5:20-CV-90, 2020 WL 6109430, at *7 (N.D.W. Va. June 26, 2020) (Bailey, J.).

Based on the record before it, the Court finds Plaintiffs are likely to suffer irreparable harm. Plaintiffs' Free Exercise rights vis-à-vis their legal obligation to educate K.P. have been burdened. K.P. has been denied her parents' preferred method of constitutionally-required education. As alleged in their Complaint, and there is no present dispute, Plaintiffs have and will continue to face obstacles in homeschooling K.P. as Mrs. Perry works full-time to provide for her family and Mr. Perry suffers from physical disabilities. Of course, Plaintiffs face criminal prosecution and sanctions if they fail to educate their daughter. See W. Va. Code § 18-8-2. These hardships are imposed solely because Plaintiffs refused to sacrifice their religious beliefs. K.P. was enrolled and excelling in the Upshur County Virtual School program prior to Defendants' refusal to afford her a religious exemption from West Virginia's mandatory vaccine statute in response to the December 2023 email blast from the State Superintendent.[24] Plaintiffs have satisfied their burden to demonstrate irreparable harm at this stage.

[24] The record presently before the Court does not reveal any particular prompt for the State Superintendent's email about virtual students and their vaccination status. That missive was the impetus for K.P. being disenrolled and this Free Exercise challenge being filed.

4. Balance of Equities and Public Interest

With respect to the third and fourth Winter factors, the Court turns to Judge Bailey's analysis and summary in Recht.

> [T]he third and fourth Winter factors (the balance of equities and the public interest) are established when there is a likely First Amendment violation. Id. at 191. "[A] state is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction." Giovani Carandola, Ltd. v. Bason, 303 F.3d 507, 521 (4th Cir. 2002) (internal quotation marks omitted). It also teaches that "upholding constitutional rights surely serves the public interest." Id.

Recht, 2020 WL 6109430, at *7. The Court, having found Plaintiffs are likely to succeed on their First Amendment claim, also concludes the remaining Winter factors counsel in favor of issuing the requested injunctive relief.

IV. CONCLUSION

As the Supreme Court has long observed, "religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection." Fulton, 593 U.S. at 533 (quoting Thomas v. Review Bd. Of Ind. Employment Security Div., 450 U.S. 707, 714 (1981)). "If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force

citizens to confess by word or act their faith therein." Barnette, 319 U.S. at 642. The wisdom of Plaintiffs' choices about vaccines is rightfully not before this Court. Vindication of their First Amendment rights is, however. Their burden to secure proactive injunctive relief is not a light one. Defendants' burden in surviving strict scrutiny is a heavier one.

A. Scope of Injunction

Here, Plaintiffs have satisfied their burden while Defendants have failed in theirs; thus, the Court grants the injunctive relief sought in the Complaint. To be clear, Plaintiffs assert **only** an as-applied challenge with respect to W. Va. Code § 16-3-4 and specifically as to how Defendants have applied that statute to K.P. in refusing to enroll her in the Upshur County Virtual School program. The preliminary injunction issued here is **only** designed to prevent Defendants from continuing to violate Plaintiffs' First Amendment rights and to permit K.P.'s enrollment in that virtual schooling program if she seeks a valid religious exemption from Defendants. This Court makes no finding on the facial constitutionality of W. Va. Code § 16-3-4; nor does the Court's order apply to any other students in any other educational program elsewhere in the State of West Virginia.

Therefore, pursuant to Fed. R. Civ. P. 65(d), Defendants and their officers, agents, servants, and employees, and anyone acting

in active concert or participation with them (collectively hereinafter, "the Enjoined Parties"), are hereby **PRELIMINARILY ENJOINED** as follows:

> **Effective October 15, 2024, the Enjoined Parties shall be enjoined from enforcing W. Va. Code § 16-3-4 against Plaintiffs, unless Defendants provide an option for requesting a religious exemption that is meaningfully processed. K.P. shall not be prevented from enrolling in the Upshur County Virtual School due to her unvaccinated status.**

This injunction shall remain in place as stated herein pending further Order of this Court.

B. Rule 65(c) Security

Rule 65(c) states that a court may issue a preliminary injunction "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). "This rule is mandatory and unambiguous." Hoechst Diafoil Co. v. Nan Ya Plastics Corp., 174 F.3d 411, 421 (4th Cir. 1999). Failure to require a bond upon issuing injunctive relief is considered reversible error. See District 17, UMWA v. A&M Trucking, Inc., 991 F.2d 108, 110 (4th Cir. 1993). Here, no party has requested any specific bond be required or set. The record does not reveal significant risk of grave potential harm to either Defendant if this injunction ultimately proves

improvidently granted. In such circumstances, the Fourth Circuit has instructed:

> In fixing the amount of an injunction bond, the district court should be guided by the purpose underlying Rule 65(c), which is to provide a mechanism for reimbursing an enjoined party for harm it suffers as a result of an improvidently issued injunction or restraining order. The amount of the bond, then, ordinarily depends on the gravity of the potential harm to the enjoined party:
>
> > [T]he judge usually will fix security in an amount that covers the potential incidental and consequential costs as well as either the losses the unjustly enjoined or restrained party will suffer during the period he is prohibited from engaging in certain activities or the complainant's unjust enrichment caused by his adversary being improperly enjoined or restrained.
>
> 11A Charles Alan Wright et al., Federal Practice & Procedure § 2954, at 292 (2d ed.1995). Where the district court determines that the risk of harm is remote, or that the circumstances otherwise warrant it, the court may fix the amount of the bond accordingly. In some circumstances, a nominal bond may suffice. See, e.g., International Controls Corp. v. Vesco, 490 F.2d 1334 (2d Cir.1974) (approving district court's fixing bond amount at zero in the absence of evidence regarding likelihood of harm).

Hoechst Diafoil Co., 174 F.3d at 421 n.3.

Considering the totality of the record and circumstances before the Court, the Rule 65(c) bond is fixed at zero dollars.

See, e.g., Bernstein v. Sims, 643 F. Supp.3d 578, 589 (E.D.N.C. 2022) ("In light of the important federal rights at issue in this case, and absent any request from defendants for plaintiff to provide security, the Court determines a zero dollar bond is appropriate in this instance.").

In summary, for the reasons set forth herein, the pending motions are decided as follows:

1. Plaintiffs' Motion for Preliminary Injunction [ECF No. 7] is **GRANTED;**
2. Defendant Christiansen's Motion to Stay [ECF No. 22] is **DENIED;** and
3. Defendants Marteney and Miller's Motion to Dismiss [ECF No. 29] is **DENIED.**

Furthermore, Dr. Mathew Christiansen is hereby **DISMISSED** as a Defendant in this action.

It is so **ORDERED.**

The Clerk is hereby directed to forward a copy of this Order to all counsel or record.

The Clerk is **DIRECTED** to transmit copies of this Order to counsel of record.

DATED: October 15, 2024

Tom S Kleeh

THOMAS S. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA

Exhibit 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 30, 2020

Elizabeth Brehm
Siri & Glimstad
200 Park Ave, 17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

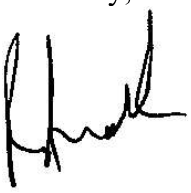
This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 9, 2020, for 'documentation sufficient to reflect any case(s) of transmission of Hepatitis B in an elementary, middle, or high school setting.'

A search of our records failed to reveal any documents pertaining to your request.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by February 28, 2021.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

#21-00200-FOIA

Exhibit 5

Raleigh County Schools

105 Adair Street, Beckley WV 25801 Phone: 304-256-4500 Fax: 304-256-4739 http://boe.rale.k12.wv.us

May 24, 2024

Aaron Siri, Esq.
Siri Glimstad
745 Fifth Avenue, Suite 500
New York, NY 10151

E-mailed to: foia@sirillp.com

Dear Mr. Siri:

My office received your request pursuant to the West Virginia Freedom of Information Act on April 14, 2024. Available responses were provided to you on April 22, 2024 *(see attached letter)*. It was also noted in the initial letter that other responses would be provided on or before May 31, 2024. Please find below the remaining responses.

1. **The total number of currently enrolled students;**
   - 10,330 (as provided April 22, 2024)

2. **The total number of students currently enrolled in and using the West Virginia Virtual Academy powered by K12;**
   - 17

3. **The number of currently enrolled students who have been enrolled for more than 30 days, and who do not have all required vaccinations;**
   - 16 (1 medical exemption, 15 incomplete and enrolled greater than 30 days)

4. **The number of currently enrolled students who have been granted a medical exemption to any required vaccination;**
   - 1

5. **The number of currently enrolled students who have been granted a religious exemption to any required vaccination; and**
   - None (as provided April 22, 2024).

6. **The number of students who have been excluded from school based on their vaccination status due to an outbreak of any infectious disease. Please provide this data for the 2018-2019 school year through the present date.**
   - None (as provided April 22, 2024).

Our duty to respond to your request under the Freedom of Information Act is at an end. As you may know, I am required to inform you that, if you believe that the Board has wrongfully responded to your request, you may have a right to seek injunctive or declaratory relief in the Circuit Court of Raleigh County pursuant to the provisions set forth in W. Va. Code §29B-1-3.

Sincerely,

Serena L. Starcher, Ed.D.
Superintendent

Enclosure

Raleigh County Schools

105 Adair Street, Beckley WV 25801 Phone: 304-256-4500 Fax: 304-256-4739 http://boe.rale.k12.wv.us

April 22, 2024

Aaron Siri, Esq.
Siri | Glimstad
20200 West Dixie Highway, Suite 902
Aventura, FL 33180

Electronically emailed to: foia@sirllp.com

Dear Mr. Siri:

My office received your request pursuant to the West Virginia Freedom of Information Act on April 14, 2024. As authorized by West Virginia's Freedom of Information Act, WV Code §29B-1-3(4)(b), we will respond by providing information as requested in your e-mail. Per your request, please find responses available as of today's date. Other responses will be provided on or before May 31, 2024.

1. **The total number of currently enrolled students;**
   - 10,330

2. **The total number of students currently enrolled in and using the West Virginia Virtual Academy powered by K12;**
   - To be provided by May 31, 2024

3. **The number of currently enrolled students who have been enrolled for more than 30 days, and who do not have all required vaccinations;**
   - To be provided by May 31, 2024

4. **The number of currently enrolled students who have been granted a medical exemption to any required vaccination;**
   - To be provided by May 31, 2024

5. **The number of currently enrolled students who have been granted a religious exemption to any required vaccination; and**
   - None

6. **The number of students who have been excluded from school based on their vaccination status due to an outbreak of any infectious disease. Please provide this data for the 2018-2019 school year through the present date.**
   - None

Please note that pursuant to county policy Official Record A.8, individuals who request that the information contained in the public record(s) be reproduced in copy form, the Raleigh County Board of Education will charge 50 cents per page, payable prior to release of the requested copies.

Upon receipt of a check or money order, payable to the Raleigh County Board of Education, the documents will be mailed to the address provided. If you wish to view the documents in person during office hours, please contact Ms. Carla Daniel, Executive Secretary at 304 256-4500, extension 3308.

As you may know, I am required to inform you that if you believe that the Board has wrongfully responded to your request, you may have a right to seek injunctive or declaratory relief in the Circuit Court of Raleigh County pursuant to the provisions set forth in W.Va. Code §29B-1-3.

Sincerely,

Serena L. Starcher, Ed.D.
Superintendent

SS/cjd

Exhibit 6

Fayette County Board of Education

111 Fayette Avenue
Fayetteville, West Virginia 25840
304-574-1176

April 11, 2024

Aaron Siri
745 5th Ave Suite 500
New York, NY 10151

Dear Aaron Siri,

My office received your request pursuant to the West Virginia Freedom of Information Act on Friday April 5, 2024. Per your request, the information is as follows:

1) Total Number of students currently enrolled is 5382
2) The total number of students currently enrolled in and using the West Virginia Virtual Academy cannot be answered by Fayette County Schools. West Virginia Virtual Academy is a charter school not part of Fayette County.
3) The number of currently enrolled students who have been enrolled for more than 30 days and who do not have all required vaccinations -440
4) The number of currently enrolled students who have been granted a medical exemption to any required vaccination- 1
5) The number of currently enrolled students who have been granted a religious exemption to any required vaccination-none
6) The number of students who have been excluded from school based on their vaccination status due to an outbreak of any infectious disease from 2018-2019 to the present- none

Should you need additional information, please contact my office.

Sincerely,

Gary Hough

Mr. Gary Hough
Superintendent

Exhibit 7

From: Jennifer Caradine [redacted]
Sent: Friday, April 26, 2024 12:57 PM
To: S&G Information Request Staff [redacted]
Subject: Unvaccinated Students (IR#10010ZF)

Mr. Siri,
This message is in response to your April 5, 2024 request.

