UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

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

Plaintiffs,

Against

STACY MARTENEY *in her official capacity as the Virtual Learning Coordinator of the Upshur County Virtual School;* THE BOARD of EDUCATION of the COUNTY of UPSHUR; CHRISTINE MILLER, *in her official capacity as Superintendent of the Upshur County School District*; DR. MATTHEW CHRISTIANSEN, *in his official capacities as the State Health Officer and Commissioner of the Bureau of Public Health*; AND DOUG CIPOLETTI *in his official capacity as Executive Director of the West Virginia Virtual School Academy*;

Defendants.

Civil Action No.: 2:24-cv-18 Kleeh

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

SUMMARY

1. Plaintiffs Krystle Perry and Anthony Perry individually and on behalf of their minor child, K.P. ("**Plaintiffs**" or "the **Perrys**"), maintain profound religious objections to injecting their eight-year-old child, K.P., with the vaccinations required under W.VA. CODE § 16-3-4 (c) and (e) ("the **Compulsory Vaccination Law**" or the "**CVL**"). West Virginia prohibits K.P. from attending school in West Virginia unless she receives all the vaccines required under the CVL.

This prohibition on education, confoundingly, extends to virtual school, an option available in West Virginia.

2. Until very recently, Plaintiffs were able to ensure K.P. received a quality education, while simultaneously upholding their religious integrity. Plaintiffs did so through enrolling K.P. in the West Virginia Virtual Academy (the "**Virtual Academy**"), a robust online learning program created by statute in W.VA. CODE §18-2E-9 in which K.P. was not physically present in a classroom with other children.

3. This program is a tuition-free online public school available to all West Virginia residents.[1]

4. When Plaintiffs attempted to re-enroll K.P. in the Virtual Academy during the 2024 school year, including by requesting a religious exemption to the CVL, the request was denied. Virtual Academy officials explained that West Virginia prohibits religious exemptions to the CVL, including for students desiring to further their education remotely.

5. However, all schools in West Virginia, including the Virtual Academy, permit unvaccinated children to apply for medical exemptions.

6. Because K.P. is unvaccinated, and lacks secular reasons for being unvaccinated, she was ejected from the Virtual Academy. As a mother who works outside the home, Mrs. Perry is unable to homeschool K.P. Equally problematic, Mr. Perry is 100% disabled and has historically relied heavily on Virtual Academy staff to help facilitate K.P.'s education. Mr. Perry is now homeschooling K.P., while Mrs. Perry tries her very best to help after she finishes work, causing

[1] *See* WEST VIRGINIA VIRTUAL ACADEMY, *available at* https://wvva.k12.com (last visited July 5, 2024).

an irregular learning schedule for K.P. Consequently, Plaintiffs have been left for the last six months without viable options to ensure K.P. receives the education her peers enjoy.

7. Plaintiffs face potential criminal prosecution under W.VA. CODE §18-8-2 if they fail to educate K.P.

8. The straightforward legal issue presented in the Complaint is whether the State of West Virginia violated and continues to violate the Free Exercise clause of the First Amendment through denying K.P. continued enrollment in the Virtual Academy after she sought a religious exemption to the CVL, while permitting children who remain unvaccinated for secular reasons to enroll in the Virtual Academy, and, in addition, in other public and private schools throughout the state and in other settings that undermine any asserted interest in the prevention of communicable diseases.

9. Recent and directly on point Supreme Court precedent, as applied specifically to Plaintiffs' situation, makes crystal clear that West Virginia's vaccination policy flagrantly violates the United States Constitution. Accordingly, for the reasons more fully detailed below, Plaintiffs request declaratory and injunctive relief.

INTRODUCTION

10. According to the Pew Research Center, 77% of West Virginians say that "they believe in God with absolute certainty."[2] West Virginia is among the most religious states in America.[3]

[2] *See* PEW RESEARCH CENTER, *Religious Landscape Study*, https://www.pewresearch.org/religious-landscape-study/database/west-virginia/ (last visited July 5, 2024).

[3] *See* PEW RESEARCH CENTER, *How religious is you state?* https://www.pewresearch.org/fact-tank/2016/02/29/how-religious-is-your-state/?state=west-virginia (last visited July 5, 2024).

11. Plaintiffs possess deeply held religious beliefs that forbid them from vaccinating K.P.

12. Those beliefs have been substantially burdened by West Virginia through the CVL.

13. Mr. and Mrs. Perry's decision to maintain their and K.P.'s religious convictions have required significant sacrifices. Under threat of criminal penalties, Plaintiffs must ensure K.P. receives an education. However, West Virginia has made it virtually impossible in Plaintiffs' specific case to educate their child**, even remotely from home**, and simultaneously uphold their religious convictions.

14. West Virginia's compulsory school attendance law requires children between the ages of six and seventeen to be enrolled in an education program. *See* W. VA. CODE § 18-8-1a.

15. 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 (W. Va. 1979); *see also State v. Beaver*, No. 22-616, 2022 W. Va. LEXIS 700, at *36 ("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) (when state law creates a right to public education, that right becomes protected by the Due Process Clause of the Fourteenth Amendment).

16. Despite access to public education in West Virginia being deemed as a fundamental right, Plaintiffs' child has nevertheless been excluded from West Virginia's educational system—including the Virtual Academy—because of her parents' religious beliefs.

17. K.P. is unable to access the practical and social benefits of a formal education that her peers enjoy, including peers that remain unvaccinated for secular reasons.

18. 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 [*i.e.*, varicella], 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).

19. While it prohibits the option for a religious exemption, West Virginia permits discretionary medical exemptions to the CVL. *See* W. VA. CODE § 16-3-4 (h) (the State Health Officer may grant a medical exemption "upon sufficient medical evidence that immunization is contraindicated or there exists a specific precaution to a particular vaccine.").

20. This exemption scheme is neither neutral nor generally applicable, and therefore, triggers strict scrutiny. A law triggers strict scrutiny if it is either not generally applicable, or if it lacks neutrality. *Employment Division v. Smith*, 494 U.S. 872 (1990).

21. The *Smith* framework to addressing free exercise claims grew out of a concern that allowing religious exemptions to certain neutral and generally applicable laws "would be courting anarchy," *Smith*, 494 U.S. at 888, because such laws "could not function" in the face of religious exemptions, *United States v. Lee*, 455 U.S. 252, 260 (1982). In other words, the rationale behind *Smith's* general applicability framework does not hold where a law is readily amenable to a workable religious exemption option, because allowing a religious exemption in such cases does not invoke the concern that every citizen with a purported religious exemption to the law could become a law unto themselves, and permitting exceptions to the law would not "court anarchy." *Smith*, 494 U.S. at 888,

22. West Virginia's vaccination scheme is amenable to exemptions. The government allows for medical exemptions, and does in fact grant many medical exemptions every year. And religious exemptions can just as easily be allowed as medical exemptions are in West Virginia.

23. That the state refuses to allow for religious exemptions renders the law as not neutral and not generally applicable.

24. West Virginia is a radical outlier; forty-five states permit both medical and religious exemptions to childhood vaccination laws. Mississippi's vaccination scheme, which also previously lacked a religious exemption option while providing a medical exemption, was recently struck down under the First Amendment. *See Bosarge v. Edney*, 2023 U.S. Dist. LEXIS 67439, at *27 (S.D. Miss. Apr. 18, 2023) (holding that Mississippi's mandatory vaccination scheme, which lacked a religious exemption option but allowed for a medical exemption option, violated the First Amendment).

25. The overwhelming majority of states have for many decades offered religious exemptions to their school vaccination requirements without generating the "anarchy" the *Smith* Court was so concerned about. Thus, *Smith's* animating rationale does not apply where the government has shown that the law can be seamlessly administered while also permitting exceptions.

26. West Virginia is also tremendously relaxed in enforcing the CVL, permitting functional exceptions for children who are willfully non-complaint to continue attending school.

27. As such, childhood vaccination schemes, including in West Virginia, are clearly amenable to exemptions. The government's refusal to allow for a religious exemption option renders the CVL not generally applicable and not neutral under *Smith*. The existence of a religious

exemption in West Virginia would not generate anarchy, because an exemption scheme is already in place.

28. And the CVL triggers strict scrutiny on additional grounds.

29. The CVL fails the general applicability test on other grounds because the government permits medical exemptions that are reviewed and accepted or denied on an individualized basis.

30. Multiple layers of personalized and individualized review of medical exemption requests are performed. At each level, West Virginia officials possess discretion to approve or deny each medical exemption request.

31. However, Defendants have made a categorical decision that no commensurate process shall be allowed for those desiring to be exempt from the CVL for religious reasons. Under recent Supreme Court precedent in *Fulton v. City of Philadelphia*, 593 U.S. 522, 537, (2021), the Court held that the "creation of a formal mechanism for granting exceptions renders a policy not generally applicable" where a commensurate mechanism is unavailable to religious adherents. *Id.*

32. As applied specifically to Plaintiffs' situation, the CVL violates the First Amendment on additional alternative grounds. Independent of *Fulton*, West Virginia's CVL violates the First Amendment because it permits, from a risk perspective, "comparable" secular activity that fatally undermines the State's infectious disease related goals.

33. A law intended to counteract the spread of infectious diseases is unconstitutional where it permits secular activity while prohibiting similar religious activity. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 592 U.S. 14, 17-18 (2021) (holding that a New York regulation involving COVID-19 restrictions that prohibited religious gatherings but permitted similar secular gatherings violated the First Amendment); *see also Tandon v. Newsom*, 593 U.S. 61, 62 (2021)

(holding that a California law intended to slow the spread of COVID-19 violated the First Amendment because it treated "comparable secular activity more favorably than religious exercise.").

34. Whether two activities are comparable for purposes of the free exercise clause depends on "the asserted government interest that justifies the regulation at issue." *Tandon*, 593 U.S. at 62. Whether religious and secular conduct is comparable in the infectious disease context, courts are "concerned with the risks [the] activities pose, not the reasons why" the activities are carried out. *Tandon*, 593 U.S. at 62.

35. West Virginia maintains that it has a compelling infectious disease mitigation interest in requiring children to comply with the CVL while they are physically present at school. However, as applied to the Virtual Academy, this interest is non-sensical, because there is no physical congregation for a course of instruction that is conducted solely online, where the child is physically located only in his or her home.

36. Further, West Virginia permits a series of comparable secular activities that endanger the state interests undergirding the CVL.

37. *First*, West Virginia has granted many medical exemptions to 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 with other children on a daily basis. From a risk perspective, a single child with a medical exemption who attends in-person instruction presents an exponentially greater threat to any purported West Virginia public health interests than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

38. *Second*, West Virginia permits scores of unvaccinated children to continue their education, despite non-compliance with the CVL, and these children intermingle 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. From a risk perspective, a single child out of compliance with the law permitted to continue attending school presents an exponentially greater threat to West Virginia's public health goals than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

39. *Third*, West Virginia permits adults working in the school system—teachers, administrators, lunch staff, bus drivers, etc.—to altogether disregard the vaccination requirements of the CVL. Most adults working in the system have never been required to receive the full menu of vaccines required under the CVL. From a risk perspective, a single adult working in person in the school system who has not received the vaccines required by the CVL presents an exponentially greater threat to West Virginia's public health goals than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

40. *Fourth*, West Virginia does not place restrictions on unvaccinated children or adults outside of the school setting, or outside of school hours. One unvaccinated child or adult attending a University of West Virginia Mountaineers' basketball game—under the government's logic—presents a considerably greater threat to West Virginia's public health goals than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

41. *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.V. 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 public health goals than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

42. Collectively, the aggregation of individual behaviors the government 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 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 risk to West Virginia's goals than would permitting K.P. a process to pursue a religious exemption in order to obtain a **virtual** education.

43. Further, this aggregation of individual behaviors Defendants permit pose a significantly greater risk to Defendants' goals than would permitting a religious exemption option to the CVL to all students who attend virtual online schools without in-person instruction such as the Plaintiff.

44. Defendants' actions have deprived and will continue to deprive Plaintiffs of their inalienable rights under the United States Constitution.

45. To be clear, this is an "as applied" challenge. Plaintiffs assert the CVL's specific application to K.P.'s situation violates the First Amendment. Plaintiffs do not assert or seek a ruling on whether the law violates the First Amendment in every conceivable application statewide.

46. Defendants' actions have deprived and will continue to deprive Plaintiffs of their inalienable rights under the United States Constitution.

47. Defendants' actions have irreparably harmed and will continue to irreparably harm Plaintiffs.

48. Defendants committed each act alleged herein under the color and authority of West Virginia law.

JURISDICTION AND VENUE

49. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C.§§ 1331 and 1343(a). This action arises under the First Amendment to the United States Constitution.

50. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(1) and (2) because one or more Defendants reside in this judicial district and a substantial part of the events or omissions giving rise to this action occurred in this judicial district. More specifically, this action involves K.P.'s disenrollment from West Virginia Virtual Academy, administered through the Upshur County School District. Venue is proper in the District because: (i) Plaintiffs registered and enrolled K.P. in the Virtual Academy through the Upshur County School District; (ii) K.P.'s online learning was administered through the Upshur County School District, from this judicial district and division; (iii) Defendants, by and through their course instruction, communicated such instruction to Plaintiffs and K.P. from this district and division; (iv) Defendants denied Plaintiffs' religious exemption request from this judicial district and division; and (v) the coercion and punishment of Plaintiffs for their religious beliefs were directed from this judicial district and division.

51. This Court has the authority to grant declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, implemented through Rule 57, Federal Rules of Civil Procedure.

PARTIES

I. PLAINTIFFS ANTHONY AND KRYSTLE PERRY

A. Plaintiffs Maintain Profound Religious Objections to Vaccination

52. Mrs. Perry has been a Christian for most of her adult life. Her Christian beliefs inform every aspect of her life, including how she raises K.P.

53. The Perrys attend Brooklyn Community Church in Fayetteville, West Virginia.

54. K.P attends Sunday school with her peers. As a family, the Perrys regularly pray and seek guidance from God. They pray in the mornings, before meals, and regularly read the Bible.

55. Mrs. Perry has experienced God's healing power in the darkest moments of her life. When she was diagnosed with a blastomycosis, Mrs. Perry feared she would not survive to raise K.P. After much prayer, Mrs. Perry believes God miraculously intervened and healed the condition. She attributes her recovery to the number of people who prayed for her healing and to God's mercy. After this experience, Mrs. Perry's faith grew considerably stronger, and she vowed to put her faith in her God in all aspects of life, especially for health and wellness decisions.

56. Mrs. Perry presently holds, and for many years has held, sincere religious beliefs in conflict with vaccinating K.P.

57. When K.P. was born, Mrs. Perry was unaware that many vaccines had illicit connections to abortion.

58. Mrs. Perry became aware of fetal cell involvement in childhood vaccine development and production in 2018, when K.P. was two years old. Before Mrs. Perry became aware of these connections, K.P. received doses of the vaccines required under the Compulsory Vaccination Law.

59. Relying on the Bible verse Job 31:15, Plaintiffs believe it is God who forms children in the womb. As a mother and devout Christian, Mrs. Perry strongly opposes what she deems as the sin of abortion. She views the taking of an unborn life through abortion as murder. She considers injecting a vaccine that relies on abortion to exist to be a sin – a sin that, in her system of religious beliefs would have eternal consequences for herself, her family, and K.P.

60. Mr. Perry shares these beliefs.

61. Religious objections to vaccination based on fetal cell involvement in the development and production of vaccines on the childhood schedule is not an attenuated or foundationless religious objection. Abortion and fetal cell research in the development of childhood vaccines is well-documented. For example, in just one study over 75 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 chopping up their tongues, livers, intestines, pituitary glands, kidneys, and hearts. *See* **Exhibit 1**, 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).

62. In sworn testimony, Dr. Stanley Plotkin—who is commonly referred to as the "Godfather" of childhood vaccines, and one of 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 mutilated bodies were utilized in furtherance of his vaccine research. *See* **Exhibit 2**, excerpts of Deposition of Stanley Plotkin, Jan. 11, 2018, at pdf pp. 9-12 of 17. *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).

63. Additionally, many of the required vaccines contain genetic material derived from aborted fetuses, materials that would be injected directly into K.P.'s body were Plaintiffs to comply with West Virginia's mandatory vaccination requirements. *See, e.g.,* Food and Drug Administration ("**FDA**") Package Insert for M-M-R II Vaccine, attached hereto as **Exhibit 3**, 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 4**, 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").

64. For Plaintiffs, to vaccinate K.P. would be to force them into participating in an action with illicit connections to the termination of an innocent life, and into activity that condones abortion. *See Kennedy v. Bremerton Sch. Dist*., 597 U.S. 507, 524 (2022) (the First Amendment protects the right to abstain from "performing physical acts) (citation omitted); *see also Wisconsin v. Yoder*, 406 U.S. 205, 209 (1972) (the First Amendment protects one's right to abstain from activities that would "endanger [a parent's] own salvation and that of their children").

65. 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, the Perrys ceased vaccinating when K.P. was two years old. Plaintiffs cannot in good conscience knowingly inject K.P. with anything that would make them complicit in the sin of abortion. Plaintiffs believe abortion constitutes a taking of an innocent human life, relying on Proverbs 6:16-17 (instructing that God hates those who "shed innocent blood".). Accordingly, Plaintiffs believe that supporting abortion would potentially endanger their and K.P.'s souls.

66. After thoughtful prayer and reflection, Plaintiffs also developed religious objections to vaccination based on the belief that they must not alter K.P.'s God-given natural immune system. Plaintiffs believe that human beings were created in God's image, according to God's perfect plan (even though physical imperfections exist). Based on the Bible passage Mark 2:17, which counsels that healing is to be directed towards those who are actually sick, Plaintiffs do not seek medical attention unless they or K.P. are sick, and additionally, only in cases where, after thought and prayer, they are certain their God-given immune systems are incapable of eliminating that sickness. To do otherwise would be to preemptively alter the immune system God designed and would demonstrate a lack of faith in God.

67. While Plaintiffs are not opposed to all medication, they do not seek out medical intervention where no serious illness exists. As such, for religious reasons, Plaintiffs do not initiate medical procedures preemptively, like vaccination, for K.P. In Plaintiffs' system of religious beliefs, preemptively altering God's perfect and unique design for K.P.'s immune system would violate God's plan for K.P.'s life.

B. Plaintiffs' Religious Beliefs and Practices are Substantially Burdened by the CVL

68. Plaintiffs have been negatively impacted on multiple fronts by the decision to exercise their sincerely held religious beliefs in conflict with vaccination. K.P. has been categorically excluded from West Virginia's educational system, including the irrational and punitive exclusion of K.P. from pursuing her education at home, online, through the Virtual Academy.

69. In or around May 2022, and as permitted by state law, Mrs. Perry enrolled K.P. in the Virtual Academy through the Upshur County School District. She did this because her cousin informed Mrs. Perry that the Upshur County School District did an exceptional job of keeping parents informed regarding Virtual Academy requirements and did an excellent job at facilitating

enrollment and administration of Virtual Academy requirements. The Virtual Academy enrollment process is very easy to navigate and is efficient. In 2022, Plaintiffs were able to get K.P. enrolled in less than a week.

70. From August of 2022 through January of 2024, K.P. excelled in learning in the Virtual Learning Academy.

71. K.P. received high grades in English, Math, Science, History and Art. In the Virtual Academy, K.P. was enthusiastic about learning, and thrived in the structure and social interactions the Academy provided.

72. K.P. enjoyed interacting with her peers virtually through the Virtual Academy. Daily interactions with her peers were an integral aspect of K.P.'s educational and social development.

73. Mrs. Perry's husband is 100% disabled and receives Supplemental Security Income ("**SSI**") through the Social Security Administration. Mr. Perry was born prematurely and has experienced profound health complications throughout his life. He is 100% blind in one eye and has been diagnosed with a learning disability.

74. While Mrs. Perry worked, Mr. Perry was able to seamlessly oversee K.P.'s education with the significant resources provided by Virtual Academy administrators.

75. After K.P. had been enrolled and learning in the Virtual Academy for approximately 16 months, Mrs. Perry was contacted by Virtual Learning Coordinator for the Upshur County Schools, Stacy Marteney, sometime in December 2023. Ms. Marteney inquired regarding K.P.'s vaccination status, informing Mrs. Perry that K.P. had to receive the vaccines required under the CVL if she desired to continue her education in the Virtual Academy.

76. On or around December 27, 2023, Ms. Marteney followed up and asked Mrs. Perry if K.P. was up to date on her vaccines. Mrs. Perry replied that she cannot vaccinate K.P.

77. On January 3, 2024, Mrs. Perry was again contacted by Ms. Marteney regarding K.P.'s vaccination status, and when Mrs. Perry again confirmed that she could not vaccinate K.P. Ms. Marteney notified Mrs. Perry that K.P. would promptly be dis-enrolled from the Virtual Academy.

78. K.P. was permitted to finish out the week, and then her online virtual learning credentials were cancelled on or around January 5, 2024, leaving her with no access to her teachers, classmates, or curricula materials.

79. On April 1, 2024, Mrs. Perry inquired whether she could submit a religious exemption to the CVL to continue K.P.'s education through the Virtual Academy. On April 3, 2024, Ms. Marteney replied that "unfortunately there is still not a religious exemption available." *See* **Exhibit 7**, Denial of Religious Exemption.

80. K.P. must now be homeschooled, with little to no interaction with children of her age for her education.

81. This change has caused a significant decrease in K.P.'s enthusiasm for learning. K.P was thriving at the Virtual Academy, but her appetite for learning diminished once she was transitioned to full-time homeschool.