(1) the total number of currently enrolled students - **Please see the attachment entitled Question 1**;

(2) the total number of students currently enrolled in and using the West Virginia Virtual Academy powered by K12 - **Please see the attachment entitled Question 2**;

(3) the number of currently enrolled students who have been enrolled for more than 30 days, and who do not have all required vaccinations - **Please see the attachment entitled Questions 3 and 4**;

(4) the number of currently enrolled students who have been granted a medical exemption to any required vaccination - **Please see the attachment entitled Questions 3 and 4**;

(5) the number of currently enrolled students who have been granted a religious exemption to any required vaccination - **zero**;

(6) the number of students who have been excluded from school based on their vaccination status due to an outbreak of any infectious disease. Please provide this data for the 2018-2019 school year through the present date. - **zero.**

As you may know, I am required to inform you that if you believe that the Monongalia County Board of Education has wrongfully responded to your request, you may have a right to seek injunctive or declaratory relief in the Circuit Court of Monongalia County pursuant to the provisions set forth in W. Va. Code § 29B-1-3.
Thank you,

Jennifer S. Caradine

Legal Counsel, Monongalia County Schools

1751 Earl L Core Rd, Morgantown, WV 26505

[redacted]

[redacted]

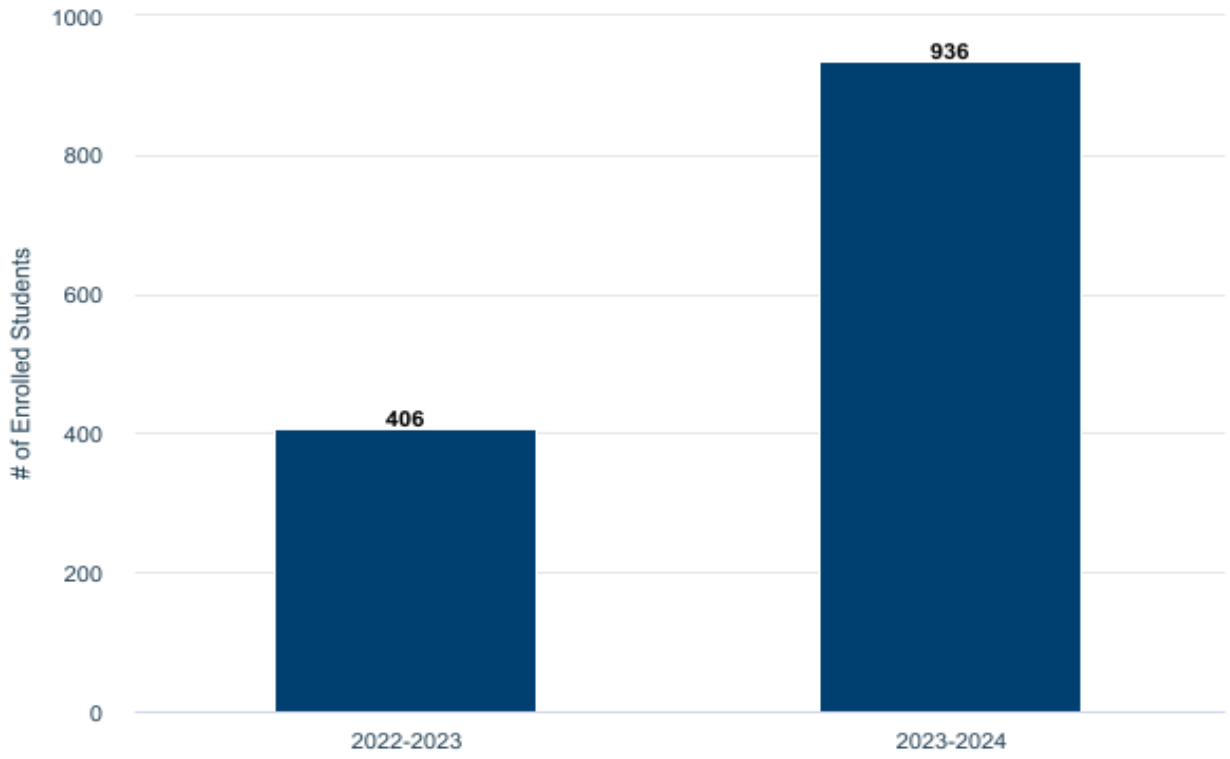
Monongalia
COUNTY SCHOOLS

	Totals
Brookhaven Elementary School	544
Ridgedale Elementary School	553
Daybrook Early Headstart Center	112
North Elementary School	587
Suncrest Elementary School	566
Cheat Lake Elementary School	779
Mountainview Elementary School	664
Mason Dixon Elementary	298
Skyview Elementary School	423
Mylan Park Elementary School	452
Eastwood Elementary School	663
Mountaineer Middle School	608
Westwood Middle School	323
South Middle School	775
Suncrest Middle School	498
Clay-Battelle High School	342
Morgantown High School	1811
University High School	1356

Enrollment Trend

Filter Criteria:

School Year	2023-2024	**District/County**	[All Districts]
School	(105) - West Virginia Virtual Academy		



Total of 2 row(s) with 10000 Row Limit

School Year	Total
2022-2023	406
2023-2024	936

	Total # of current students who have **been enrolled for 30 days**, who **do not have all required immunizations**	Total # of current students who have a **medical exemption for any required immunization.**
Total	**147**	**7**

Exhibit 8

Raleigh County Schools

Department of Nursing and Health Services
105 Adair Street, Beckley WV 25801 *Office: 304-256-4500 ext. 3333* *Fax: 304-256-4557*

To: Raleigh County Principals

From: Angie Foster, Director Health Services

Date: June 16, 2025

Subject: **Immunization Requirements for Students – WV Code 16-3-4. This supersedes previous communications regarding immunizations and is EFFECTIVE IMMEDIATELY.**

The West Virginia State Board of Education voted Wednesday, June 11, 2025 to enforce **WV Code §16-3-4** regarding required school immunizations.

As a result, public schools are required to comply with the current compulsory immunization law**.** It is important to note:

- The current law **does not allow for religious exemptions** to immunization requirements.
- **Medical exemptions** are permitted, provided they follow the established process outlined in the statute.

Principals it is your responsibility to communicate these changes and obtain the required documentation of immunizations for student athletes.

1. Any student athlete who **was** enrolled in RCS for the 2024-25 school year, must provide record of the following:
   - Rising 7th - must provide documentation of receiving Tdap and MCV4
   - Rising 12th - must provide documentation of receiving Tdap and MCV4. See attachment.
2. Any prospective student athlete who **was not** enrolled in RCS for the 2024-25 school year:
   - Must provide complete immunization record to be reviewed prior to participation. Please ensure this information is communicated appropriately within your school and that any questions or concerns are directed to Eric Dillon, Assistant Superintendent. On Monday, August 4, 2025 all calls may be directed to Angie Priddy, RN, Director of School Health Services.

Thank you for your attention to this important matter.

School Nurses

Care for Kids

WV Vaccine Requirements for 7th and 12th Graders

7th Grade School Entry Requirement

Vaccine	Requirement	Provisional Enrollment
Tdap (tetanus, diphtheria, acellular pertussis)	Proof of booster dose of Tdap vaccine.	No provisional enrollment permitted.
MCV4 (meningococcal/meningitis)	Proof of 1st dose of MCV4 vaccine.	No provisional enrollment permitted.

12th Grade School Entry Requirement

Vaccine	Requirement	Provisional Enrollment
Tdap (tetanus, diphtheria, acellular pertussis)	Proof of booster dose of Tdap vaccine.	No provisional enrollment permitted.
MCV4 (meningococcal)	**One or two doses required.** One dose of MCV4 is required if received after the 16th birthday. Second dose is required if first dose was before 16th birthday.	No provisional enrollment permitted.

WV Code §16-3-4 and 64CSR95

Exhibit 9

Proceedings

of the

Society

for

Experimental Biology and Medicine

INCLUDING THE FOLLOWING SECTIONS

Cleveland, O.	Northern California
District of Columbia	Northwest
Illinois	Ohio Valley
Iowa	Rocky Mountain
Maryland	Southern
Michigan	Southern California
Minnesota	Southeastern
Missouri	Southwestern
New York	Western New York

Wisconsin

May—Aug.-Sept., 1966 (inclusive)

VOLUME 122

New York

CONTENTS

SCIENTIFIC PROCEEDINGS, VOLUME 122

Printed by
THOMAS J. GRIFFITHS SONS, INC.
Utica, N. Y.

Proceedings of the Society for Experimental Biology and Medicine, Vol. 122, No. 4, Aug. Sept., 1966. Published monthly except September at 104 Liberty St., Utica, N. Y. Entered as second class matter, December 6, 1922 at P.O., Utica, N. Y. under Act of March 3, 1879. Subscription per year $17, single numbers $2.00.

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6. Dounce, A. L., Witter, R. F., Monty, K. J., Pate, S., Cottone, M. A., J. Biophys. Biochem. Cytol., 1955, v1, 139.

7. Schneider, W. C., Hogeboom, G. H., J. Biol. Chem., 1950, v183, 123.

8. Lowry, O. H., Rosebrough, N. J., Farr, A. L., Randall, R. J., ibid., 1951, v193, 265.

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10. Klotz, I. M., Walker, F. M., Pivan, R. B., J. Am. Chem. Soc., 1946, v68, 1486.

11. Sterling, K., Rosen, P., Tabachnick, M., J. Clin. Invest., 1962, v41, 1021.

12. Way, E. L., Adler, T. K., Pharmacol. Rev., 1960, v12, 383.

13. Sanner, J. H., Woods, L. A., J. Pharmacol. Exp. Ther., 1965, v148, 176.

Received January 3, 1966. P.S.E.B.M., 1966, v122.

Cytological Virological and Chromosomal Studies of Cell Strains From Aborted Human Fetuses.* (31037)

ANDRÉ BOUÉ,† CLAUDE HANNOUN,‡ JOELLE G. BOUÉ,† AND STANLEY A. PLOTKIN¶
(Introduced by David Kritchevsky)
The Wistar Institute of Anatomy and Biology, Philadephia, Pa.

Spontaneous abortion, usually without obvious cause, is a frequent occurrence in human pregnancies. To test the hypothesis that viral infections may play a part in the development of spontaneous abortion, a technique was sought to obtain dividing cells from human embryos that might be carrying latent viruses. We used a method developed by Jensen *et al,* for studying mouse tissues, in which cells could be obtained readily from organ explants. In the course of this work we collected cytological and chromosomal data on human fibroblast cell strains.

Materials and methods. Collection and preparation of specimens. Embryos were obtained from 2 sources: (A) surgical abortions performed in Scandinavia for social and psychiatric reasons, and (B) spontaneous abortions that occurred at the Philadelphia General Hospital and the Hospital of the University of Pennsylvania. The surgically removed embryos were placed in antibiotics containing Hanks' solution and shipped to us by air at a temperature of approximately 0°C. The spontaneous abortions were refrigerated in plastic bags without solution or antibiotics until collected, usually within 12 hours. Only those embryos which were expected to have viable tissues were studied. Aside from the decomposed external appearance, one of the best indicators of the embryo's condition appeared to be the physical aspect of the liver. All assays performed on embryos with friable and discolored livers were discarded, because the cells failed to grow.

Organ culture technique. The organ culture technique described by Jensen *et al*(1) was used: a grid of stainless steel mesh‖ was enclosed in a small Petri dish containing 10 ml of double strength Eagle's Basal Medium in isotonic Earle's solution with 10% calf serum; a small disc of open mesh paper (tea bag paper)** was moistened in the medium and applied to the top of the grid. Fragments of organs were cut into pieces about one cubic mm with a surgical blade and placed directly on the tea bag paper without being washed. Two explants were placed on top of each paper; the volume of the individual explants did not exceed 2 cu mm. The

* This work was supported, in part, by USPHS research grant AI 01799 from Nat. Inst. of Allergy and Infect. Dis. and by The Joseph P. Kennedy, Jr. Foundation.

† Present address: Laboratoire de la S.E.S.E.P., Chateau de Longchamp, Bois de Boulogne, Paris 16.

‡ Chef de Laboratoire, Institut Pasteur, Paris.

¶ Joseph P. Kennedy, Jr. Foundation Scholar, Wistar Inst. of Anatomy and Biology.

‖ Joseph E. Frankle Co., Philadelphia, Pa.

** C. H. Dexter & Sons, Inc., Windsor Locks, Conn. (10-V-7-1/4).

cultures were incubated at 37°C in a CO_2 incubator and the medium changed once a week. Cells migrated from the cut surfaces of the explant and dropped to the bottom of the Petri dish, where they multiplied to form colonies and, in some cases, confluent cultures.

Establishment of cell strains. If the colonies became confluent and covered the entire surface of the Petri dish, a cell strain was established by trypsinizing the cells and subcultivating them, either in Petri dishes or in milk dilution bottles at a 1:2 split ratio.

During the first trypsinization, the grid was removed and placed in a second Petri dish and new colonies proliferated. After establishment of the cell strain, the technique used was the same as that of Hayflick(2) for cultivation of human diploid cell strains, whereby cultures were passaged approximately once a week with 2-fold subdivision.

Cytologic studies. Cytologic studies were conducted either on the colonies of cells that developed on the surface of the Petri dish or on established cell strains. Preparations stained with May-Grünwald-Giemsa were obtained by placing coverslips on the floor of the Petri dish under the grid bearing the organ culture or under passaged cells.