82. K.P no longer has any routine or structure in her day. While attending the Virtual Academy, K.P. would meet with her homeroom on Mondays and Fridays at 9:00 AM. After homeroom, K.P. would attend optional elective courses.

83. K.P.'s lessons targeted core subjects each day.

84. On occasions where K.P. was unable to immediately grasp concepts, K.P. and Mr. Perry had access to a full range of support through the Virtual Academy to help K.P. grapple through and conquer the learning issues she confronted.

85. K.P. earned straight A's while in the Virtual Academy.

86. With the support system the Virtual Academy provided, Mr. Perry was able, despite his disabilities, to seamlessly guide K.P. through the virtual educational program. Without the support system the Virtual Academy provides, Mr. Perry has struggled to advance K.P.'s education at the same level K.P. was learning through the Virtual Academy.

87. If West Virginia continues to prohibit religious exemptions to the Virtual Academy, the only remaining option for the Perrys to ensure K.P. receives an education is to homeschool. Because of the Perrys' unique situation, homeschooling is a less-than-optimal situation for K.P.'s learning needs.

88. K.P. is unable to access the practical and social benefits of a typical education that her secular peers enjoy. In short, without a religious exemption, the Perrys have been deprived of the West Virginia's guarantee of a public education, unless they violate their sincerely held religious beliefs.

89. West Virginia's refusal to allow K.P. to continue her education through the Virtual Academy is having and will have lifelong and negative impacts on K.P.

C. Despite Being Categorically Excluded from Receiving an Education in West Virginia, K.P. Regularly Interacts with her Peers

90. Notwithstanding the CVL, K.P regularly socializes with other children her age. K.P. interacts regularly with her West Virginia peers outside of school on a weekly basis (*e.g.,* at group church gatherings and at various other community activities).

91. K.P frequently visits with her cousins, friends, and plays with and learns alongside children at Sunday school.

II. DEFENDANTS

92. Defendant, Stacy Marteney ("**Ms. Marteney**") is the Virtual Learning Coordinator for the Upshur School District, the District through which Plaintiffs enrolled, and attempted to re-enroll, K.P. into the Virtual Academy. Ms. Marteney is sued solely in her official capacity. Ms. Marteney is tasked with implementing and enforcing, and does implement and enforce, the mandatory vaccination requirements of the CVL against school-aged children desiring to attend the Virtual Academy, and she enforced the CVL against the Plaintiffs and excluded K.P. from the Virtual Academy. She is located at 102 Smithfield St. Buckhannon, West Virginia, 26201.

93. The Board of Education of the County of Upshur ("**Board**") is the duly empaneled school board for Upshur County, which pursuant to W. VA. CODE §§ 18-5-1, 18-5-5, 18-5-34, has authority and control over the school district, and, pursuant to state law, was responsible for enforcing the CVL against Plaintiffs, resulting in the exclusion of K.P. from school. The Board is located at 102 Smithfield St. Buckhannon, West Virginia, 26201.

94. Christine Miller ("**Ms. Miller**") is the duly empaneled Superintendent of the Upshur County School District, being sued only in her official capacity as Superintendent, with the duties as outlined in W. VA. CODE § 18-4-10 to include enforcement of all policies and procedures by state law, including, as is relevant here, enforcement of the CVL against Plaintiffs and K.P. Ms. Miller is located at 102 Smithfield St. Buckhannon, West Virginia, 26201, and is sued solely in her official capacity.

95. Defendant Dr. Mathew Christiansen ("**Dr. Christiansen**") is made party to this action in his official capacity as State Health Officer and Commissioner for the West Virginia Department of Health and Human Resources. Under West Virginia law, and specifically the CVL,

at W. VA. CODE § 16-3-4 (c), (d), (e), and (h), Dr. Christiansen is specifically tasked with implementing and enforcing, and does implement and enforce, the mandatory vaccination requirements of the CVL for school-aged children, including children wishing to enroll in the Virtual Academy, while simultaneously granting medical exemptions under the CVL to unvaccinated West Virginia schoolchildren. He is sued solely in his official capacity.

96. Defendant, Doug Cipoletti ("**Mr. Cipoletti**") is the Executive Director of the Virtual Academy.[4] Mr. Cipoletti is tasked with implementing and enforcing, and does implement and enforce, the mandatory vaccination requirements of the CVL against school-aged children desiring to attend the Virtual Academy, including K.P. The West Virginia Virtual Academy is a tuition free online Public School offered to children grades K-12. While the Virtual Academy has a psychical location at 3508 Staunton Ave., 3rd Floor, Charleston, West Virginia, 25304, the Virtual Academy enforces the CVL against schoolchildren throughout the state, including in this judicial division and district, and was involved in enforcing the CVL generally resulting in the exclusion of K.P. He is sued solely in his official capacity.

STATEMENT OF FACTS

I. DEFENDANTS' CATEGORICAL "NO RELIGIOUS EXEMPTION POLICY" AND NON-ENFORCEMENT OF THE CVL.

A. CVL Requirements and Limitations of the Mandated Vaccines

97. Under the CVL, every "child entering school or a state-regulated childcare center in this state must" receive certain vaccines. W. VA. CODE § 16-3-4 (b).

98. 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

[4] *See* WEST VIRGINIA VIRTUAL ACADEMY, *available at* https://wvva.k12.com/about-our-school/letter-from-our-head-of-school/ (last visited July 5, 2024).

[*i.e.*, varicella], hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough [i.e., pertussis]" 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).

99. No child may be "admitted or received in any of the schools of the state" unless they have received these vaccines. *Id.* at § 16-3-4 (c). And § 16-3-4 (d) requires school and childcare personnel to report to the commissioner (who is also the State Health Officer) any attempts to enroll unvaccinated children in schools.

100. Many of these vaccines have been combined into single dose shots (e.g., the measles, mumps, and rubella ("**MMR**"), whereby multiple vaccinations are combined into one injection, and multiple vaccination are administered in a single dose.

101. Most of the injections required under the CVL provide at best personal protection.

102. For example, the tetanus, diphtheria, and pertussis vaccine ("**DTaP**" and/or "**Tdap**") does not prevent infection or transmission of the diseases it targets. This vaccine potentially provides only a level of personal protection by preventing a recipient from experiencing the symptoms of these infections.

103. Tetanus is not even an infectious disease. 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. *See* CDC Pink Book, *available at* https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html#:~:text=Tetanus%20is%20not%20contagious%20from,is%20infectious%20but%20not%20contagious (stating "Tetanus is not contagious from person to person.") (Last visited July 5, 2024).

104. Likewise, the pertussis vaccine provides only personal protection. *See e.g.,* https://pubmed.ncbi.nlm.nih.gov/31333640/ (stating "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 July 5, 2024).

105. The same is true of the diphtheria vaccine—it is at best a personal protection device. *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 July 5, 2024).

106. The meningococcal vaccine also does not contribute to herd immunity but at best provides an undefined 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 vaccines have **provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity**)." *See* CDC, *Meningococcal Vaccination: What Everyone Should Know*, *available at* https://www.cdc.gov/vaccines/vpd/mening/public/index.html (emphasis added) (last visited July 5, 2024).

107. 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 device. That is because the "inactivated polio vaccine (IPV) is the only polio vaccine that has been given in the United States since 2000."[5] "IPV… protects people from polio **disease but does not stop transmission of the virus**." *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/polio-today/polio-prevention/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 July 5, 2024).

108. Like COVID-19 vaccines, these vaccines are not designed to create, nor do they result in "herd immunity."

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

110. Further, hepatitis B is not transmitted 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 elementary, middle or high school setting." *See* **Exhibit 5**, CDC FOIA Response Regarding Hep B Vaccine. This makes sense

[5] *See* CDC webpage, *Polio Vaccination*, *available at* https://www.cdc.gov/vaccines/vpd/polio/index.html (Last visited July 5, 2024).

since hepatitis B is not transmitted through activities that occur in a school setting. It is also worth noting that "almost all children 6 years and older and adults infected with the hepatitis B virus recover completely and do not develop chronic infection." *See* CDC, *Hepatitis B, available at* https://www.cdc.gov/hepatitis/hbv/index.htm. (Last visited July 5, 2024).

111. Thus, four of the six injections[6] required under the CVL are incapable of preventing infection and transmission of target pathogens in the school setting and are, at best, personal protection devices.

112. The only remaining vaccines required under the CVL are the MMR and varicella injections. K.P. has received the first dose of both these vaccines, before they Perrys learned of these injections illicit connections to abortion.

113. The difference of protection stated by the CDC is negligible between one and two doses of the MMR vaccine. The CDC states that a single dose of the MMR K.P. received is 93% effective against the disease, as compared to 97% for two doses.[7]

114. Further, for the varicella vaccine (i.e., the chickenpox), CDC states that a single dose of the varicella K.P. received is 100% effective against "severe varicella," and 82% effective at "preventing any form of varicella," while two doses are likewise 100% effective against "severe varicella," and 92% effective at "preventing all varicella."[8] The gains from additional injections are, therefore, marginal at best.

---

[6] 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.

[7] *See CDC, About Measles, available at* https://www.cdc.gov/measles/vaccination.html (Last visited July 5, 2024).

[8] *See CDC, About the Varicella Vaccines, available at* https://www.cdc.gov/vaccines/vpd/varicella/hcp/about-vaccine.html (Last visited July 5, 2024).

115. 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 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]reganant women … [and] [n]ewborn infants of mothers without documented history of varicella." *See* https://www.fda.gov/media/76008/download?attachment. (Last visited July 5, 2024). Nonetheless, Defendants do not exclude those vaccinated with this product from schools for six weeks after vaccination to prevent transmission.

B. The Government Grants Medical Exemptions and Practical Exceptions Through Non-Enforcement of the CVL

116. While West Virginia requires that unvaccinated children enrolled in school be reported to the Department of Health pursuant to W. VA. CODE § 16-3-4 (d), Defendants liberally allow unvaccinated children to remain in school.

117. West Virginia allows unvaccinated children to remain enrolled in school and to attend in-person classes, provided they do not, like Plaintiffs, request a religious exemption before enrolling or re-enrolling. For example, in response to requests under the West Virginia Freedom of Information Act, W. VA. CODE § 29B-1-1, et seq., ("**WVFOIA**"), the Fayette County Board of Education responded that currently, in the 2023/2024 school year, 440 unvaccinated children were

enrolled in in-person classes for more than thirty days.[9] The Monongalia County School District reported 147 children out of compliance with the Compulsory Vaccination Law were enrolled in in-person classes for more than thirty days,[10] and the Upshur County School District—the district K.P. enrolled in the Virtual Academy, and the district in which her virtual education was administered—reported that 46 unvaccinated children who are out of compliance with the CVL were enrolled in in-person classes for more than thirty days.[11]

118. These are just three examples of school districts who permit unvaccinated students to attend in-person classes. On information and belief, many more unvaccinated students are permitted to attend in-person classes while out of compliance with the CVL in school districts throughout the state.