Chromosomal technique. This technique was derived from Lejeune(3). All the chromosomal studies were done on coverslips placed on the floor of the Petri dish under the grid or in Leighton tubes or on Petri dishes inoculated with resuspended cells after the cell strain had been established.

The cells were pretreated with colchicine by adding one drop of a stock solution of "Colcemide" (Ciba) containing 25 μg/ml to 5 ml of supernatant medium with a syringe and 24-gauge needle. The culture was incubated at 37°C for 3½ hours. The coverslip was transferred, face up, to a Petri dish that contained a hypotonic solution and was kept at 37°C for 35 minutes.

The hypotonic solution was a mixture of one part calf serum, 10 parts distilled water, and sufficient hyaluronidase ("Widase," Wyeth) to give 2.5 USP units per ml of the mixture.

The concentration of serum in the hypotonic solution varied, depending on the density of the cells on the coverslip. When the density of the cells was high, the concentration of serum was lowered.

After hypotonic treatment, the coverslips were removed and put into a new Petri dish with the fixative and left for 45 minutes at room temperature.

The fixative consisted of 3 parts chloroform, one part acetic acid, and 6 parts absolute ethyl alcohol. The coverslips were then air dried and placed in a 1 N HCl solution at 60°C for 7 minutes so that the cytoplasm could be hydrolyzed. The coverslips were washed thoroughly in buffered water and stained with Giemsa solution diluted 1 to 10.

Results. These studies were performed from March to July, 1962, when 36 embryos were used, and again from November, 1963 to May, 1964, with 40 embryos.

Growth of cells from organ cultures. Each Petri dish was examined at least once a week with an inverted microscope. The time interval between the start of the organ culture and the formation of the first colonies of a few cells growing on the bottom of the Petri dish differed greatly from one embryo to another. In some cases, the colonies started at the end of the first week, while in other cases, they started only after 3 to 4 weeks of incubation. Most colonies grew well and after 3 weeks measured several millimeters in diameter.

The criterion of success of a culture was whether or not cell colonies developed after one month on the bottom of the Petri dish that contained the tissue-bearing grid. Cell growth from at least one tissue failed to occur only in 14 out of 76 aborted embryos: 8 from Scandinavia, 4 from PGH and 2 from HUP.

In the first series, the last 7 out of 26 embryos received from Scandinavia did not give viable cultures. The non-viability of cultures was probably due to the high external temperature during their shipment in July. Of the 12 received from HUP, 2 were lost by contamination and 2 failed to grow. Successful cultures, however, were obtained from 25 embryos (6 from the HUP and 19 from Finland).

Of the 40 aborted fetuses studied between

TABLE I. Cell Growth Under Organ Cultures.

Organ	Embryos studied from Nov. '63 to May '64 — No. of embryos studied	Confluent cultures	Cell colonies	No growth	Successful*	Embryos studied Mar. to July '62 Successful	Total
Pituitary	21	15	4	2	19/21	25/27	44/48
Lung	30	27		3	27/30	12/15	39/45
Skin	30	25		4	26/30	8/8	34/38
Kidney	14	10	4		14/14	6/7	20/22
Spleen	12	3	8	1	11/12	4/7	15/19
Thymus	15	11	2	2	13/15	2/2	15/17
Heart	8		1	7	1/8	1/5	2/13
Intestine	8	1	4	3	5/8	0/4	5/12
Liver	7		6	1	6/7	0/4	6/11
Thyroid	5	5			5/5	2/3	7/8
Salivary glands						5/5	5/5
Adrenals						2/5	2/5
Pharyngeal mucosa	2	2			2/2		2/2
Whole embryo	1	1				1/1	2/2
Cornea						1/1	1/1
Meningea						1/1	1/1
Tongue						1/1	1/1

* Denominator: No. of embryo studied; numerator: No. of cultures with successful growth.

November, 1963, and May, 1964, 13 were sent from Scandinavia, 20 came from PGH, and 7 from HUP. Successful cultures were obtained from 12, 16 and 7 embryos, respectively. Table I presents the results of organ cultures initiated with tissues from 60 embryos (31 from Scandinavia, 16 from PGH, and 13 from HUP). At least one organ culture from this group was successful.

There is a distinction between confluent culture and cell colonies: in the former case, the cultures came to confluence and could then be used to establish a cell strain, while in the latter case, only discrete colonies formed.

From these results it appears that, with the exception of heart organ cultures, most preparations resulted in cell growth on the glass. It was usually possible to obtain confluent cultures from such tissues as skin, lung, pituitary, kidney, thymus, thyroid, and pharyngeal mucosa.

The extremely low proportion of bacterial and fungal contaminations (2 of 76) in these organ cultures was noteworthy.

Establishment of cell strains. Table II summarizes the results of attempts to establish cell strains from the confluent cultures developed under the grids. While cell strains were easily established from skin, lung, pharyngeal mucosa and pituitary, it was difficult to establish strains from intestine, thymus and thyroid.

All the cell strains were composed of fibroblast-like cells. With skin, lung and pharyngeal mucosa organ cultures, the cells under the grid were already predominantly fibroblastic; in the case of other organ cultures such as pituitary, thymus and thyroid the cultures at first appeared to be epithelial, but after the first trypsinizations became fibroblastic.

All of the cell strains had the previously described characteristics(2) for human diploid cell strains.

Virological studies. Two types of speci-

TABLE II. Establishment of Cell Strains.

Organ	No. of embryos studied	Culture sucessful for: More than 4 splits 1:2	Fewer than 4 splits 1:2	Culture unsuccessful at 1st split
Skin	16	15	1	
Lung	12	10	2	
Kidney	5		4	1
Pituitary	5	3	1	1
Pharyngeal mucosa	4	4		
Intestine	4	1		3
Liver	3			3
Thymus	3	1	2	
Thyroid	3	1	2	
Whole embryo	1	1		

mens were tested in an attempt to isolate viruses from embryos. The test systems used in both types were primary vervet monkey kidney, primary human amnion, and human diploid cells (the WI-38 lung strain) (2).

In an attempt to detect latent viruses, the first type of specimen used was obtained from the cell cultures that became cell strains. No cytopathic effects were seen in any of the cells continuously cultured for periods ranging from one to six months. Tissue culture fluids obtained from cell strains cultured for 2 to 4 weeks were inoculated undiluted onto monolayers of the 3 tissue culture test systems. The test systems were maintained under Eagle's medium and 2% calf serum for 3 weeks before being discarded.

Suspension of cells derived from organ cultures were inoculated onto green monkey kidney cell monolayers, a technique described by Gerber and Kirschstein (4) for the transfer of cell-associated virus. All of these inoculations were negative.

The second type of specimen was the supernatant fluids from cultures which failed to grow. One might consider that the failure to establish a cell strain was due to a cytopathic effect. Tissue culture fluids were harvested over several weeks from organ cultures prepared from 5 embryos which yielded no cell growth from any culture. Inoculation of these fluids onto the test systems showed no evidence of cytopathogenicity.

When explants from a particular embryo gave both successful and unsuccessful cultures, the tissue culture fluids from unsuccessful explants were also tested for the presence of virus. Once more all attempts were negative. It is important to note that failure to grow cells from explants occurred in the same proportion in embryos from surgical abortions as in embryos obtained from spontaneous abortions.

We prepared organ cultures from 3 tonsils to test the sensitivity of the organ culture techniques for isolation of latent viruses when no cells grew from the explant. No cells grew in any of these cultures on the bottom of the Petri dish; however, in one case, 2 weeks after the beginning of the cultures, an adenovirus was recovered by passage on a sensitive cell system of the medium harvested.

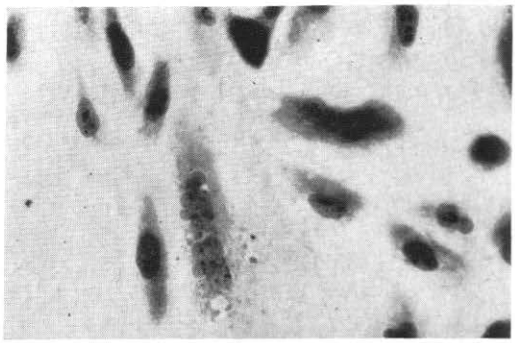

FIG. 1. Multinucleated giant cells seen in explant culture from a spontaneous abortion.

Cytological studies. Multinucleated cells were observed in many of the organ cultures, including explants from spontaneous and surgical abortions. Typical giant cells are illustrated in Fig. 1. Pituitary explants, in particular, gave rise to multinucleated cells, but when the cells were seen, their presence was noted in other cultures from the same embryo. Several days after the beginning of the culture, numerous giant-like cells containing 3 to 20 nuclei appeared. They were usually observed for the first time about the 12th day, but occasionally appeared before the seventh or as late as the 25th day of culture. The formation of multinucleated cells did not, in the majority of cases, prevent the eventual outgrowth of fibroblasts and development of a diploid strain. In pituitary cultures, the following sequence of events was observed: small colonies of epithelial-like cells appeared below the fragments, and later degenerated, giving way to a population of fibroblasts. As mentioned above, the fluids harvested from these cultures were tested on different cell systems with negative results. Some of the supernatant fluids were also inoculated into animals—such as baby mice by intraperitoneal and intracerebral routes, and baby hamsters by subcutaneous and intraperitoneal routes—without the isolation of a transmissible agent.

Chromosomal studies. Chromosomal study of cell cultures from 18 embryos of 2 to 4 months gestation was undertaken. Of these 18 embryos, all of which were obtained during the second time period of this work, 12

were male and 6 female. Four out of the 18 were surgically aborted, and the rest were obtained from spontaneous abortions.

All of the cell strains were diploid with a normal karyotype of 46 chromosomes. In 2 cases, both spontaneous abortions, chromosomal breaks were observed. In a male embryo, 24 of 79 metaphases analyzed (30%), had true breaks or gaps of one chromatid or of the two chromatids. The distribution of these breaks was of a random type. In a female embryo, which was one of twins, breaks were observed in 11 of 49 metaphases or 22%. The other twin, a male, had a normal karyotype. In 5 cells these breaks were on chromosome 3, at the same region in one or both chromatids, while in 3 other cells a constriction was observed at the same region.

In the remainder of cell strains, the percentage of gaps was below 10%.

Discussion. In this study it has been demonstrated that it is possible to derive cell strains from organ explants of human tissues, using the simple method described by Jensen *et al.* This method could be useful when dealing with small amounts of tissue such as fetal organs. The strains derived seem to be similar in behavior to the human diploid fibroblast cell strains obtained from minced tissues by Hayflick and Moorhead.

It seems important to have techniques that permit the establishment of cell strains from different organs. Recent studies have shown that human diploid cell strains vary in their sensitivity to viruses. For example, we have shown(5) that the effects of rubella virus infection are related to the organ from which these cell strains were initiated. Recently Behbehani *et al*(6) found that cell strains derived from human atheromatous lesions seem to be particularly susceptible to rhinoviruses.

The failure to isolate viruses from the spontaneously aborted fetuses must of course be qualified by the fact that only cytopathogenic agents would have been detected. However, insofar as the results are negative, some support should be given to the view that human diploid cell strains are normally free of extraneous viruses, and they are, therefore, advantageous for the fabrication of vaccines and for studies on chronic viral infection in human cells.

The negative results do not entirely exclude the possibility that viral infection plays a role in spontaneous abortion because the abortion might be due to a secondary effect of viral infection of the mother that has occurred without passage of the virus to the embryo itself.

No abnormality of the karyotype was observed among the 18 embryos studied. The only aberration found was due to breakages in 30% and 22% of cells of two of them. These results were in accordance with the results of Makino *et al*(7), who found only 2 aberrations out of 135 embryos obtained from therapeutic abortions: one aberration was D Trisomic, and in the other, the cells were found to contain a high incidence of chromosome breakage.

Chromosomal aberrations were found in spontaneous abortions by Carr(8), Clendenin (9), Szulmann(10), Hall(11) and Thiede (12), but in each case, where chromosomal abnormalities were described, the specimen was pathologic and consisted of a degenerating embryo or of an empty sac without a trace of fetal tissue—the so-called blighted ovum. Moreover, these pathologic specimens led to abortion which occurred early in pregnancy, or before the third month. In our study, most of the specimens were obtained from abortions that occurred in the third month or later, and which produced normally developed embryos.

Summary. An organ culture technique was used to investigate the possibility that latent viruses are present in spontaneously aborted human fetuses. All attempts to isolate virus from 74 human embryos were negative. In the course of these studies, numerous cell strains were derived from human tissue, and cytological features of these cells are described. Multinucleated giant cells were frequently found, but chromosomal aberration in this material was infrequent.

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Received January 24, 1966. P.S.E.B.M., 1966, v122.