119. Official government records also indicate considerable non-compliance rates for West Virginia kindergarteners attending in-person classes. For example, according to CDC records for the 2022-2023 school year, as many 4.4% of West Virginia kindergarteners are out of compliance with the CVL. *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 July 5, 2024)).

[9] *See* **Exhibit 8**, Fayette County WVFOIA response.

[10] *See* **Exhibit 9**, Monongalia County WVFOIA response.

[11] *See* **Exhibit 10** Upshur County WVFOIA response.

120. 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 K.P. was ejected from the Virtual Academy after seeking a religious exemption.

121. 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.

122. 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 for liability for injuries caused by childhood vaccines, that the explosion in the childhood vaccine schedule occurred. *See* 42 U.S.C. §§ 300aa-11. And on the tails of this liability protection, West Virginia first required the recombinant Hep-b vaccine (first licensed in 1986) for school; the varicella vaccine (first licensed in 1995); the pertussis vaccine (licensed in 2005); and conjugate meningococcal vaccine (first licensed in 2005).

123. This means that most adults in the State, who comprise over 80% of the state's population,[12] were never subject to most of the State's school vaccine requirements.

124. West Virginia also permits medical exemptions to its childhood vaccination requirements. While religious exemptions are prohibited, a child may be exempt from the

[12] *See* UNITED STATES CENSUS BUREAU, QuickFacts, West Virginia, *available at* https://www.census.gov/quickfacts/fact/table/WV,US/PST045223 (last visited July 5, 2024)

requirements upon producing a certificate "granting the child . . . a[] [medical] exemption from the compulsory immunization requirements." W. VA. CODE § 16-3-4 (h).

125. For example, in response to WVFOIA requests, the Harrison County School District reported that it had recently granted nine medical exemptions to the CVL,[13] the Monongalia County School District reported seven medical exemptions,[14] and the Upshur County School District reported two medical exemptions.[15]

126. These are just three examples of school districts who grant medical exemptions to in-person students. On information and belief, many more unvaccinated students are permitted to attend in-person classes with medical exemptions, and the Virtual Academy also allows for medical exemptions.

C. K.P. was Thriving at the West Virginia Virtual Academy, Where She Posed a Non-Existent Threat to Defendants' Infectious Disease Related Goals

127. West Virginia's justification for the CVL is to mitigate against infectious disease, specifically amongst children in school settings.

128. Because infectious diseases do not only spread in school settings, and impact adults and schoolchildren alike, the CVL can never credibly fulfill West Virginia's contagious disease mitigation goals.

129. Even if the State's interest in vaccinating its citizens could somehow logically be limited exclusively to children in a formal school setting, allowing K.P. to access a religious exemption to the Virtual Academy—**where she does not interact in person with classmates**—

[13] *See* **Exhibit 11**, Harrison County WVFOIA response.

[14] *See* **Exhibit 9**, Monongalia County WVFOIA response.

[15] *See* **Exhibit 10**, Upshur County WVFOIA response.

does not remotely threaten Defendants' goals, and certainly not to the degree that medical exemptions do.

130. The Virtual Academy is a tuition-free online public school offering virtual education to children from kindergarten through grade twelve.[16] The program is available for all West Virginia residents.[17]

131. The Virtual Academy is administered through local school districts. Parents must enroll in virtual school through a county school district.

132. Once enrolled, administrators from the sponsoring school district provide the family with credentials to access the program. Plaintiffs were provided enrollment credentials through representatives from the Upshur County School District.

133. The Virtual Academy offers a flexible learning curriculum with core subjects in English, Science, Math, History and Art. The program allows for a customized educational experience for each child.

134. For approximately 17 months, from August of 2022 to January of 2024, K.P. was enrolled in and thrived at the Virtual Academy without her vaccination status being an issue and without endangering the government's public health goals.

135. The situation was ideal for Plaintiffs as Mrs. Perry is a working mother and is unable to personally homeschool K.P. full time, which, prior to the availability of the Virtual Academy, was the only educational option in West Virginia for children who remained unvaccinated for religious reasons.

[16] *See* WEST VIRGINIA VIRTUAL ACADEMY, *available at* https://wvva.k12.com/ (last visited July 5, 2024).
[17] *Id.*

136. Mr. Perry, who is 100% disabled, shepherded K.P. through Virtual Academy from home, with considerable assistance for Virtual Academy staff.

137. All learning materials, books, and lesson plans are provided to the family free of charge, or at very low cost. This virtual learning program allows for flexible learning hours to fit the child's needs and schedule.

138. Even though Virtual Academy students learn from home and are not required to interact in person with their virtual classmates, Virtual Academy students are subject to the CVL's requirements.

139. Plaintiffs have requested that they be permitted to seek a religious exemption to the CVL so their child can continue her education. Their request for a religious exemption and accommodation were rejected.

140. However, the CVL and Defendants have made clear that medical exemptions are available for schoolchildren with secular reasons for declining vaccination, including those enrolled for in person learning as well as for Virtual Academy students.

D. West Virginia's Categorical Intolerance for Non-Vaccination for Religious Reasons, Even in Virtual Settings

141. West Virginia simply cannot tolerate non-vaccination for religious reasons. The State is perfectly fine if children remain unvaccinated for medical reasons and attend in person school, or even if they are willfully non-compliant with the law (for any reason they choose) and attend school, provided they do not, like Plaintiffs, request a religious exemption to continue in school.

142. However, from a disease prevention and risk perspective, there is no reason "why religion alone must bear the burden" of the State's push to mitigate against infectious disease. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 544 (1993).

143. As conclusive evidence of West Virginia's intolerance for non-vaccination for religious reasons, West Virginia Governor Jim Justice recently vetoed a bill that would have allowed for religious exemptions in virtual public schools, like the Virtual Academy.[18]

144. The medical exemption option, however, remains intact and children unvaccinated for secular reasons are permitted to intermingle daily with their classmates at school.

145. Further, while the State made the conscious choice to prohibit religious exemptions even in virtual settings, West Virginia continues in its relaxed enforcement of the CVL, allowing many hundreds of unvaccinated schoolchildren who are willfully noncompliant with the law to continue to attend classes in-person.

146. Because of Governor Justice's veto, Plaintiffs specifically chose not to challenge the CVL under the recently enacted West Virginia Equal Protection for Religion Act, West Virginia Code § 35-1A-1 (2023) (the "**EPRA**"), which arguably contains protections that may overlap with the concrete protections the First Amendment affords.

147. This is because, whatever protection EPRA may hypothetically provide, that theoretical shield for religious freedom in West Virginia is transient and passing, contingent on the shifting opinions of elected officials (like Governor Justice and a future legislature).

148. Elected officials can just as easily rescind EPRA, and whatever religious freedoms it may protect. And given Governor Justice's veto, it is clear that EPRA would not have been enacted if it included an option for a religious exemption to childhood vaccination.

149. Thus, Plaintiffs seek the bedrock, unchanging protections only accessible under the First Amendment. *See W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 638 (1943) (observing

[18] *See* WV HB5105, *A Bill to Eliminate Vaccine Requirements for Public Virtual Schools*, https://www.billtrack50.com/billdetail/1687129 (last visited July 5, 2024).

that one's "right to . . . freedom of worship . . . and other fundamental rights may not be submitted to vote; they depend on the outcome of no elections.").

E. Recent First Amendment Free Exercise Developments

150. Directly applicable constitutional jurisprudence has fundamentally evolved to require strict scrutiny review for situations virtually identical to the issues presented here.

151. 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 to their school vaccination laws.[19]

152. West Virginia is a radical outlier in prohibiting a religious exemption option. Only five states do not currently allow for 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.[20]

---

[19] *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).

[20] *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). West Virginia is the only state that has never offered a religious exemption. W. Va. Code § 16-3-4.

153. More importantly, First Amendment jurisprudence has fundamentally evolved in recent years. There have been five Supreme Court cases that are particularly relevant to the First Amendment issues at hand, and those cases each in isolation dictate strict scrutiny review here.

154. Before *Emp't Div. v. Smith,* 494 U.S. 872 (1990), courts struggled with what level of judicial scrutiny to apply to free exercise claims. Because of the country's diversity of religious beliefs, almost every government regulation burdened, to some degree or another, a religious belief system. The *Smith* Court confronted this issue and held that laws that only "incidentally" burden religion expression ordinarily are not subject to strict scrutiny under the Free Exercise Clause, reasoning to do otherwise would be "courting anarchy." *Id.* at 888.

155. However, the *Smith* Court held that strict scrutiny would apply to regulations that either were not neutral (because they overtly targeted out religious observance for worse treatment), or did not apply generally to the population, containing no exceptions the law.

156. The *Smith* Court's animating rationale was that allowing religious exemptions to certain neutral and generally applicable laws "would be courting anarchy," *Smith*, 494 U.S. at 888, because such laws "could not function" in the face of religious exemptions, *United States v. Lee*, 455 U.S. 252, 260 (1982.

157. That is not the case here. Childhood vaccination schemes are clearly capable of smoothly functioning with exemption options, including for religious reasons.

158. Again, West Virginia permits many hundreds of unvaccinated children out of compliance with the CVL to remain in school, and it does not require the tens of thousands of adults working in the school system to comply with the CVL's requirements.

159. Consequently, the government has shown through action and inaction that its infectious disease related goals can be accomplished while allowing exceptions to the CVL.

160. Finally, the overwhelming majority of states have for decades recognized the compelling interest in respecting their citizens' religious freedoms and allow for a religious exemption option to childhood vaccination requirements, further demonstrating childhood vaccination requirements are more than capable of allowing for religious exemptions without generating the anarchy the *Smith* Court was so concerned about.

161. Here, the option for a religious exemption mechanism can be seamlessly implemented, like it has been in forty-five other states, without endangering ordered governance and preservation of the CVL.

162. The CVL also provokes strict scrutiny under *Smith's* progeny.[21]

163. The *Smith* Court held that strict scrutiny would apply to regulations that either were not neutral (because they targeted religious observance) or were not generally applicable. *Smith*, 494 U.S. at 881.

164. A couple of years later, in *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993), the Court outlined the parameters of the neutrality and general applicability standards when examining a local ordinance that banned animal sacrifice, a practice of the Santeria faith. Because it appeared that the government had targeted religious observance for exclusion, and because the local government allowed similar secular conduct (absence of restrictions on how hunters were to dispose of an animal carcass), the Court applied strict scrutiny and struck the ordinance. *Lukumi*, 508 U.S. at 547.

165. More recently, the Supreme Court has protected Free Exercise rights in the face of state regulations related to infectious diseases. In *Tandon v. Newsom*, 593 U.S. 61, 62 (2021), the

[21] Plaintiffs also believe *Smith* was wrongly decided and preserve the right to argue *Smith* should be overturned.