Activation of Factors XII (Hageman) and XI (PTA) by Skin Contact.* (31038)

H. L. NOSSEL (Introduced by L. R. Wasserman)
Department of Hematology, Mount Sinai Hospital, New York City

Blood coagulation can be initiated *in vitro* by contact with a foreign surface such as glass which activates Factors XII (Hageman) and XI (PTA)(1). Most known activating surfaces do not occur in the body and it is unknown whether similar reactions initiate *in vivo* coagulation. Recently stearic acid(2-6), uric acid(7) collagen and elastin(8) which are found *in vivo* have been shown to activate the Hageman and PTA factors. Evidence is presented below that blood contact with unbroken human skin results in accelerated clotting due to activation of the Hageman and PTA factors.

Materials and methods. Platelet-poor plasma was prepared without contact with glass or similar surfaces as previously described(6). Plasma deficient in Factors VIII, IX, XI or XII was obtained from patients with congenital deficiency of these factors. Celite exhausted plasma deficient only in Factors XII and XI was prepared by treating normal plasma with 20 mg celite per ml as previously described(6). Cephalin prepared as previously described(9) was used in a 1/100 dilution.

Coagulation was carried out in 10 × 75 mm glass tubes coated with siliclad (Clay-Adams). 0.1 volumes of plasma and cephalin were added to a silicone treated tube. The tube was inverted over an area of skin which had been carefully cleaned with ether, alcohol and then distilled water and the plasma-cephalin mixture was incubated in contact with the cutaneous surface for a variable time period. The tube was turned upright, 0.1 ml 0.025 M $CaCl_2$ was added and the tube re-inverted over the same cutaneous site so that the clotting mixture was again in contact with the skin surface. The time required to form a solid clot was measured from the time calcium was added. In the control experiments exactly the same procedure was carried out except that parafilm (Marathon, Wisconsin) was interposed between the clotting mixture and the skin surface during both the incubation and clotting periods. Each clotting time was recorded as the average of those obtained in 3 tubes.

Results. Incubation of normal plasma in contact with a cutaneous surface resulted in progressive shortening of the clotting time (Fig. 1). Most of the acceleration of clotting occurred during the first minute of incubation and after 5 minutes incubation an almost maximal effect was noted. Skin surfaces in various sites exerted different degrees of clot promoting activity—the palmar surface of the hands and the skin of the face were particularly active. Prior cleansing of the skin with distilled water, ether or alcohol did not appear to affect the clot-promoting activity. When plasma samples from patients with congeni-

* This study was supported in part by Grant HE-08631 from Nat. Inst. Health, USPHS.

Exhibit 10

STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF OAKLAND
FAMILY DIVISION
- - -

LORI MATHESON, f/k/a LORI ANN SCHMITT, Plaintiff,	:	
vs.	:	CASE NO. 2015-831539-DM
MICHAEL SCHMITT, Defendant.	:	

VIDEOTAPED DEPOSITION OF STANLEY A. PLOTKIN, M.D.
New Hope, Pennsylvania
January 11, 2018

Reported by:
Maureen Broderick, RPR
JOB NO. 135522

January 11, 2018

8:30 a.m.

Videotape deposition of STANLEY A. PLOTKIN, M.D., taken at the Golden Plough Inn, 5883 Lower York Road, New Hope, Pennsylvania, before Maureen E. Broderick, Registered Professional Reporter and Notary Public in and of the Commonwealth of Pennsylvania.

APPEARANCES

SIRI GLIMSTAD
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Walled Lake, MI 48390
BY: AMY RUBY, ESQ.

(Via Telephone)
KARLSTROM COONEY
Attorneys for Defendant
6480 Citation Drive
Clarkston, MI 48346
BY: LAURA NIEUSMA, ESQ.

ALSO PRESENT: Tom Leibman, Videographer

MS. NIEUSMA: I'm going to ask that everybody speak up. You're all coming across a little soft other than Maureen. She's doing fine.

VIDEO OPERATOR: This is the start of media labeled number one of the video-recorded deposition of Dr. Stanley Plotkin in the matter of Lori Matheson, formerly known as Lori Ann Schmitt, versus Michael Schmitt, filed in the State of Michigan, Circuit Court, County of Oakland, Family Division.

This deposition is being held at 5833 Lower York Road in New Hope, Pennsylvania, on January 11, 2018. My name is Tom Liebman, and I'm the legal video specialist for the TSG Reporting, Incorporated, headquartered at 747 Third Avenue in New York City. The court reporter is Maureen Broderick, in association with TSG Reporting.

Counsel, please introduce yourselves for the record.

MR. SIRI: Aaron Siri, co-counsel on behalf of plaintiff.

MS. RUBY: Amy Ruby, on behalf --

co-counsel on behalf of plaintiff.

MS. NIEUSMA: Laura Nieusma, counsel for defendant, Michael Schmitt.

VIDEO OPERATOR: The court reporter will now swear in the witness.

- - -

STANLEY PLOTKIN, M.D., having been first duly sworn to tell the truth, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. SIRI:

Q Good morning, Dr. Plotkin.

MS. RUBY: Can we just make a record under this...

I would just like to clarify that this is being recorded by a video deposition pursuant to MCR 2.315.

BY MR. SIRI:

Q Good morning. Can you please state your full name for the record.

A Stanley A. Plotkin.

continue.

MS. NIEUSMA: All right.

MR. SIRI: Thank you.

MS. RUBY: Ms. Nieusma, if you want to rejoin the conversation, obviously you can dial back in.

MS. NIEUSMA: Yeah. I'm just going to leave you guys on speaker in my office and do this in the conference room and I'll be back.

MS. RUBY: Okay.

BY MR. SIRI:

Q Do any vaccines on the childhood vaccine schedule contain MRC-5 human diploid cells?

A Yes.

Q What are these?

A Rubella, varicella, hepatitis A.

Q What are MRC-5 cells?

A They are human fibroblast cell strain.

Q And how are they created?

A They were created by taking fetal tissue and, from a particular fetus that was aborted by maternal choice. And the cells, so-called fibroblast cells were cultivated from that tissue. The fibroblast cells replicate for about 50 passages

and then die.

Q So MRC-5 cells are cultured cell lines from aborted fetal tissue?

A They're not cell lines.

Q What are they?

A They're cell strains cultivated from an aborted fetus, yes.

Q So cell strains from an aborted fetus?

A Yes. Yeah. They're not immortal.

Q They live for five generations and then they die?

A About 50 generations.

Q About 50 generations and then they die?

A Yes.

Q And then how is more MRC-5 created?

A Well, a seed stock is made of early passage cells so that one can go back to the seed stock, which is, let's say, at the, more or less the eighth passage and make new cells at the 20th passage and use those to make the vaccine.

Q Okay. So these are, these cell strains are human cells?

A Yes.

Q Do any vaccines on the childhood vaccine

schedule contain WI-38 human diploid lung fibroblast?

A Well, they used to, but I don't think anything is made in those cells anymore. They have been replaced by MRC-5.

Q So you're not aware of any vaccine that has in its final formulation WI-38 human diploid lung fibroblasts?

A As I said, at one point in the past, RA 27/3, for example, rubella vaccine, was grown in WI-38. But the supply is insufficient, so MRC-5 is now used.

Q And these, and WI-38 was created from an aborted fetus?

A Yes.

Q They took the lung tissue from the aborted fetus?

A Yes.

Q And from that they'd grown this cell line, correct?

A Yes. Cell strain.

Q Cell strain.

Is this cell line immortal?

A No.

vaccines, how many fetuses have been part of that work?

"A. My own personal work? Two.")

BY MR. SIRI:

Q So I'm going to ask that question again. In your work related to vaccines, how many fetuses were involved in that work?

A There were only two fetuses involved in making vaccines. When fetal strains of, fibroblast strains were first developed, I was involved in that work trying to characterize those cells; but they were not used to make vaccines.

Q Wasn't the purpose of this study to help develop a human cell line or to support the use of human cell lines in the creation of vaccines?

A The idea was to study the cell strains from fetuses to determine whether or not they could be used to make vaccines.

Q So this was related to your work?

A Well, yes, in a sense --

Q To vaccines, correct?

A Yes. It was preparatory.

Q So this study involved 74 fetuses,

correct?

A I don't remember exactly how many.

Q If you turn to page 12 of the study.

A Seventy-six.

Q Seventy-six. And these fetuses were all three months or older when aborted, correct?

A Yes.

Q And these were all normally developed fetuses, correct?

A Yes.

Q Okay. These included fetuses that were aborted for social and psychiatric reasons, correct?

A Correct.

Q What organs did you harvest from these fetuses?

A Well, I didn't personally harvest any, but a whole range of tissues were harvested by co-workers.

Q And these pieces were then cut up into little pieces, right?

A Yes.

Q And they were cultured?

A Yes.

Q Some of the pieces of the fetuses were

pituitary gland that were chopped up into pieces to --

A Mm-hmm.

Q Included the lung of the fetuses?

A Yes.

Q Included the skin?

A Yes.

Q Kidney?

A Yes.

Q Spleen?

A Yes.

Q Heart?

A Yes.

Q Tongue?

A I don't recall, but probably yes.

Q So I just want to make sure I understand. In your entire career -- this was just one study. So I'm going to ask you again, in your entire career, how many fetuses have you worked with approximately?

A Well, I don't remember the exact number, but quite a few when we were studying them originally before we decided to use them to make vaccines.

Q Do you have any sense? I mean, this one study had 76. How many other studies did you have that you used aborted fetuses for?

A I don't remember how many.

Q You're aware, are you aware that the, one of the objections to vaccination by the plaintiff in this case is the inclusion of aborted fetal tissue in the development of vaccines and the fact that it's actually part of the ingredients of vaccines?

A Yeah, I'm aware of those objections. The Catholic church has actually issued a document on that which says that individuals who need the vaccine should receive the vaccines, regardless of the fact, and that I think it implies that I am the individual who will go to hell because of the use of aborted tissues, which I am glad to do.

Q Do you know if the mother's Catholic?

A I have no idea.

Q Okay.

A But she should consult her priest.

Q If she has a -- if she's, in fact, Christian, I guess, right?

In any event, so we have 76 in this study. Would you approximate it's been a few

hundred fetuses?

A Oh, no, I don't think it was that many. Probably not many more than in this paper.

And I should stipulate that we had nothing to do with the cause of the abortion.

Q Some of these were for psychiatric institutions, correct?

A Actually, all I can say is that the fetuses that I personally worked with actually came from Sweden, from a Swedish co-worker. And so I, in no case, was able to determine what exactly the reason for the abortion was.

Q I'm just asking you, some of the fetuses that you did use did come from abortions from people who were in psychiatric institutions, correct?

A I don't know that. What I'm telling you is that I got them from a co-worker; and if it's stated in the paper, it's true. But, otherwise, I do not know.

Q So if it's in the paper, you don't contest it, right?

A I don't contest it, no.

Q Okay. Have you ever used orphans to study an experimental vaccine?

A Yes.

Q Have you ever used the mentally handicapped to study an experimental vaccine?

A I don't recollect ever doing studies in mentally handicapped individuals. At the time in the 1960s, it was not an uncommon practice.

Q So you're saying -- I'm not clear on your answer. I'm sorry. Have you ever used mentally handicapped to study an experimental vaccine?

A What I'm saying is I don't recall specifically having done that, but that in the 1960s, it was not unusual to do that. And I wouldn't deny that I may have done so.

(Discussion off the stenographic record.)

BY MR. SIRI:

Q I'm going to read you a sentence from what what's been previously marked as --

MS. RUBY: No, that wasn't.

BY MR. SIRI:

Q -- Exhibit 7.

MS. RUBY: That's not what got marked as Exhibit 7. That got -- the task force was seven.

Stanley Plotkin, M.D.

MS. NIEUSMA: All right.

VIDEO OPERATOR: This ends disc five. It concludes the deposition of Dr. Stanley Plotkin. We are going off the record. The time is 18:43.

COURT REPORTER: Ms. Nieusma, do you need a copy of today's transcript?

MS. NIEUSMA: I do not.

COURT REPORTER: Is the witness going to read and sign?

MS. NIEUSMA: He certainly can. It's generally not something we do around here. But he can do it if anybody wants him to.

(Discussion off the record.)

MR. SIRI: I'll talk to you after.

(Witness excused.)

(Deposition concluded at 6:42 p.m.)

_____

Witness Signature

C E R T I F I C A T E

COMMONWEALTH OF PENNSYLVANIA :

:

COUNTY OF PHILADELPHIA :

I, MAUREEN BRODERICK, Registered Professional Reporter - Notary Public, within and for the Commonwealth of Pennsylvania, do hereby certify that the proceedings, evidence, and objections noted are contained fully and accurately in the notes taken by me of the preceding deposition, and that this copy is a correct transcript of the same.

_____

MAUREEN BRODERICK

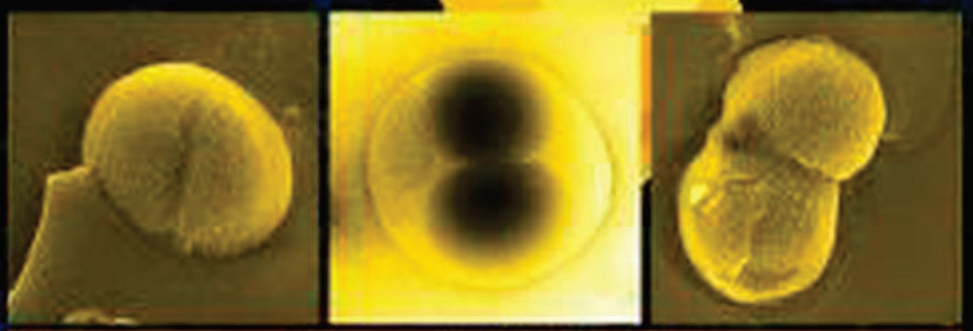
Registered Professional

Reporter - Notary Public

Dated: January 16th, 2018

Stanley A. Plotkin, Walter A. Orenstein,
Paul A. Offit, Kathryn M. Edwards

Plotkin's VACCINES



Foreword by Bill Gates

ELSEVIER

Exhibit 11

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use M-M-R II safely and effectively. See full prescribing information for M-M-R II.

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live)
Suspension for subcutaneous injection
Initial U.S. Approval: 1978

----------INDICATIONS AND USAGE----------

M-M-R II is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. (1)

---------- DOSAGE AND ADMINISTRATION----------

Administer a 0.5-mL dose of M-M-R II subcutaneously. (2.1)

- The first dose is administered at 12 to 15 months of age. (2.1)
- The second dose is administered at 4 to 6 years of age. (2.1)

----------DOSAGE FORMS AND STRENGTHS ----------

Suspension for injection (0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using accompanying sterile diluent. (3)

---------- CONTRAINDICATIONS ----------

- Hypersensitivity to any component of the vaccine. (4.1)
- Immunosuppression. (4.2)
- Moderate or severe febrile illness. (4.3)
- Active untreated tuberculosis. (4.4)
- Pregnancy. (4.5, 8.1)

---------- WARNINGS AND PRECAUTIONS ----------

- Use caution when administering M-M-R II to individuals with a history of febrile seizures. (5.1)
- Use caution when administering M-M-R II to individuals with anaphylaxis or immediate hypersensitivity following egg ingestion. (5.2)
- Use caution when administering M-M-R II to individuals with a history of thrombocytopenia. (5.3)
- Immune Globulins (IG) and other blood products should not be given concurrently with M-M-R II. (5.4, 7.2)

----------ADVERSE REACTIONS----------

See full prescribing information for adverse reactions occurring during clinical trials or the post-marketing period. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------

- Administration of immune globulins and other blood products concurrently with M-M-R II vaccine may interfere with the expected immune response. (7.2)
- M-M-R II vaccination may result in a temporary depression of purified protein derivative (PPD) tuberculin skin sensitivity. (7.3)

---------- USE IN SPECIFIC POPULATIONS----------

- Pregnancy: Do not administer M-M-R II to females who are pregnant. Pregnancy should be avoided for 1 month following vaccination with M-M-R II. (4.5, 8.1, 17)

See 17 for PATIENT COUNSELING INFORMATION and FDA approved patient labeling.

Revised: 06/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

M-M-R® II is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.

2 DOSAGE AND ADMINISTRATION

For subcutaneous use only.

2.1 Dose and Schedule

Each 0.5 mL dose is administered subcutaneously.

The first dose is administered at 12 to 15 months of age. A second dose is administered at 4 to 6 years of age.

The second dose may be administered prior to 4 years of age, provided that there is a minimum interval of one month between the doses of measles, mumps and rubella virus vaccine, live {1-2}.

Children who received an initial dose of measles, mumps and rubella vaccine prior to their first birthday should receive additional doses of vaccine at 12-15 months of age and at 4-6 years of age to complete the vaccination series *[see Clinical Studies (14.2)]*.

For post-exposure prophylaxis for measles, administer a dose of M-M-R II vaccine within 72 hours after exposure.

2.2 Preparation and Administration

Use a sterile syringe free of preservatives, antiseptics, and detergents for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. To reconstitute, use only the diluent supplied with the vaccine since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Withdraw the entire volume of the supplied diluent from its vial and inject into lyophilized vaccine vial. Agitate to dissolve completely. Discard if the lyophilized vaccine cannot be dissolved.

Withdraw the entire volume of the reconstituted vaccine and inject subcutaneously into the outer aspect of the upper arm (deltoid region) or into the higher anterolateral area of the thigh.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Visually inspect the vaccine before and after reconstitution prior to administration. Before reconstitution, the lyophilized vaccine is a light yellow compact crystalline plug, when reconstituted, is a clear yellow liquid. Discard if particulate matter or discoloration are observed in the reconstituted vaccine.

To minimize loss of potency, administer M-M-R II as soon as possible after reconstitution. If not used immediately, the reconstituted vaccine may be stored between 36°F to 46°F (2°C to 8°C), protected from light, for up to 8 hours. Discard reconstituted vaccine if it is not used within 8 hours.

3 DOSAGE FORMS AND STRENGTHS

M-M-R II vaccine is a suspension for injection supplied as a single dose vial of lyophilized vaccine to be reconstituted using the accompanying sterile diluent *[see Dosage and Administration (2.2) and How Supplied/Storage and Handling (16)]*. A single dose after reconstitution is 0.5 mL.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Do not administer M-M-R II vaccine to individuals with a history of hypersensitivity to any component of the vaccine (including gelatin) {3} or who have experienced a hypersensitivity reaction following administration of a previous dose of M-M-R II vaccine or any other measles, mumps and rubella-containing vaccine. Do not administer M-M-R II vaccine to individuals with a history of anaphylaxis to neomycin *[see Description (11)].*

4.2 Immunosuppression

Do not administer M-M-R II vaccine to individuals who are immunodeficient or immunosuppressed due to disease or medical therapy. Measles inclusion body encephalitis {4} (MIBE), pneumonitis {5} and death as a direct consequence of disseminated measles vaccine virus infection have been reported in

immunocompromised individuals inadvertently vaccinated with measles-containing vaccine. In this population, disseminated mumps and rubella vaccine virus infection have also been reported.

Do not administer M-M-R II to individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

4.3 Moderate or Severe Febrile Illness

Do not administer M-M-R II vaccine to individuals with an active febrile illness with fever >101.3°F (>38.5°C).

4.4 Active Untreated Tuberculosis

Do not administer M-M-R II vaccine to individuals with active untreated tuberculosis (TB).

4.5 Pregnancy

Do not administer M-M-R II to individuals who are pregnant or who are planning on becoming pregnant within the next month *[see Use in Specific Populations (8.1) and Patient Counseling Information (17)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Febrile Seizure

There is a risk of fever and associated febrile seizure in the first 2 weeks following immunization with M-M-R II vaccine. For children who have experienced a previous febrile seizure (from any cause) and those with a family history of febrile seizures there is a small increase in risk of febrile seizure following receipt of M-M-R II vaccine *[see Adverse Reactions (6)]*.

5.2 Hypersensitivity to Eggs

Individuals with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving M-M-R II vaccine .The potential risks and known benefits should be evaluated before considering vaccination in these individuals.

5.3 Thrombocytopenia

Transient thrombocytopenia has been reported within 4-6 weeks following vaccination with measles, mumps and rubella vaccine. Carefully evaluate the potential risk and benefit of vaccination in children with thrombocytopenia or in those who experienced thrombocytopenia after vaccination with a previous dose of measles, mumps, and rubella vaccine {6-8} *[see Adverse Reactions (6)]*.

5.4 Immune Globulins and Transfusions

Immune Globulins (IG) and other blood products should not be given concurrently with M-M-R II *[see Drug Interactions (7.2)]*. These products may contain antibodies that interfere with vaccine virus replication and decrease the expected immune response.

The ACIP has specific recommendations for intervals between administration of antibody containing products and live virus vaccines.

6 ADVERSE REACTIONS

The following adverse reactions include those identified during clinical trials or reported during post-approval use of M-M-R II vaccine or its individual components.

Body as a Whole

Panniculitis; atypical measles; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Hematologic and Lymphatic Systems

Thrombocytopenia; purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis, anaphylactoid reactions, angioedema (including peripheral or facial edema) and bronchial spasm.

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Nervous System

Encephalitis; encephalopathy; measles inclusion body encephalitis (MIBE) subacute sclerosing panencephalitis (SSPE); Guillain-Barré Syndrome (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; febrile convulsions; afebrile convulsions or seizures; ataxia; polyneuritis; polyneuropathy; ocular palsies; paresthesia.

Respiratory System

Pneumonia; pneumonitis; sore throat; cough; rhinitis.

Skin

Stevens-Johnson syndrome; acute hemorrhagic edema of infancy; Henoch-Schönlein purpura; erythema multiforme; urticaria; rash; measles-like rash; pruritus; injection site reactions (pain, erythema, swelling and vesiculation).

Special Senses — Ear

Nerve deafness; otitis media.

Special Senses — Eye

Retinitis; optic neuritis; papillitis; conjunctivitis.

Urogenital System

Epididymitis; orchitis.

7 DRUG INTERACTIONS

7.1 Corticosteroids and Immunosuppressive Drugs

M-M-R II vaccine should not be administered to individuals receiving immunosuppressive therapy, including high dose corticosteroids. Vaccination with M-M-R II vaccine can result in disseminated disease due to measles vaccine in individuals on immunosuppressive drugs *[see Contraindications (4.2)].*

7.2 Immune Globulins and Transfusions

Administration of immune globulins and other blood products concurrently with M-M-R II vaccine may interfere with the expected immune response {9-11} *[see Warnings and Precautions (5.4)].* The ACIP has specific recommendations for intervals between administration of antibody containing products and live virus vaccines.

7.3 Tuberculin Skin Testing

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin skin test with tuberculin purified protein derivative (PPD) is to be done, it should be administered before, simultaneously with, or at least 4 to 6 weeks after vaccination with M-M-R II vaccine.

7.4 Use with Other Live Viral Vaccines

M-M-R II vaccine can be administered concurrently with other live viral vaccines. If not given concurrently, M-M-R II vaccine should be given one month before or one month after administration of other live viral vaccines to avoid potential for immune interference.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

M-M-R II vaccine is contraindicated for use in pregnant women because infection during pregnancy with the wild-type viruses has been associated with maternal and fetal adverse outcomes.

Increased rates of spontaneous abortion, stillbirth, premature delivery and congenital defects have been observed following infection with wild-type measles during pregnancy. {12,13} Wild-type mumps infection during the first trimester of pregnancy may increase the rate of spontaneous abortion.

Infection with wild-type rubella during pregnancy can lead to miscarriage or stillbirth. If rubella infection occurs during the first trimester of pregnancy, it can result in severe congenital defects, Congenital Rubella Syndrome (CRS). Congenital rubella syndrome in the infant includes but is not limited to eye manifestations (cataracts, glaucoma, retinitis), congenital heart defects, hearing loss, microcephaly, and intellectual disabilities. M-M-R II vaccine contains live attenuated measles, mumps and rubella viruses. It is not known whether M-M-R II vaccine can cause fetal harm when administered to pregnant woman. There are no adequate and well-controlled studies of M-M-R II vaccine administration to pregnant women.

All pregnancies have a risk of birth defect, loss or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Available data suggest the rates of major birth defects and miscarriage in women who received M-M-R II vaccine within 30 days prior to pregnancy or during pregnancy are consistent with estimated background rates *(see Data)*.

Data

Human Data

A cumulative assessment of post-marketing reports for M-M-R II vaccine from licensure 01 April 1978 through 31 December 2018, identified 796 reports of inadvertent administration of M-M-R II vaccine occurring 30 days before or at any time during pregnancy with known pregnancy outcomes. Of the prospectively followed pregnancies for whom the timing of M-M-R II vaccination was known, 425 women received M-M-R II vaccine during the 30 days prior to conception through the second trimester. The outcomes for these 425 prospectively followed pregnancies included 16 infants with major birth defects, 4 cases of fetal death and 50 cases of miscarriage. No abnormalities compatible with congenital rubella syndrome have been identified in patients who received M-M-R II vaccine. Rubella vaccine viruses can cross the placenta, leading to asymptomatic infection of the fetus. Mumps vaccine virus has also been shown to infect the placenta {14}, but there is no evidence that it causes congenital malformations or disease in the fetus or infant .

The CDC established the Vaccine in Pregnancy registry (1971-1989) of women who had received rubella vaccines within 3 months before or after conception. Data on 1221 inadvertently vaccinated pregnant women demonstrated no evidence of an increase in fetal abnormalities or cases of Congenital Rubella Syndrome (CRS) in the enrolled women {15}.

8.2 Lactation

Risk Summary

It is not known whether measles or mumps vaccine virus is secreted in human milk. Studies have shown that lactating postpartum women vaccinated with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants.{16,17} In the breast-fed infants with serological evidence of rubella virus vaccine strain antibodies, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.{18,19}

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for M-M-R II, and any potential adverse effects on the breastfed child from M-M-R II or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

M-M-R II vaccine is not approved for individuals less than 12 months of age. Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established *[see Clinical Studies (14)]*. Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

8.5 Geriatric Use

Clinical studies of M-M-R II did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 Description

M-M-R II vaccine is a sterile lyophilized preparation of (1) Measles Virus Vaccine Live, an attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and propagated in chick embryo cell culture; (2) Mumps Virus Vaccine Live, the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture; and (3) Rubella Virus Vaccine Live, the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts. {20,21} The cells, virus pools, recombinant human serum albumin and fetal bovine serum used in manufacturing are tested and determined to be free of adventitious agents.