Supreme Court ruled that a law is not neutral and generally applicable, and thus invokes strict scrutiny review, if it treats "*any* comparable secular activity more favorably than religious exercise." *Id.* at 62 (emphasis in original). In *Tandon,* California regulations intended to slow the spread of COVID-19 limited religious gatherings but treated comparable secular gatherings – such as getting haircuts and retail shopping – more favorably. *Id.* at 63. The Court applied strict scrutiny and granted a preliminary injunction in favor of the religious plaintiffs. *Id.* at 64.

166. The Court employed similar reasoning in *Roman Catholic Diocese v. Cuomo*, 592 U.S. 14 (2020), holding that a New York regulation that prohibited religious gatherings but permitted similar secular gatherings violated the First Amendment where the secular and religious activities in question presented comparable contagion risks. *Id.* at 17.

167. A couple of months after its *Tandon* ruling, the Supreme Court examined the issue of whether a regulation is generally applicable where it provides for secular exceptions that are unavailable to citizens with religious beliefs. In *Fulton v. City of Philadelphia*, 593 U.S. 522, 537, (2021), the Court—in a 9-0 decision—held that the "creation of a formal mechanism for granting exceptions renders a policy not generally applicable" where that mechanism is unavailable to religious adherents. In deciding to apply strict scrutiny, the Court observed that the regulation in question had a procedure that was subject to individualized review and approval at the "sole discretion" of a government official. *Id.* at 537.

F. West Virginia has Created a Discretionary Medical Exemption Process

168. West Virginia has instituted an individualized discretionary exemption to the CVL that categorically preferences non-vaccination for secular reasons above non-vaccination for religious reasons.

169. Students are categorically prohibited from seeking exemption from the required vaccines for religious reasons. However, students are permitted to seek a medical exemption from the required vaccines.

170. Through the plain language of the relevant statute, West Virginia has reserved discretion to accept or deny medical exemptions.

171. The statute dictates in relevant part that 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).

172. It offers no similar pathway for an exemption where the requirement substantially burdens a sincerely held religious belief.

173. The medical exemption process includes even more individualized discretion than what may be initially apparent.

174. Under the statutory scheme, there are multiple levels of discretionary review whereby government officials and private physicians are empowered to press the red light or green light on each medical exemption request, and at each level, the government prefers non-vaccination for secular reasons above non-vaccination for religious reasons.

175. At the first level of review, the state has delegated private health care providers discretion to determine the variety of circumstances which are eligible for a medical exemption, and those which are not.

176. Acting on behalf of the state, these physicians conduct an individualized assessment of each request for a medical exemption and have latitude to decide whether to certify the request, and then submit their opinion for medical exemption on a government form.[22]

177. In practice, West Virginia physicians exercise broad discretion when deciding to grant or deny each medical exemption request. Different decisions can be reached, and are reached, depending on which physician evaluates the request.

178. If and when the medical exemption form is signed by a physician, it is then forwarded to the State Immunization Officer who reviews each medical exemption request on a case-by-case basis. If the exemption is ultimately approved by the State Immunization Officer, the student is permitted to attend school without having received all of the mandated vaccines.

179. 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); *see also* **Exhibit 6**, Medical Exemption Denial Reconsideration Form.

180. In practice, government officials and physicians acting on behalf of the Government exercise individualized discretion as to whether to grant or deny each medical exemption request.

181. 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. Different outcomes can be reached, and are reached, depending on who reviews the request.

182. Even the implementing regulations for the medical exemption in West Virginia provide that Defendant Dr. Christiansen shall consider "evidence from medical sources, such as

[22] *See* **Exhibit 12**, West Virginia Medical Exemption Request Form.

medical history, opinions, and statements about treatment the child has received." W. Va. Code R. § 64-95-17.2.a.2.

183. A similar exemption process is unavailable to citizens with religious objections to compulsory vaccination. For example, Plaintiffs requested that they be permitted to re-enroll K.P. in the Virtual Academy with a religious exemption, but they were rejected.[23]

184. In case there were any doubt that religious exemptions shall not be allowed, while medical exemptions are permitted, the West Virginia Department of Health's webpage outlines the process for seeking and receiving a medical exemption but makes clear that religious exemption cannot be pursued because "West Virginia does not grant non-medical exemptions."

185. While West Virginia will not entertain a religious exemption request and forbids those tasked with enforcing the CVL to consider granting one, the State grants many medical exemptions annually.

G. West Virginia Permits Additional Comparable Secular Activity

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

187. Again, Defendants allow for and do in fact grant many medical exemptions to the CVL.

188. Defendants have granted many medical exemptions to students who attend classes in person and who interact with other students and staff significantly more frequently (indeed, every day of classroom instruction, year-round) than K.P. would as a student in the Virtual Academy.

[23] *See* **Exhibit 7**, Re-Enrollment and Religious Exemption Request.

189. On belief, Defendants have also granted medical exemptions to the Virtual Academy.

190. From a risk perspective, one online student with a medical exemption to the CVL poses the same risk to Defendants' goals as allowing Plaintiff a religious exemption – which is to say virtually no risk at all.

191. From a risk perspective and following the government's logic, one in-person student with a medical exemption to the CVL poses a much greater risk to West Virginia's goals than allowing Plaintiffs a mechanism to pursue a religious exemption for K.P. to the Virtual Academy.

192. Further, West Virginia does not strictly enforce its childhood vaccination policies and permit functional exemptions through non-enforcement of the CVL. In other words, as discussed *supra,* West Virginia presently permit many hundreds of students lacking one or more of the required vaccines to attend class in person, even though they are willfully non-compliant with the CVL.

193. The government also permit 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 or even adhering to enhanced safety protocols.

194. Even if the government'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.V. Code § 18-8-1, the government permits unvaccinated children—whatever their reasons for declining vaccination—to be educated

in these learning pods. This too constitutes comparable activity under *Tandon*, and, under the government's logic, presents a considerably greater threat to West Virginia's public health goals than permitting K.P. to continue her education in the Virtual Academy with a religious exemption.

195. 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.

196. Defendants also permit unvaccinated members of the public to attend high transmissibility events in which there are large crowds gathered in close proximity, such as high school basketball and football games, without showing proof of vaccination, and then enter school campuses the next day, if desired.

197. However, Defendants prohibit Plaintiffs from pursuing an education for K.P., even in virtual settings, based on their religious objections to the CVL.

198. A single unvaccinated person or student on a West Virginia school campus poses a greater risk to Defendants' goals than permitting K.P. access to an online education through the Virtual Academy.

199. Collectively, the aggregation of individual secular behaviors Defendants permit (e.g., medical exemptions, unvaccinated teachers and staff, lax enforcement of the CVL, unvaccinated children in learning pods, and unvaccinated members of the general public intermingling at high transmissibility events who then access school campuses unprohibited) pose an infinitely greater threat to any possible goals undergirding the CVL than permitting Plaintiffs' child—an online student—to access the State's educational benefits from her own home with a religious exemption to the CVL.

H. The CVL is Amenable to Exemptions; there are Many Less Burdensome Alternatives; and the Law is Both Under- and Over-Inclusive Relative to Defendants' Infectious Disease Related Goals

200. Every state in the country has a mandatory vaccination policy for childhood education. However, the overwhelming majority of these states—forty-five—have a process for both religious and medical exemptions to compulsory vaccination requirements.

201. These states have demonstrated their goals undergirding vaccination requirements can be satisfied while simultaneously respecting students' religious freedoms.

202. In short, the CVL can be seamlessly implemented without endangering West Virginia's disease mitigation goals while also allowing for exceptions to the policy.

203. 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, or face masking, distancing, sanitation, and others. Notably, the states contiguous to West Virginia that allow for religious exemptions to childhood vaccination laws all implement the less restrictive alternative of quarantining, if an outbreak of an infectious disease were ever to occur.[24]

---

[24] *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.").

204. West Virginia does not even require any of these countermeasures for children with medical exemptions, or for unvaccinated teachers and staff working in the school system. Indeed, if vaccination is effective against transmission of disease, as West Virginia claims 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 position that the mandated vaccines work.

205. Plaintiffs will comply with any reasonable, less burdensome alternatives that would allow them to continue pursuing their child's online education.

206. Moreover, the CVL also fails to regulate enough conduct to satisfy West Virginia's goals. In short, the CVL is glaringly and substantially underinclusive relative to the objectives the government seeks to achieve.

207. For example, sporting events on West Virginia school campuses, graduation ceremonies, or any other student and/or community gatherings do not require proof of vaccination.

208. These mass gatherings pose a significantly greater risk to West Virginia's goals to mitigate against infectious disease spread than would permitting K.P. to pursue her online education with a process for obtaining a religious exemption.

209. Notwithstanding being ejected from the Virtual Academy, however, K.P. can attend sporting events, just as any other member of the public can and does. As such, the CVL does not mitigate against the purported risk of transmission on campuses, and therefore, it is severely underinclusive. This is true, even when engaging in the fiction that all the required vaccines are capable of preventing infection and transmission of the targeted pathogens, given that CDC and other public health authorities document breakthrough infections following receipt of several of the required vaccines.

210. The CVL is also underinclusive because it permits medical exemptions for students (both online and in person). The CVL is underinclusive relative to West Virginia's objectives because it permits unvaccinated online and in-person students possessing medical exemptions to receive an education throughout the state.

211. If a student with a medical exemption can safely attend in-person class every single school day of instruction, then K.P., an online student, can certainly complete her education with a religious exemption without endangering the government's goals.

212. The CVL is further substantially underinclusive because West Virginia does not require vaccines meant to protect from highly contagious viruses spread via respiratory secretions, such as COVID-19 and influenza, which are arguably more lethal and result in more hospitalizations every year than those diseases for which vaccines are required under the CVL.

213. In fact, West Virginia outright prohibits requiring COVID-19 vaccines as a condition of entering school. *See* W.V. Code §§ 16-3-4b, 16-3-4c.

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

215. First, the CVL fails to include a reasonable religious exemption for the miniscule fraction of families who, like Plaintiffs, hold sincere religious beliefs in conflict with the CVL and who desire to enroll their children in the Virtual Academy.

216. 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 by forcing Plaintiffs to violate their sincerely held religious beliefs by injecting K.P. with the required vaccines as a condition of education. While the Government 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).

217. Third, the Policy is overbroad because many of the required vaccines, including pertussis, tetanus, diphtheria, polio, and meningococcal do not prevent transmission or infection of the diseases they target. *See supra,* §I.B. Rather, these vaccines merely provide a level of personal protection by potentially preventing recipients from experiencing the symptoms of these infections.

218. Fourth, K.P. has received doses of the vaccines required under the CVL. Thus, West Virginia can only, at best, point to miniscule gains to its disease mitigation goals by forcing K.P. to receive the few additional doses she lacks.