After reconstitution, each 0.5 mL dose contains not less than 3.0 $\log_{10}$ $TCID_{50}$ (tissue culture infectious doses) of measles virus; 4.1 $\log_{10}$ $TCID_{50}$ of mumps virus; and 3.0 $\log_{10}$ $TCID_{50}$ of rubella virus.

Each dose is calculated to contain sorbitol (14.5 mg), sucrose (1.9 mg), hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), approximately 25 mcg of neomycin and other buffer and media ingredients. The product contains no preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

M-M-R II vaccination induces antibodies to measles, mumps, and rubella associated with protection which can be measured by neutralization assays, hemagglutination-inhibition (HI) assays, or enzyme linked immunosorbent assay (ELISA) tests. Results from efficacy studies or effectiveness studies that were previously conducted for the component vaccines of M-M-R II were used to define levels of serum antibodies that correlated with protection against measles, mumps, and rubella *[see Clinical Studies (14)]*.

12.6 Persistence of Antibody Responses After Vaccination

Neutralizing and ELISA antibodies to measles, mumps, and rubella viruses are still detectable in 95-100%, 74-91%, and 90-100% of individuals respectively, 11 to 13 years after primary vaccination. {22-28}

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

14 CLINICAL STUDIES

14.1 Clinical Efficacy

Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled trials. {29-34} These studies also established that seroconversion in response to vaccination against measles, mumps and rubella paralleled protection. {35-38}

14.2 Immunogenicity

Clinical studies enrolling 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II vaccine is immunogenic. In these studies, a single injection of the vaccine induced measles HI antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible individuals.

A study of 6-month-old and 15-month-old infants born to mothers vaccinated with a measles vaccine in childhood, demonstrated that, following infant and toddler vaccination with Measles Virus Vaccine, Live (previously US-licensed, manufactured by Merck), 74% of the 6-month-old infants developed detectable neutralizing antibody titers while 100% of the 15-month-old infants vaccinated with Measles Virus Vaccine, Live or M-M-R II vaccine developed neutralizing antibodies {39}. When the 6-month-old infants of immunized mothers were revaccinated at 15 months with M-M-R II vaccine, they developed antibody titers similar to those of toddlers who were vaccinated previously at 15-months of age.

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16 HOW SUPPLIED/STORAGE AND HANDLING

No. 4681 — M-M-R II vaccine is supplied as follows:

(1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4681-00

(2) a box of 10 vials of diluent (package B)

Exposure to light may inactivate the vaccine viruses.

Before reconstitution, refrigerate the lyophilized vaccine at 36°F to 46°F, (2°C to 8°C).

Store accompanying diluent in the refrigerator with the lyophilized vaccine or separately at room temperature (68° to 77°F, 20° to 25°C). **Do not freeze the diluent**.

Administer M-M-R II vaccine as soon as possible after reconstitution. If not administered immediately, reconstituted vaccine may be stored between 36°F to 46°F (2°C to 8°C), protected from light, for up to 8 hours. Discard reconstituted vaccine if it is not used within 8 hours.

For information regarding the product or questions regarding storage conditions, call 1-800-MERCK-90 (1-800-637-2590).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Package Insert).

Discuss the following with the patient:

- Provide the required vaccine information to the patient, parent, or guardian.
- Inform the patient, parent, or guardian of the benefits and risks associated with vaccination.
- Question the patient, parent, or guardian about reactions to a previous dose of M-M-R II vaccine or other measles-, mumps-, or rubella-containing vaccines.
- Question females of reproductive potential regarding the possibility of pregnancy. Inform female patients to avoid pregnancy for 1 month following vaccination *[see Contraindications (4.5) and Use in Specific Populations (8.1)]*.
- Inform the patient, parent, or guardian that vaccination with M-M-R II may not offer 100% protection from measles, mumps, and rubella infection.
- Instruct patients, parents, or guardians to report any adverse reactions to their health-care provider. The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, including but not limited to the reporting of events required by the National Childhood Vaccine Injury Act of 1986. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967, or report online at https://www.vaers.hhs.gov.

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For patent information: www.merck.com/product/patent/home.html

uspi-v205c-i-2006r009

Exhibit 12

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VARIVAX safely and effectively. See full prescribing information for VARIVAX.

VARIVAX®
Varicella Virus Vaccine Live
Suspension for subcutaneous injection
Initial U.S. Approval: 1995

----------INDICATIONS AND USAGE----------
VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
Each dose is approximately 0.5 mL after reconstitution and is administered by subcutaneous injection. (2.1)
Children (12 months to 12 years of age)
- If a second dose is administered, there should be a minimum interval of 3 months between doses. (2.1)

Adolescents (≥13 years of age) and Adults
- Two doses, to be administered a minimum of 4 weeks apart. (2.1)

---------- DOSAGE FORMS AND STRENGTHS ----------
Suspension for injection (approximately 0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using the accompanying sterile diluent. (2.2, 3, 16)

----------CONTRAINDICATIONS----------
- History of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine. (4.1)
- Primary or acquired immunodeficiency states. (4.2)
- Any febrile illness or active infection, including untreated tuberculosis. (4.3)
- Pregnancy. (4.4, 8.1, 17)

---------- WARNINGS AND PRECAUTIONS----------
- Evaluate individuals for immune competence prior to administration of VARIVAX if there is a family history of congenital or hereditary immunodeficiency. (5.2)
- Avoid contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus. (5.4)
- Defer vaccination for at least 5 months following blood or plasma transfusions, or administration of immune globulins (IG). (5.5, 7.2)
- Avoid use of salicylates for 6 weeks following administration of VARIVAX to children and adolescents. (5.6, 7.1)

---------- ADVERSE REACTIONS ----------
- Frequently reported (≥10%) adverse reactions in children ages 1 to 12 years include:
  - fever ≥102.0°F (38.9°C) oral: 14.7%
  - injection-site complaints: 19.3% (6.1)
- Frequently reported (≥10%) adverse reactions in adolescents and adults ages 13 years and older include:
  - fever ≥100.0°F (37.8°C) oral: 10.2%
  - injection-site complaints: 24.4% (6.1)
- Other reported adverse reactions in all age groups include:
  - varicella-like rash (injection site)
  - varicella-like rash (generalized) (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- Reye syndrome has been reported in children and adolescents following the use of salicylates during wild-type varicella infection. (5.6, 7.1)
- Passively acquired antibodies from blood, plasma, or immunoglobulin potentially may inhibit the response to varicella vaccination. (5.5, 7.2)
- Tuberculin skin testing may be performed before VARIVAX is administered or on the same day, or six weeks following vaccination with VARIVAX. (7.3)

---------- USE IN SPECIFIC POPULATIONS ----------
Pregnancy: Do not administer VARIVAX to females who are pregnant. Pregnancy should be avoided for 3 months following vaccination with VARIVAX. (4.4, 8.1, 17)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 02/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VARIVAX® is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age and older.

2 DOSAGE AND ADMINISTRATION

Subcutaneous administration only

2.1 Recommended Dose and Schedule

VARIVAX is administered as an approximately 0.5-mL dose by subcutaneous injection into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh.

Do not administer this product intravascularly or intramuscularly.

Children (12 months to 12 years of age)

If a second dose is administered, there should be a minimum interval of 3 months between doses *[see Clinical Studies (14.1)].*

Adolescents (≥13 years of age) and Adults

Two doses of vaccine, to be administered with a minimum interval of 4 weeks between doses *[see Clinical Studies (14.1)]*.

2.2 Reconstitution Instructions

When reconstituting the vaccine, use only the sterile diluent supplied with VARIVAX. The sterile diluent does not contain preservatives or other anti-viral substances which might inactivate the vaccine virus.

Use a sterile syringe free of preservatives, antiseptics, and detergents for each reconstitution and injection of VARIVAX because these substances may inactivate the vaccine virus.

To reconstitute the vaccine, first withdraw the total volume of provided sterile diluent into a syringe. Inject all of the withdrawn diluent into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into the syringe and inject the total volume (approximately 0.5 mL) of reconstituted vaccine subcutaneously. VARIVAX, when reconstituted, is a clear, colorless to pale yellow liquid.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use the product if particulates are present or if it appears discolored.

To minimize loss of potency, administer VARIVAX immediately after reconstitution. Discard if reconstituted vaccine is not used within 30 minutes.

Do not freeze reconstituted vaccine.

Do not combine VARIVAX with any other vaccine through reconstitution or mixing.

3 DOSAGE FORMS AND STRENGTHS

VARIVAX is a suspension for injection supplied as a single-dose vial of lyophilized vaccine to be reconstituted using the accompanying sterile diluent *[see Dosage and Administration (2.2) and How Supplied/Storage and Handling (16)]*. A single dose after reconstitution is approximately 0.5 mL.

4 CONTRAINDICATIONS

4.1 Severe Allergic Reaction

Do not administer VARIVAX to individuals with a history of anaphylactic or severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of a varicella-containing vaccine.

4.2 Immunosuppression

Do not administer VARIVAX to immunosuppressed or immunodeficient individuals, including those with a history of primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant neoplasms affecting the bone marrow or lymphatic system, AIDS, or other clinical manifestations of infection with human immunodeficiency virus (HIV).

Do not administer VARIVAX to individuals receiving immunosuppressive therapy, including individuals receiving immunosuppressive doses of corticosteroids.

VARIVAX is a live, attenuated varicella-zoster vaccine (VZV) and may cause an extensive vaccine-associated rash or disseminated disease in individuals who are immunosuppressed or immunodeficient.

4.3 Concurrent Illness

Do not administer VARIVAX to individuals with any febrile illness. Do not administer VARIVAX to individuals with active, untreated tuberculosis.

4.4 Pregnancy

Do not administer VARIVAX to individuals who are pregnant because the effects of the vaccine on fetal development are unknown. Wild-type varicella (natural infection) is known to sometimes cause fetal harm. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination *[see Use in Specific Populations (8.1) and Patient Counseling Information (17)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Allergic Reactions

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should anaphylaxis occur.

5.2 Family History of Immunodeficiency

Vaccination should be deferred in patients with a family history of congenital or hereditary immunodeficiency until the patient's immune status has been evaluated and the patient has been found to be immunocompetent.

5.3 Use in HIV-Infected Individuals

The Advisory Committee for Immunization Practices (ACIP) has recommendations on the use of varicella vaccine in HIV-infected individuals.

5.4 Risk of Vaccine Virus Transmission

Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has been reported.

Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals for up to six weeks following vaccination with VARIVAX. Susceptible high-risk individuals include:

- Immunocompromised individuals;
- Pregnant women without documented history of varicella or laboratory evidence of prior infection;
- Newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.

5.5 Immune Globulins and Transfusions

Immunoglobulins should not be given concomitantly with VARIVAX. Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin(s) {1}.

Following administration of VARIVAX, immune globulin(s) should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination {1}. *[See Drug Interactions (7.2).]*

5.6 Salicylate Therapy

Avoid use of salicylates (aspirin) or salicylate-containing products in children and adolescents 12 months through 17 years of age for six weeks following vaccination with VARIVAX because of the association of Reye syndrome with aspirin therapy and wild-type varicella infection. *[See Drug Interactions (7.1).]*

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in clinical practice. Vaccine-related adverse reactions reported during clinical trials were assessed by the study investigators to be possibly, probably, or definitely vaccine-related and are summarized below.

In clinical trials {2-9}, VARIVAX was administered to over 11,000 healthy children, adolescents, and adults.

In a double-blind, placebo-controlled study among 914 healthy children and adolescents who were serologically confirmed to be susceptible to varicella, the only adverse reactions that occurred at a significantly ($p<0.05$) greater rate in vaccine recipients than in placebo recipients were pain and redness at the injection site {2}.

Children 1 to 12 Years of Age

One-Dose Regimen in Children

In clinical trials involving healthy children monitored for up to 42 days after a single dose of VARIVAX, the frequency of fever, injection-site complaints, or rashes were reported as shown in Table 1:

Table 1: Fever, Local Reactions, and Rashes (%) in Children 1 to 12 Years of Age 0 to 42 Days After Receipt of a Single Dose of VARIVAX

Reaction	N	% Experiencing Reaction	Peak Occurrence During Postvaccination Days
Fever ≥102.0°F (38.9°C) Oral	8824	14.7%	0 to 42
Injection-site complaints (pain/soreness, swelling and/or erythema, rash, pruritus, hematoma, induration, stiffness)	8913	19.3%	0 to 2
Varicella-like rash (injection site) Median number of lesions	8913	3.4% 2	8 to 19
Varicella-like rash (generalized) Median number of lesions	8913	3.8% 5	5 to 26

In addition, adverse events occurring at a rate of ≥1% are listed in decreasing order of frequency: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, heat rash/prickly heat, arthralgia, eczema/dry skin/dermatitis, constipation, itching.

Pneumonitis has been reported rarely (<1%) in children vaccinated with VARIVAX.

Febrile seizures have occurred at a rate of <0.1% in children vaccinated with VARIVAX.

Clinical safety of refrigerator-stable VARIVAX (n=635) was compared with that of the licensed frozen formulation of VARIVAX (n=323) for 42 days postvaccination in U.S. children 12 to 23 months of age. The safety profiles were comparable for the two different formulations. Pain/tenderness/soreness (24.8 to 28.9%) and erythema (18.4 to 21.0%) were the most commonly reported local reactions. The most common systemic adverse events (reported by ≥10% of subjects in one or more treatment groups, irrespective of causal relationship to vaccination) were: fever ≥102.0°F, oral equivalent (27.0 to 29.2%), upper respiratory infection (26.9 to 29.7%), otitis media (12.0 to 14.1%), cough (11.0 to 15.1%), rhinorrhea (8.7 to 10.6%), and irritability (6.5 to 11.9%). Six subjects reported serious adverse events.

Two-Dose Regimen in Children

Nine hundred eighty-one (981) subjects in a clinical trial received 2 doses of VARIVAX 3 months apart and were actively followed for 42 days after each dose. The 2-dose regimen of varicella vaccine had a safety profile comparable to that of the 1-dose regimen. The overall incidence of injection-site clinical complaints (primarily erythema and swelling) observed in the first 4 days following vaccination was 25.4% Postdose 2 and 21.7% Postdose 1, whereas the overall incidence of systemic clinical complaints in the 42-day follow-up period was lower Postdose 2 (66.3%) than Postdose 1 (85.8%).

Adolescents (13 Years of Age and Older) and Adults

In clinical trials involving healthy adolescents and adults, the majority of whom received two doses of VARIVAX and were monitored for up to 42 days after any dose, the frequencies of fever, injection-site complaints, or rashes are shown in Table 2.

Table 2: Fever, Local Reactions, and Rashes (%) in Adolescents and Adults 0 to 42 Days After Receipt of VARIVAX

Reaction	N	% Post Dose 1	Peak Occurrence in Postvaccination Days	N	% Post Dose 2	Peak Occurrence in Postvaccination Days
Fever ≥100.0°F (37.8°C) Oral	1584	10.2%	14 to 27	956	9.5%	0 to 42
Injection-site complaints (soreness, erythema, swelling, rash, pruritus, pyrexia, hematoma, induration, numbness)	1606	24.4%	0 to 2	955	32.5%	0 to 2
Varicella-like rash (injection site)	1606	3.1%	6 to 20	955	1%	0 to 6
Median number of lesions		2			2	
Varicella-like rash (generalized)	1606	5.5%	7 to 21	955	0.9%	0 to 23
Median number of lesions		5			5.5	

In addition, adverse events reported at a rate of ≥1% are listed in decreasing order of frequency: upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, diarrhea, stiff neck, irritability/nervousness, lymphadenopathy, chills, eye complaints, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, constipation, lower respiratory illness, allergic reactions (including allergic rash, hives), contact rash, cold/canker sore.

6.2 Post-Marketing Experience

Broad use of VARIVAX could reveal adverse events not observed in clinical trials.

The following additional adverse events, regardless of causality, have been reported during post-marketing use of VARIVAX:

Body as a Whole

Anaphylaxis (including anaphylactic shock) and related phenomena such as angioneurotic edema, facial edema, and peripheral edema.

Eye Disorders

Necrotizing retinitis (in immunocompromised individuals).

Hemic and Lymphatic System

Aplastic anemia; thrombocytopenia (including idiopathic thrombocytopenic purpura (ITP)).

Infections and Infestations

Varicella (vaccine strain).

Nervous/Psychiatric

Encephalitis; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; non-febrile seizures; aseptic meningitis; dizziness; paresthesia.

Respiratory

Pharyngitis; pneumonia/pneumonitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; herpes zoster.

7 DRUG INTERACTIONS

7.1 Salicylates

No cases of Reye syndrome have been observed following vaccination with VARIVAX. Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with VARIVAX, as Reye syndrome has been reported following the use of salicylates during wild-type varicella infection *[see Warnings and Precautions (5.6)]*.

7.2 Immune Globulins and Transfusions

Blood, plasma, and immune globulins contain antibodies that may interfere with vaccine virus replication and decrease the immune response to VARIVAX. Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin(s) {1}.

Following administration of VARIVAX, immune globulin(s) should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination {1}. *[See Warnings and Precautions (5.5).]*

7.3 Tuberculin Skin Testing

Tuberculin skin testing, with tuberculin purified protein derivative (PPD), may be performed before VARIVAX is administered or on the same day, or at least 4 weeks following vaccination with VARIVAX, as other live virus vaccines may cause a temporary depression of tuberculin skin test sensitivity leading to false negative results.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

VARIVAX is contraindicated for use in pregnant women because the vaccine contains live, attenuated varicella virus, and it is known that wild-type varicella virus, if acquired during pregnancy, can cause congenital varicella syndrome [see Contraindications (4.4) and Patient Counseling Information (17)]. No increased risk for miscarriage, major birth defect or congenital varicella syndrome was observed in a pregnancy exposure registry that monitored outcomes after inadvertent use. There are no relevant animal data.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively.

Human Data

A pregnancy exposure registry was maintained from 1995 to 2013 to monitor pregnancy and fetal outcomes following inadvertent administration of VARIVAX. The registry prospectively enrolled 1522 women who received a dose of VARIVAX during pregnancy or within three months prior to conception. After excluding elective terminations (n=60), ectopic pregnancies (n=1) and those lost to follow-up (n=556), there were 905 pregnancies with known outcomes. Of these 905 pregnancies, 271 (30%) were in women who were vaccinated within the three months prior to conception. Miscarriage was reported for 10% of pregnancies (95/905), and major birth defects were reported for 2.6% of live born infants (21/819). These rates of assessed outcomes were consistent with estimated background rates. None of the women who received VARIVAX vaccine delivered infants with abnormalities consistent with congenital varicella syndrome.

8.2 Lactation

Risk Summary

It is not known whether varicella vaccine virus is excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VARIVAX, and any potential adverse effects on the breastfed child from VARIVAX or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

No clinical data are available on safety or efficacy of VARIVAX in children less than 12 months of age.

8.5 Geriatric Use

Clinical studies of VARIVAX did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION

VARIVAX [Varicella Virus Vaccine Live] is a preparation of the Oka/Merck strain of live, attenuated varicella virus. The virus was initially obtained from a child with wild-type varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures (WI-38). Further passage of the virus for varicella vaccine was performed at Merck Research Laboratories (MRL) in human diploid cell cultures (MRC-5) that were free of adventitious agents. This live, attenuated varicella vaccine is a lyophilized preparation containing sucrose, phosphate, glutamate, processed gelatin, and urea as stabilizers.

Refrigerator-stable VARIVAX, when reconstituted as directed, is a sterile preparation for subcutaneous injection. Each approximately 0.5-mL dose contains a minimum of 1350 plaque-forming units (PFU) of Oka/Merck varicella virus when reconstituted and stored at room temperature for a maximum of 30 minutes. Each 0.5-mL dose also contains approximately 18 mg of sucrose, 8.9 mg hydrolyzed gelatin, 3.6 mg of urea, 2.3 mg of sodium chloride, 0.36 mg of monosodium L-glutamate, 0.33 mg of sodium

phosphate dibasic, 57 mcg of potassium phosphate monobasic, and 57 mcg of potassium chloride. The product also contains residual components of MRC-5 cells including DNA and protein and trace quantities of neomycin and bovine calf serum from MRC-5 culture media. The product contains no preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

VARIVAX induces both cell-mediated and humoral immune responses to varicella-zoster virus. The relative contributions of humoral immunity and cell-mediated immunity to protection from varicella are unknown.

12.2 Pharmacodynamics

Transmission

In the placebo-controlled efficacy trial, transmission of vaccine virus was assessed in household settings (during the 8-week postvaccination period) in 416 susceptible placebo recipients who were household contacts of 445 vaccine recipients. Of the 416 placebo recipients, three developed varicella and seroconverted, nine reported a varicella-like rash and did not seroconvert, and six had no rash but seroconverted. If vaccine virus transmission occurred, it did so at a very low rate and possibly without recognizable clinical disease in contacts. These cases may represent either wild-type varicella from community contacts or a low incidence of transmission of vaccine virus from vaccinated contacts *[see Warnings and Precautions (5.4)]* {2,12}. Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has also been reported.

Herpes Zoster

Overall, 9454 healthy children (12 months to 12 years of age) and 1648 adolescents and adults (13 years of age and older) have been vaccinated with VARIVAX in clinical trials. Eight cases of herpes zoster have been reported in children during 42,556 person-years of follow-up in clinical trials, resulting in a calculated incidence of at least 18.8 cases per 100,000 person-years. The completeness of this reporting has not been determined. One case of herpes zoster has been reported in the adolescent and adult age group during 5410 person-years of follow-up in clinical trials, resulting in a calculated incidence of 18.5 cases per 100,000 person-years. All 9 cases were mild and without sequelae. Two cultures (one child and one adult) obtained from vesicles were positive for wild-type VZV as confirmed by restriction endonuclease analysis {13}. The long-term effect of VARIVAX on the incidence of herpes zoster, particularly in those vaccinees exposed to wild-type varicella, is unknown at present.

In children, the reported rate of herpes zoster in vaccine recipients appears not to exceed that previously determined in a population-based study of healthy children who had experienced wild-type varicella {14}. The incidence of herpes zoster in adults who have had wild-type varicella infection is higher than that in children.

12.4 Duration of Protection

The duration of protection of VARIVAX is unknown; however, long-term efficacy studies have demonstrated continued protection up to 10 years after vaccination {15} *[see Clinical Studies (14.1)]*. A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella which could account for the apparent long-term protection after vaccination in these studies.

14 CLINICAL STUDIES

14.1 Clinical Efficacy

The protective efficacy of VARIVAX was established by: (1) a placebo-controlled, double-blind clinical trial, (2) comparing varicella rates in vaccinees versus historical controls, and (3) assessing protection from disease following household exposure.

Clinical Data in Children

One-Dose Regimen in Children

Although no placebo-controlled trial was carried out with refrigerator-stable VARIVAX, a placebo-controlled trial was conducted using a prior formulation containing 17,000 PFU per dose {2,16}. In this trial, a single dose of VARIVAX protected 96 to 100% of children against varicella over a two-year period. The study enrolled healthy individuals 1 to 14 years of age (n=491 vaccine, n=465 placebo). In the first year, 8.5% of placebo recipients contracted varicella, while no vaccine recipient did, for a calculated

protection rate of 100% during the first varicella season. In the second year, when only a subset of individuals agreed to remain in the blinded study (n=163 vaccine, n=161 placebo), 96% protective efficacy was calculated for the vaccine group as compared to placebo.

In early clinical trials, a total of 4240 children 1 to 12 years of age received 1000 to 1625 PFU of attenuated virus per dose of VARIVAX and have been followed for up to nine years post single-dose vaccination. In this group there was considerable variation in varicella rates among studies and study sites, and much of the reported data were acquired by passive follow-up. It was observed that 0.3 to 3.8% of vaccinees per year reported varicella (called breakthrough cases). This represents an approximate 83% (95% confidence interval [CI], 82%, 84%) decrease from the age-adjusted expected incidence rates in susceptible subjects over this same period {14}. In those who developed breakthrough varicella postvaccination, the majority experienced mild disease (median of the maximum number of lesions <50). In one study, a total of 47% (27/58) of breakthrough cases had <50 lesions compared with 8% (7/92) in unvaccinated individuals, and 7% (4/58) of breakthrough cases had >300 lesions compared with 50% (46/92) in unvaccinated individuals {17}.

Among a subset of vaccinees who were actively followed in these early trials for up to nine years postvaccination, 179 individuals had household exposure to varicella. There were no reports of breakthrough varicella in 84% (150/179) of exposed children, while 16% (29/179) reported a mild form of varicella (38% [11/29] of the cases with a maximum total number of <50 lesions; no individuals with >300 lesions). This represents an 81% reduction in the expected number of varicella cases utilizing the historical attack rate of 87% following household exposure to varicella in unvaccinated individuals in the calculation of efficacy.

In later clinical trials, a total of 1114 children 1 to 12 years of age received 2900 to 9000 PFU of attenuated virus per dose of VARIVAX and have been actively followed for up to 10 years post single-dose vaccination. It was observed that 0.2% to 2.3% of vaccinees per year reported breakthrough varicella for up to 10 years post single-dose vaccination. This represents an estimated efficacy of 94% (95% CI, 93%, 96%), compared with the age-adjusted expected incidence rates in susceptible subjects over the same period {2,14,18}. In those who developed breakthrough varicella postvaccination, the majority experienced mild disease, with the median of the maximum total number of lesions <50. The severity of reported breakthrough varicella, as measured by number of lesions and maximum temperature, appeared not to increase with time since vaccination.