219. However, despite these realities, the government has completely destroyed the option for religious objections in the compulsory vaccination arena, including in the virtual school setting, a plainly overbroad application of its justification for requiring vaccination to mitigate the spread of infectious diseases.

COUNT I

42 U.S.C. § 1983
VIOLATION OF PLAINTIFF'S FIRST AMENDMENT FREE EXERCISE RIGHTS
For Declaratory and Injunctive Relief (as applied challenge to the CVL)

220. Plaintiffs incorporate the allegations in the foregoing paragraphs as if set forth fully herein.

221. The First Amendment of the U.S. Constitution provides that: "Congress shall make no law respecting an establishment of religion or prohibiting the free exercise thereof." This clause has been incorporated against the states. *Cantwell v. Connecticut*, 310 U.S. 296 (1940).

222. The Supreme Court recently reaffirmed that the First Amendment's Free Exercise Clause "does perhaps its most important work by protecting the ability of those who hold religious beliefs of all kinds to live out their faiths in daily life through 'the performance of (or abstention from) physical acts.'" *Kennedy v. Bremerton Sch. Dist.*, 142 S.Ct. 2407, 2421 (2022) (quoting *Smith,* 494 U. S. at 877)).

223. The Supreme Court has repeatedly recognized that "[t]he free exercise of religion means, first and foremost, the right to believe and profess whatever religious doctrine one desires." *Smith*, 494 U.S. at 877.

224. Parents have the right to "direct the religious upbringing of their children" and "when the interests of parenthood are combined with a free exercise claim […] more than merely a 'reasonable relation to some purpose within the competency of the State' is required to sustain the validity of the State's requirement under the First Amendment." *Wisconsin v. Yoder*, 406 U.S. 205, 233 (1972).

225. Courts should 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).

226. 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).

227. Plaintiffs' sincerely held religious beliefs that prohibit them from vaccinating their minor child have been unconstitutionally burdened by the State of West Virginia. Plaintiffs'

attempts to maintain K.P.'s enrollment in the Virtual Academy with a religious exemption request were rejected.

228. As such, West Virginia has pitted Plaintiffs' religious integrity against educating their child. 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").

229. The Free Exercise Clause of the First Amendment protects against "indirect coercion or penalties on the free exercise of religion, not just outright prohibitions." *Carson v. Makin*, 142 S. Ct. 1987 (2022) (quoting *Lyng v. Northwest Indian Cemetery Protective Assn*., 485 U. S. 439, 450 (1988)). "In particular, [the U.S. Supreme Court has] repeatedly held that a State violates the Free Exercise Clause when it excludes religious observers from otherwise available public benefits." *Id.*

230. Nevertheless, despite West Virginia's guarantee of a free public-school education, K.P. cannot obtain a formal education because of her parents' convictions, not in public school, private school, or even the Virtual Academy.

231. However, West Virginia families with secular, medical motivations for declining compulsory immunization can be exempted from the CVL's requirements. Those exempt children are then free to attend class in person.

232. Considering the foregoing, and directly on-point Supreme Court precedent, the CVL provokes and cannot survive strict scrutiny.

The CVL Triggers Strict Scrutiny under Smith

233. The CVL substantially burdens Plaintiffs' religious beliefs and practices, and the law triggers strict scrutiny under *Smith,* 494 U.S. at 888, because the State has shown the CVL is readily amenable to exceptions to the state's vaccination policy. The prohibition of a religious exemption option, despite the reality of a feasible exemption scheme, reveals the CVL's lack of neutrality and lack of general applicability under *Smith.* Because the CVL is readily amenable to a religious exemption option, the law triggers strict scrutiny.

234. The State of West Virginia has made an unconstitutional value judgment that secular (*i.e*., medical) motivations for opting out of compulsory immunization are permitted, but that religious motivations are not.

The CVL Clearly Triggers Strict Scrutiny on Additional Grounds under Smith's Progeny

235. Further, should the Court determine the CVL does not trigger strict scrutiny under *Smith* because the law is readily amenable to a religious exemption option, the CVL fails both the general applicability and neutrality tests under *Smith's* progeny.

236. While West Virginia may have a general healthcare interest in promoting childhood immunization, the First Amendment's Free Exercise Clause prohibits the government from enacting non-neutral and non-generally applicable legislation unless it is narrowly tailored to a compelling government interest. *Lukumi*, 508 U.S. at 531.

237. The CVL fails the general applicability test under *Fulton* because the medical exemption system provides for individualized discretionary review. "The creation of a formal mechanism for granting exceptions renders a policy not generally applicable . . . ." *Fulton,* 593 U.S. at 537.

238. In such instances, the government may not refuse to extend the possibility for an exemption "to cases of religious hardship without compelling reason." *Id.* at 534 (cleaned up).

239. Because its medical exemption process provides for discretionary review at multiple levels, West Virginia's CVL fails the general applicability test. West Virginia has instituted a system of customized review – delegated first to private physicians and second to the State Immunization Officer and the Health Officer – who at each level conduct individualized review of medical exemption requests.

240. The CVL also fails the neutrality test because the government made a categorical choice to prohibit the option for religious exemptions in virtual settings and in private schools, but it made the deliberate choice to maintain the medical exemption option. On March 29, 2024, Governor Jim Justice vetoed a bill that would have allowed for religious exemptions in the Virtual Academy. Conclusively demonstrating its non-neutrality and animus towards any possibility of religious observance in the compelled vaccination arena, the government made the deliberate choice that non-vaccination for religious reasons, even in virtual learning settings, cannot be tolerated, whole continuing to allow for secular exemptions to the CVL for in-person students.

241. The CVL also fails the general applicability and neutrality tests on alternative grounds because West Virginia treats non-vaccination for secular reasons more favorably than non-vaccination for religious reasons.

242. Government regulations "are not neutral and generally applicable, and therefore trigger strict scrutiny under the free exercise clause of the First Amendment, whenever they treat **any** comparable secular activity more favorably than religious exercise." *Tandon*, 593 U.S. at 62 (emphasis in original).

243. Whether two activities are comparable for purposes of the free exercise clause depends on "the asserted government interest that justifies the regulation at issue." *Id.*

244. Here, with regard to regulating the conduct of its secular and religious citizens, the government holds the same interest in mitigating against infectious disease in school settings. Further, the secular and religious activities at issue are not only comparable, but they are also exactly the same (non-vaccination).

245. A law "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way." *Fulton,* 593 U.S. at 534 (cleaned up).

246. Whatever interest West Virginia may have in promoting childhood vaccination, its interests are not so extraordinary as to prohibit an exemption for secular reasons, and hence can similarly provide an exemption for religious reasons, particularly for students who only attend online classes. Further, West Virginia liberally allows functional exemptions through non-enforcement of the CVL, and it does not prohibit unvaccinated children from visiting public libraries or museums, or from interacting with their peers in any other way. Nor does West Virginia require that teachers, staff members, or school visitors provide proof of vaccination. West Virginia also allows unvaccinated students to be educated in learning pods in unlimited numbers.

247. These activities in which West Virginia permits non-vaccination for secular reasons, each in isolation pose a greater threat to its infectious disease-related goals than would permitting K.P. to be educated with a religious exemption. Collectively, these activities pose a dramatically greater threat under the *Tandon* framework and thus invoke strict scrutiny under the First Amendment on additional grounds.

The CVL Infringes on Other Constitutionally Protected Rights and also Triggers Strict Scrutiny because it Implicates Hybrid Rights

248. In *Yoder*, 406 US at 234-35, the Supreme Court acknowledged that Free Exercise rights can overlap with and can be inherently intertwined with the right to make decisions regarding the upbringing of one's child as recognized in *Pierce v. Socy. of Sisters*, 268 U.S. 510 (1925). There, the Court reached this conclusion due to the Amish's "religious beliefs, the interrelationship of belief with their mode of life, the vital role that belief and daily conduct play in the continued survival of … Amish communities and their religious organization, and the hazards presented by the State's enforcement of a statute generally valid as to others." *Id.* at 235.

249. In such circumstances, "when the interests of parenthood are combined with a free exercise claim of the nature revealed by this record, more than merely a reasonable relation to some purpose within the competency of the State is required to sustain the validity of the State's requirement under the First Amendment" (i.e., requires the application of strict scrutiny). *Yoder*, 406 U.S. at 233. *See also Smith*, 494 U.S. at 881-81 (acknowledging hybrid rights that triggered strict scrutiny).

250. Here, the CVL implicates Plaintiffs' right to free exercise as well as their right to free speech, to associate, and to regulate the upbringing and education of K.P. These provide independent reasons for applying strict scrutiny to the CVL in Plaintiffs' specific case.

The CVL Fails Strict Scrutiny

251. For the reasons detailed throughout, West Virginia lacks a sufficiently compelling interest to enforce the CVL against Plaintiffs specifically.

252. Whatever interests West Virginia may advance in support of its law, its interests are not so compelling as to prohibit secular exceptions. As applied to Plaintiffs, the government lacks a sufficiently compelling interest to restrict Plaintiffs' religious freedoms because this case

involves a student attending a course of instruction that occurs online in which the child is physically located in their own home.

253. A law cannot be regarded as protecting an interest of the highest order when it leaves appreciable damage to that supposedly vital interest unprohibited (e.g., here, granting medical exemptions for students physically attending school, permitting functional exemptions through lax enforcement, and by allowing adults out of compliance with the CVL to work in the educational system).

254. Further, Defendants cannot rely on a broad policy goal, but must demonstrate a compelling interest in denying a religious exemption to K.P. specifically – a remote student who was enrolled in Virtual Academy for more than seventeen months before she was excluded.

255. In reviewing refusal of a religious exemption, courts cannot "rely on 'broadly formulated interests'"; instead "courts must 'scrutinize[] the asserted harm of granting specific exemptions to particular religious claimants.'" *Fulton,* 593 U.S. at 541 (cleaned up).

256. Thus, the "question, then, is not whether the [West Virginia] has a compelling interest in enforcing its" vaccination "policies generally, but whether it has such an interest in denying an exception to" Plaintiffs. *Id.*

257. Even if West Virginia could substantiate a sufficiently compelling interest to enforce the CVL specifically against Plaintiffs and specifically to exclude K.P. from the Virtual Academy, the law still fails strict scrutiny.

258. For the reasons detailed throughout, CVL Policy also is not narrowly tailored, is overinclusive, and substantially underinclusive, and therefore fails strict scrutiny on these additional grounds.

259. West Virginia's CVL cannot withstand strict scrutiny because it is not narrowly tailored. In the context of government regulations targeting infectious disease, "narrow tailoring requires the government to show that measures less restrictive of the First Amendment activity could not address its interest." *Tandon*, 593 U.S. at 63. Where utilization of such less restrictive means is required, the government "may no more create an underinclusive statute, one that fails truly to promote its purported compelling interest, than it may create an overinclusive statute, one that encompasses more protected conduct than necessary to achieve its goal." *Lukumi,* 508 U.S. at 578.

260. Regarding under-inclusivity, where the government permits secular activities, such as a medical exemption, "it must show that the religious exercise at issue is more dangerous." *Tandon*, 593 U.S. at 63.

261. When a law is over-inclusive, its "broad scope . . . is unnecessary to serve the interest, and the statute fails for that reason." *Lukumi*, 508 U.S. at 578.

262. West Virginia's CVL cannot withstand heightened scrutiny because it is both over-inclusive and under-inclusive relative to the state interests it purportedly attempts to achieve. Instead of regulating with the precision necessary to avoid conflict with its citizens' free exercise rights, West Virginia eliminated every possibility for religious observance in the mandatory vaccination arena.

263. West Virginia's compulsory vaccination scheme is under-inclusive because it only applies to children in a school setting. The 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 percent of West Virginia's population.

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

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

266. Given that West Virginia boasts one of the highest vaccination rates in the country, allowing a religious exemption for a handful of students, just as secular medical exceptions are permitted, would constitute an actual attempt at narrow tailoring.

267. Because West Virginia's CVL is simultaneously too narrow and too broad to fulfill the government interests it supposedly attempts to accomplish, and considering that forty-five other states have religious exemption options, the regulation lacks the narrow tailoring necessary to survive strict scrutiny review.

268. Accordingly, the CVL fails strict scrutiny and, at least as applied to online students such as K.P., would fail even rational basis review.

269. Therefore, as applied specifically to Plaintiffs, the CVL violates Plaintiffs' right to free exercise of religion.

Plaintiffs Have Suffered and Continue to Suffer Irreparable Harm

270. "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). Because of Defendants' actions, Plaintiffs have suffered and continue to suffer irreparable harm.

271. Absent injunctive and declaratory relief against the CVL and injunctive relief against Defendants, Plaintiffs will have been and will continue to be harmed.

272. Plaintiffs are entitled to a declaration that Defendants violated and continue to violate their First Amendment rights to free exercise of religion and an injunction against Defendants' actions as they relate to West Virginia's CVL.

INJUNCTIVE RELIEF ALLEGATIONS

273. Plaintiffs incorporate the allegations in the foregoing paragraphs as if set forth fully herein.

274. Plaintiffs allege that, as applied, the CVL violates their First Amendment rights and her right to be free from unlawful statutes.

275. Plaintiffs are being and will continue to be irreparably harmed unless this Court enjoins Defendants from enforcing the CVL against K.P.

276. Plaintiffs have no plain, speedy, and adequate remedy at law to prevent Defendants from enforcing the CVL against K.P.

277. If not enjoined by this Court, Defendants will continue to implement and enforce the CVL in violation of Plaintiffs' constitutional rights.

278. Accordingly, injunctive relief is appropriate.

DECLARATORY RELIEF ALLEGATIONS

279. Plaintiffs incorporate the allegations in the foregoing paragraphs as if set forth fully herein.

280. Plaintiffs are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201. An actual and substantial controversy exists between Plaintiffs 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 to the Virtual Academy, violates the United States Constitution.

281. The case is presently justiciable because the CVL and absence of any religious exemption to the same applies to Plaintiffs and K.P., who is currently harmed by being excluded from the Virtual Academy.

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

PRAYER FOR RELIEF

283. Pursuant to 28 U.S.C. § 2201 and 42 U.S.C. § 1983, it is appropriate and proper that a declaratory judgment be issued by this Court, declaring that the CVL is unconstitutional as applied to Plaintiffs.

284. Pursuant to 28 U.S.C. § 2202 and Fed. R. Civ. P. 65, and 42 U.S.C. § 1983 it is appropriate and hereby requested that the Court issue preliminary and permanent injunctions prohibiting Defendants from enforcing the CVL against Plaintiffs, unless the government allows for religious exemption option for Plaintiffs.

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

A. Declare the "no religious accommodation" policy to the CVL, as applied specifically to Plaintiffs, unconstitutional;

B. Issue a preliminary and permanent injunction prohibiting Defendants, their agents, servants, employees and any other persons acting on their behalf 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;

C. Declare that W. VA. CODE § 16-3-4 is unconstitutional as applied specifically to Plaintiffs;

D. Declare that W. VA. CODE § 16-3-4, as applied specifically to Plaintiffs, has violated and continues to violate Plaintiffs' First Amendment right to free exercise of religion;

E. Grant Plaintiffs reasonable attorneys' fees and costs under 42 U.S.C. § 1988 and any other applicable authority; and

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

Dated: July 5, 2024.

Respectfully submitted,

JOHN H. BRYAN LAW

/s/ *John H. Bryan*
John H. Bryan, Attorney
West Virginia Bar No. 102159
411 Main Street
P.O. Box 366
Union, West Virginia 24983
Tel: (304) 772-4999
jhb@johnbryanlaw.com

SIRI & GLIMSTAD LLP

Aaron Siri, Attorney*
Elizabeth A. Brehm, Attorney*
Walker D. Moller, Attorney*
745 Fifth Ave, Suite 500
New York, NY 10151
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com
ebrehm@sirillp.com
wmoller@sirillp.com

Christopher Wiest, Attorney*
25 Town Center Blvd., Suite 104
Crestview, KY 41017
Tel: (513) 257-1895
Fax: (859) 495-0803
chris@cwiestlaw.com

Attorneys for Plaintiff

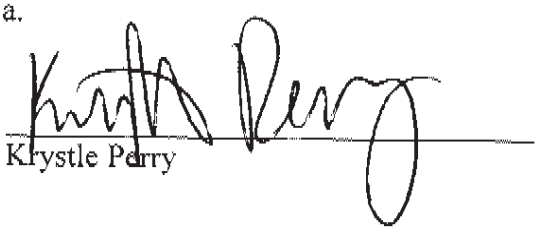
**pro hac vice* to be submitted

VERIFICATION

I, Krystle Perry, a citizen of the United States and of West Virginia, have read the foregoing Complaint and know the contents thereof as to myself and my minor child, K.P., and that the facts therein that relate to me and K.P., are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

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

Executed on July 4, 2024, in Oak Hill, West Virginia.



Krystle Perry

VERIFICATION

I, Anthony Perry, a citizen of the United States and of West Virginia, have read the foregoing Complaint and know the contents thereof as to myself and my minor child, K.P., and that the facts therein that relate to me and K.P., are true to my knowledge and as to all other matters on information and belief and I believe them to be true.

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

Executed on July 4, 2024, in Oak Hill, West Virginia.

anthony perry
Anthony Perry

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

RECEIVED 7/05/2024 2:24-cv-18

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Krystle Perry and Anthony Perry, *individually and on behalf of their minor child K.P.*

(b) County of Residence of First Listed Plaintiff Fayette
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

John H. Bryan Law, 411 Main Street, P.O. Box 366
Union, West Virginia, 24983, (304) 772-4999; jhb@johnbryanlaw.com

DEFENDANTS

See attachment for Defendant information.

County of Residence of First Listed Defendant Upshur
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ❒ 365 Personal Injury - Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 444 Welfare
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ☒ 440 Other Civil Rights

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900Appeal of Fee Determination Under Equal Access to Justice
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district (specify) ❒ 6 Multidistrict Litigation ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
42 U.S.C. § 1983

Brief description of cause:
VIOLATION OF FIRST AMENDMENT FREE EXERCISE RIGHTS

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ❒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
7/5/2024

SIGNATURE OF ATTORNEY OF RECORD
/s/ John H. Bryan

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

EXHIBIT 1

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.

5. ———, Pharmacol. Rev., 1956, v8, 175.

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.

9. Bray, G. A., Analyt. Biochem., 1960, v1, 279.

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.

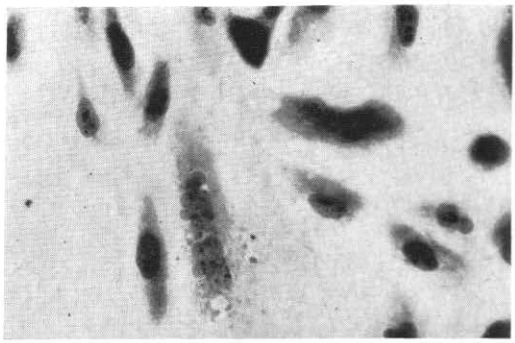


FIG. 1. Multinucleated giant cells seen in explant culture from a spontaneous abortion.

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.

1. Jensen, F. C., Gwatkin, R. B. L., Biggers, J. D., Exp. Cell Res., 1964, v34, 440.
2. Hayflick, L., Moorhead, P. S., ibid., 1961, v25, 585.

3. Lejeune, M. J., Turpin, R., Gautier, M., Rev. Fr. Etud. Clin. Biol., 1960, v5, 406.

4. Gerber, P., Kirschstein, R. L., Virology, 1962, v18, 582.

5. Boué, A., Plotkin, S. A., Boué, J. G., Arch. Ges. Virus, 1965, v16, 443.

6. Behbehani, A. M., Melnick, J. L., DeBakey, M. E., Proc. Soc. Exp. Biol. and Med., 1965, v118, 759.

7. Makino, S., Kikuchi, Y., Sasaki, M. S., Sasaki, M., Yoshida, M., Chromosoma (Berl) 1962, v13, 148.

8. Carr, D. H., Lancet, 1963, v2, 603.

9. Clendenin, T. M., Benirschke, K., Lab. Invest., 1963, v12, 1281.

10. Szulman, A. E., New England J. Med., 1965, v272, 811.

11. Hall, B., Källén, B., Lancet, 1964, v1, 110.

12. Thiede, H. A., Salm, S. B., Am. J. Obs. and Gynecol., 1964, v90, 205.

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 2

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
Attorneys for Plaintiff
200 Park Avenue
New York, NY 10166
BY: AARON SIRI, ESQ.
and
MICHAEL W. REEDS
1038 E. West Maple
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