Among a subset of vaccinees who were actively followed in these later trials for up to 10 years postvaccination, 95 individuals were exposed to an unvaccinated individual with wild-type varicella in a household setting. There were no reports of breakthrough varicella in 92% (87/95) of exposed children, while 8% (8/95) reported a mild form of varicella (maximum total number of lesions <50; observed range, 10 to 34). This represents an estimated efficacy of 90% (95% CI, 82%, 96%) based on the historical attack rate of 87% following household exposure to varicella in unvaccinated individuals in the calculation of efficacy.

Two-Dose Regimen in Children

In a clinical trial, a total of 2216 children 12 months to 12 years of age with a negative history of varicella were randomized to receive either 1 dose of VARIVAX (n=1114) or 2 doses of VARIVAX (n=1102) given 3 months apart. Subjects were actively followed for varicella, any varicella-like illness, or herpes zoster and any exposures to varicella or herpes zoster on an annual basis for 10 years after vaccination. Persistence of VZV antibody was measured annually for 9 years. Most cases of varicella reported in recipients of 1 dose or 2 doses of vaccine were mild {15}. The estimated vaccine efficacy for the 10-year observation period was 94% for 1 dose and 98% for 2 doses ($p<0.001$). This translates to a 3.4-fold lower risk of developing varicella >42 days postvaccination during the 10-year observation period in children who received 2 doses than in those who received 1 dose (2.2% vs. 7.5%, respectively).

Clinical Data in Adolescents and Adults

Two-Dose Regimen in Adolescents and Adults

In early clinical trials, a total of 796 adolescents and adults received 905 to 1230 PFU of attenuated virus per dose of VARIVAX and have been followed for up to six years following 2-dose vaccination. A total of 50 clinical varicella cases were reported >42 days following 2-dose vaccination. Based on passive follow-up, the annual varicella breakthrough event rate ranged from <0.1 to 1.9%. The median of the maximum total number of lesions ranged from 15 to 42 per year.

Although no placebo-controlled trial was carried out in adolescents and adults, the protective efficacy of VARIVAX was determined by evaluation of protection when vaccinees received 2 doses of VARIVAX 4

or 8 weeks apart and were subsequently exposed to varicella in a household setting. Among the subset of vaccinees who were actively followed in these early trials for up to six years, 76 individuals had household exposure to varicella. There were no reports of breakthrough varicella in 83% (63/76) of exposed vaccinees, while 17% (13/76) reported a mild form of varicella. Among 13 vaccinated individuals who developed breakthrough varicella after a household exposure, 62% (8/13) of the cases reported maximum total number of lesions <50, while no individual reported >75 lesions. The attack rate of unvaccinated adults exposed to a single contact in a household has not been previously studied. Utilizing the previously reported historical attack rate of 87% for wild-type varicella following household exposure to varicella among unvaccinated children in the calculation of efficacy, this represents an approximate 80% reduction in the expected number of cases in the household setting.

In later clinical trials, a total of 220 adolescents and adults received 3315 to 9000 PFU of attenuated virus per dose of VARIVAX and have been actively followed for up to six years following 2-dose vaccination. A total of 3 clinical varicella cases were reported >42 days following 2-dose vaccination. Two cases reported <50 lesions and none reported >75. The annual varicella breakthrough event rate ranged from 0 to 1.2%. Among the subset of vaccinees who were actively followed in these later trials for up to five years, 16 individuals were exposed to an unvaccinated individual with wild-type varicella in a household setting. There were no reports of breakthrough varicella among the exposed vaccinees.

There are insufficient data to assess the rate of protective efficacy of VARIVAX against the serious complications of varicella in adults (*e.g.*, encephalitis, hepatitis, pneumonitis) and during pregnancy (congenital varicella syndrome).

14.2 Immunogenicity

In clinical trials, varicella antibodies have been evaluated following vaccination with formulations of VARIVAX containing attenuated virus ranging from 1000 to 50,000 PFU per dose in healthy individuals ranging from 12 months to 55 years of age {2,9}.

One-Dose Regimen in Children

In prelicensure efficacy studies, seroconversion was observed in 97% of vaccinees at approximately 4 to 6 weeks postvaccination in 6889 susceptible children 12 months to 12 years of age. Titers ≥5 gpELISA units/mL were induced in approximately 76% of children vaccinated with a single dose of vaccine at 1000 to 17,000 PFU per dose. Rates of breakthrough disease were significantly lower among children with VZV antibody titers ≥5 gpELISA units/mL compared with children with titers <5 gpELISA units/mL.

Immunogenicity of refrigerator-stable VARIVAX (6550 PFU per dose, n=320 and 28,400 PFU per dose, n=315) was compared with that of the licensed frozen formulation of VARIVAX (9189 PFU per dose, n=323) in a double-blind, randomized, multicenter study in U.S. children 12 to 23 months of age, all of whom received M-M-R II concomitantly. The per-protocol analysis included all subjects with prevaccination varicella antibody titers <1.25 gpELISA units (n=267 to 276 per group); the antibody responses were comparable across the 3 treatment groups, with 6-week postvaccination varicella antibody titers ≥5 gpELISA units in 93.3%, 93.8%, and 95.1% of subjects, respectively.

Two-Dose Regimen in Children

In a multicenter study, 2216 healthy children 12 months to 12 years of age received either 1 dose of VARIVAX or 2 doses administered 3 months apart. The immunogenicity results are shown in Table 3.

Table 3: Summary of VZV Antibody Responses at 6 Weeks Postdose 1 and 6 Weeks Postdose 2 in Initially Seronegative Children 12 Months to 12 Years of Age (Vaccinations 3 Months Apart)

	VARIVAX 1-Dose Regimen (N=1114)	VARIVAX 2-Dose Regimen (3 months apart) (N=1102)	
	6 Weeks Postvaccination (n=892)	6 Weeks Postdose 1 (n=851)	6 Weeks Postdose 2 (n=769)
Seroconversion Rate	98.9%	99.5%	99.9%
Percent with VZV Antibody Titer ≥5 gpELISA units/mL	84.9%	87.3%	99.5%
Geometric mean titers in gpELISA units/mL (95% CI)	12.0 (11.2, 12.8)	12.8 (11.9, 13.7)	141.5 (132.3, 151.3)

N = Number of subjects vaccinated.
n = Number of subjects included in immunogenicity analysis.

The results from this study and other studies in which a second dose of VARIVAX was administered 3 to 6 years after the initial dose demonstrate significant boosting of the VZV antibodies with a second

dose. VZV antibody levels after 2 doses given 3 to 6 years apart are comparable to those obtained when the 2 doses are given 3 months apart.

Two-Dose Regimen in Adolescents and Adults

In a multicenter study involving susceptible adolescents and adults 13 years of age and older, 2 doses of VARIVAX administered 4 to 8 weeks apart induced a seroconversion rate of approximately 75% in 539 individuals 4 weeks after the first dose and of 99% in 479 individuals 4 weeks after the second dose. The average antibody response in vaccinees who received the second dose 8 weeks after the first dose was higher than that in vaccinees who received the second dose 4 weeks after the first dose. In another multicenter study involving adolescents and adults, 2 doses of VARIVAX administered 8 weeks apart induced a seroconversion rate of 94% in 142 individuals 6 weeks after the first dose and 99% in 122 individuals 6 weeks after the second dose.

14.3 Persistence of Immune Response

One-Dose Regimen in Children

In clinical studies involving healthy children who received 1 dose of vaccine, detectable VZV antibodies were present in 99.0% (3886/3926) at 1 year, 99.3% (1555/1566) at 2 years, 98.6% (1106/1122) at 3 years, 99.4% (1168/1175) at 4 years, 99.2% (737/743) at 5 years, 100% (142/142) at 6 years, 97.4% (38/39) at 7 years, 100% (34/34) at 8 years, and 100% (16/16) at 10 years postvaccination.

Two-Dose Regimen in Children

In recipients of 1 dose of VARIVAX over 9 years of follow-up, the geometric mean titers (GMTs) and the percent of subjects with VZV antibody titers ≥5 gpELISA units/mL generally increased. The GMTs and percent of subjects with VZV antibody titers ≥5 gpELISA units/mL in the 2-dose recipients were higher than those in the 1-dose recipients for the first year of follow-up and generally comparable thereafter. The cumulative rate of VZV antibody persistence with both regimens remained very high at year 9 (99.0% for the 1-dose group and 98.8% for the 2-dose group).

Two-Dose Regimen in Adolescents and Adults

In clinical studies involving healthy adolescents and adults who received 2 doses of vaccine, detectable VZV antibodies were present in 97.9% (568/580) at 1 year, 97.1% (34/35) at 2 years, 100% (144/144) at 3 years, 97.0% (98/101) at 4 years, 97.4% (76/78) at 5 years, and 100% (34/34) at 6 years postvaccination.

A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella, which could account for the apparent long-term persistence of antibody levels in these studies.

14.4 Studies with Other Vaccines

Concomitant Administration with M-M-R II

In combined clinical studies involving 1080 children 12 to 36 months of age, 653 received VARIVAX and M-M-R II concomitantly at separate injection sites and 427 received the vaccines six weeks apart. Seroconversion rates and antibody levels to measles, mumps, rubella, and varicella were comparable between the two groups at approximately six weeks postvaccination.

Concomitant Administration with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and Oral Poliovirus Vaccine (OPV)

In a clinical study involving 318 children 12 months to 42 months of age, 160 received an investigational varicella-containing vaccine (a formulation combining measles, mumps, rubella, and varicella in one syringe) concomitantly with booster doses of DTaP and OPV (no longer licensed in the United States). The comparator group of 144 children received M-M-R II concomitantly with booster doses of DTaP and OPV followed by VARIVAX six weeks later. At six weeks postvaccination, seroconversion rates for measles, mumps, rubella, and VZV and the percentage of vaccinees whose titers were boosted for diphtheria, tetanus, pertussis, and polio were comparable between the two groups. Anti-VZV levels were decreased when the investigational vaccine containing varicella was administered concomitantly with DTaP {19}. No clinically significant differences were noted in adverse reactions between the two groups.

Concomitant Administration with PedvaxHIB®

In a clinical study involving 307 children 12 to 18 months of age, 150 received an investigational varicella-containing vaccine (a formulation combining measles, mumps, rubella, and varicella in one syringe) concomitantly with a booster dose of PedvaxHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)], while 130 received M-M-R II concomitantly with a booster dose of PedvaxHIB followed by VARIVAX 6 weeks later. At six weeks postvaccination, seroconversion rates for measles, mumps, rubella, and VZV, and GMTs for PedvaxHIB were comparable between the two groups.

Anti-VZV levels were decreased when the investigational vaccine containing varicella was administered concomitantly with PedvaxHIB {20}. No clinically significant differences in adverse reactions were seen between the two groups.

Concomitant Administration with M-M-R II and COMVAX

In a clinical study involving 822 children 12 to 15 months of age, 410 received COMVAX, M-M-R II, and VARIVAX concomitantly at separate injection sites, and 412 received COMVAX followed by M-M-R II and VARIVAX given concomitantly at separate injection sites, 6 weeks later. At 6 weeks postvaccination, the immune responses for the subjects who received the concomitant doses of COMVAX, M-M-R II, and VARIVAX were similar to those of the subjects who received COMVAX followed 6 weeks later by M-M-R II and VARIVAX with respect to all antigens administered. There were no clinically important differences in reaction rates when the three vaccines were administered concomitantly versus six weeks apart.

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16 HOW SUPPLIED/STORAGE AND HANDLING

No. 4979/4309 — Refrigerator-stable VARIVAX is supplied as follows:
(1) a single-dose vial of lyophilized vaccine (package A), NDC 0006-4979-00
(2) a box of 10 vials of diluent (package B).
No. 4055/4309 — Refrigerator-stable VARIVAX is supplied as follows:
(1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4055-00
(2) a box of 10 vials of diluent (package B).

Storage

Vaccine Vial

During shipment, maintain the vaccine at a temperature of 2° to 8°C or colder (36° to 46°F or colder).

Before reconstitution, refrigerator-stable VARIVAX has a shelf-life of 24 months when refrigerated at 2° to 8°C or colder (36° to 46°F or colder). The vaccine may also be stored in a freezer; if subsequently transferred to a refrigerator, **THE VACCINE SHOULD NOT BE REFROZEN**.

Before reconstitution, protect from light.

DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES.

Diluent Vial

The vial of diluent should be stored separately at room temperature (20° to 25°C, 68° to 77°F), or in the refrigerator.

For further product information, call 1-800-9-VARIVAX (1-800-982-7482).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Discuss the following with the patient:

- Question the patient, parent, or guardian about reactions to previous vaccines.
- Provide a copy of the patient information (PPI) located at the end of this insert and discuss any questions or concerns.
- Inform patient, parent, or guardian that vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults.
- Inform female patients to avoid pregnancy for three months following vaccination.
- Inform patient, parent, or guardian of the benefits and risks of VARIVAX.
- Instruct patient, parent, or guardian to report any adverse reactions or any symptoms of concern to their healthcare professional.

The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967, or report online at http://www.vaers.hhs.gov.

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MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

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uspi-v210-i-ref-1702r911