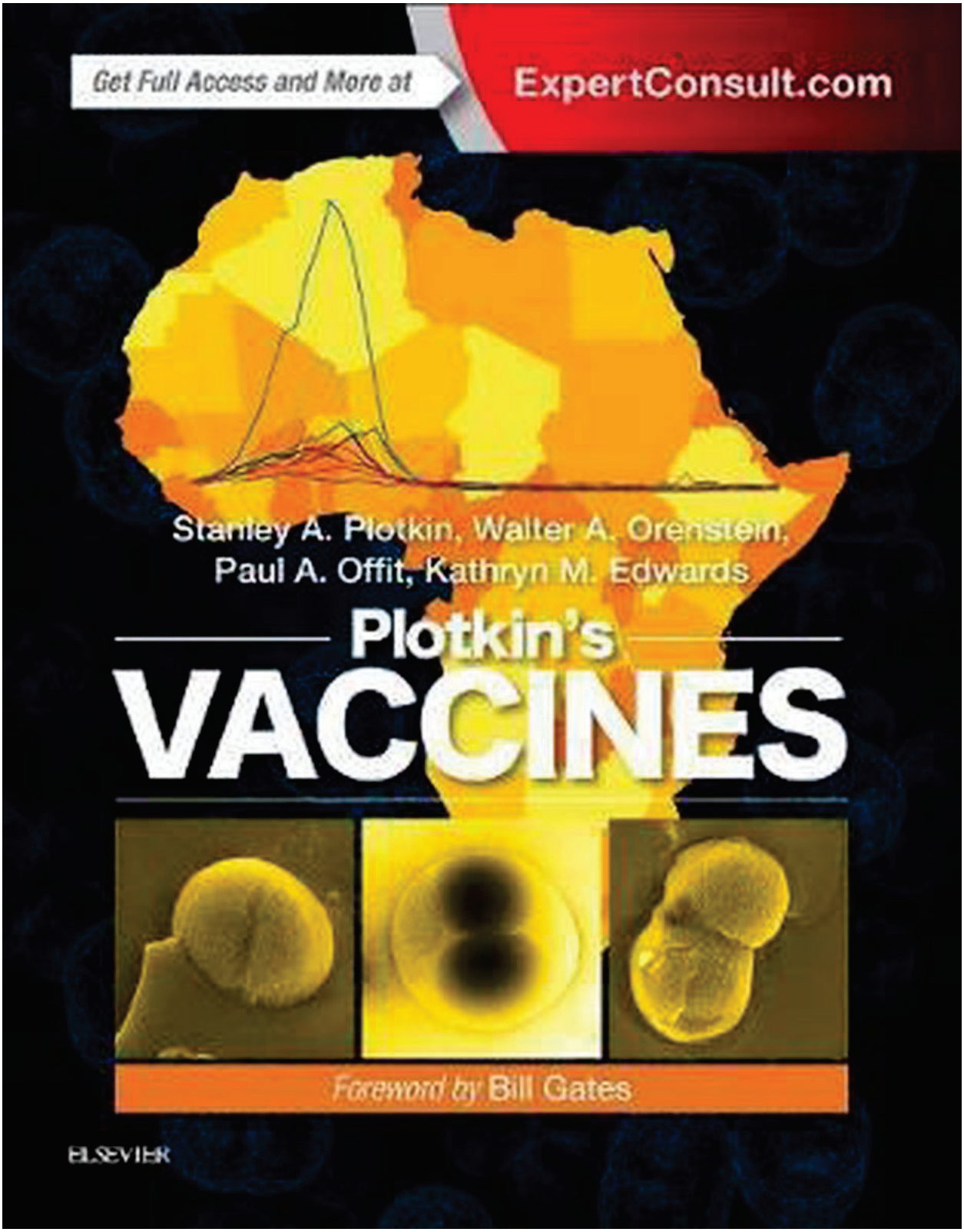

Get Full Access and More at
ExpertConsult.com
Stanley A. Plotkin, Walter A. Orenstein,
Paul A. Offit, Kathryn M. Edwards
Plotkin's
VACCINES
Foreword by Bill Gates
ELSEVIER

EXHIBIT 3

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.

15 REFERENCES

1. General Recommendations on Immunization, Recommendations of the Advisory Committee on Immunization Practices, MMWR 43(RR-1): 1-38, January 28, 1994.
2. Measles, Mumps, and Rubella — Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 47(RR-8): May 22, 1998.
3. Kelso, J.M.; Jones, R.T.; Yunginger, J.W.: Anaphylaxis to measles, mumps, and rubella vaccine mediated by IgE to gelatin, J. Allergy Clin. Immunol. 91: 867-872, 1993.
4. Bitnum, A.; et al: Measles Inclusion Body Encephalitis Caused by the Vaccine Strain of Measles Virus. Clin. Infect. Dis. 29: 855-861, 1999.
5. Angel, J.B.; et al: Vaccine Associated Measles Pneumonitis in an Adult with AIDS. Annals of Internal Medicine, 129: 104-106, 1998.
6. Cecinati V, et al. Vaccine administration and the development of immune thrombocytopenic purpura in children. Human Vaccines & Immunotherapeutics 9:5, 2013.
7. Mantadakis E, Farmaki E, Buchanan GR. Thrombocytopenic Purpura after Measles-Mumps-Rubella Vaccination: A Systematic Review of the Literature and Guidance for Management. J Ped 156(4): 2010.
8. Andrews N, Stowe J, Miller E, Svanstrom H, Johansen K, Bonhoeffer J, et al. A collaborative approach to investigating the risk of thrombocytopenic purpura after measles-mumps-rubella vaccination in England and Denmark. Vaccine. 2012;30:3042-6.
9. Rubella Prevention: Recommendation of the Immunization Practices Advisory Committee (ACIP), MMWR 39(RR-15): 1-18, November 23, 1990.

10. Peter, G.; et al (eds): Report of the Committee on Infectious Diseases, Twenty-fourth Edition, American Academy of Pediatrics, 344-357, 1997.

11. Measles Prevention: Recommendations of the Immunization Practices Advisory Committee (ACIP), MMWR 38(S-9): 5-22, December 29, 1989.

12. Eberhart-Phillips, J.E.; et al: Measles in pregnancy: a descriptive study of 58 cases. Obstetrics and Gynecology, 82(5): 797-801, November 1993.

13. Jespersen, C.S.; et al: Measles as a cause of fetal defects: A retrospective study of ten measles epidemics in Greenland. Acta Paediatr Scand. 66: 367-372, May 1977.

14. Yamauchi T, Wilson C, Geme JW Jr. Transmission of live, attenuated mumps virus to the human placenta. N Engl J Med. 1974;290(13):710-712.

15. Rubella Vaccination during Pregnancy —United States, 1971-1988. JAMA. 1989;261(23):3374–3383.

16. Losonsky, G.A.; Fishaut, J.M.; Strussenber, J.; Ogra, P.L.: Effect of immunization against rubella on lactation products. II. Maternal-neonatal interactions, J. Infect. Dis. 145: 661-666, 1982.

17. Losonsky, G.A.; Fishaut, J.M.; Strussenber, J.; Ogra, P.L.: Effect of immunization against rubella on lactation products. I. Development and characterization of specific immunologic reactivity in breast milk, J. Infect. Dis. 145: 654-660, 1982.

18. Landes, R.D.; Bass, J.W.; Millunchick, E.W.; Oetgen, W.J.: Neonatal rubella following postpartum maternal immunization, J. Pediatr. *97*: 465-467, 1980.

19. Lerman, S.J.: Neonatal rubella following postpartum maternal immunization, J. Pediatr. *98*: 668, 1981. (Letter)

20. Plotkin, S.A.; Cornfeld, D.; Ingalls, T.H.: Studies of immunization with living rubella virus: Trials in children with a strain cultured from an aborted fetus, Am. J. Dis. Child. 110: 381-389, 1965.

21. Plotkin, S.A.; Farquhar, J.; Katz, M.; Ingalls, T.H.: A new attenuated rubella virus grown in human fibroblasts: Evidence for reduced nasopharyngeal excretion, Am. J. Epidemiol. 86: 468-477, 1967.

22. Weibel, R.E.; Carlson, A.J.; Villarejos, V.M.; Buynak, E.B.; McLean, A.A.; Hilleman, M.R.: Clinical and Laboratory Studies of Combined Live Measles, Mumps, and Rubella Vaccines Using the RA 27/3 Rubella Virus, Proc. Soc. Exp. Biol. Med. 165: 323-326, 1980.

23. Watson, J.C.; Pearson, J.S.; Erdman, D.D.; et al: An Evaluation of Measles Revaccination Among School-Entry Age Children, 31st Interscience Conference on Antimicrobial Agents and Chemotherapy, Abstract #268, 143, 1991.

24. Unpublished data from the files of Merck Research Laboratories.

25. Davidkin, I.; Jokinen, S.; Broman, M. et al.: Persistence of Measles, Mumps, and Rubella Antibodies in an MMR-Vaccinated Cohort: A 20-Year Follow-up, JID 197:950–6, April 2008.

26. LeBaron, W.; Beeler J.; Sullivan, B.; et al.: Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment, Arch Pediatr Adolesc Med. 161:294-301, March 2007.

27. LeBaron, C.; Forghani, B.; Beck, C. et al.: Persistence of Mumps Antibodies after 2 Doses of Measles-Mumps-Rubella Vaccine, JID 199:552–60 , February 2009.

28. LeBaron, W.; Forghani, B.; Matter, L. et al.: Persistence of Rubella Antibodies after 2 Doses of Measles-Mumps-Rubella Vaccine, JID 200:888–99, September 2009.

29. Hilleman, M.R.; Buynak, E.B.; Weibel, R.E.; et al: Development and Evaluation of the Moraten Measles Virus Vaccine, JAMA 206(3): 587-590, 1968.

30. Weibel, R.E.; Stokes, J.; Buynak, E.B.; et al: Live, Attenuated Mumps Virus Vaccine 3. Clinical and Serologic Aspects in a Field Evaluation, N. Engl. J. Med. 276: 245-251, 1967.

31. Hilleman, M.R.; Weibel, R.E.; Buynak, E.B.; et al: Live, Attenuated Mumps Virus Vaccine 4. Protective Efficacy as Measured in a Field Evaluation, N. Engl. J. Med. 276: 252-258, 1967.

32. Cutts, F.T.; Henderson, R.H.; Clements, C.J.; et al: Principles of measles control, Bull WHO 69(1): 1-7, 1991.

33. Weibel, R.E.; Buynak, E.B.; Stokes, J.; et al: Evaluation Of Live Attenuated Mumps Virus Vaccine, Strain Jeryl Lynn, First International Conference on Vaccines Against Viral and Rickettsial Diseases of Man, World Health Organization, No. 147, May 1967.

34. Leibhaber, H.; Ingalls, T.H.; LeBouvier, G.L.; et al: Vaccination With RA 27/3 Rubella Vaccine, Am. J. Dis. Child. 123: 133-136, February 1972.

35. Rosen, L.: Hemagglutination and Hemagglutination-Inhibition with Measles Virus, Virology 13: 139-141, January 1961.

36. Brown, G.C.; et al: Fluorescent-Antibody Marker for Vaccine-Induced Rubella Antibodies, Infection and Immunity 2(4): 360-363, 1970.

37. Buynak, E.B.; et al: Live Attenuated Mumps Virus Vaccine 1. Vaccine Development, Proceedings of the Society for Experimental Biology and Medicine, 123: 768-775, 1966.

38. Hilleman M.R., Studies of Live Attenuated Measles Virus Vaccine in Man: II. Appraisal of Efficacy. Amer. J. of Public Health, 52(2):44-56, 1962.

39. Johnson, C.E.; et al: Measles Vaccine Immunogenicity in 6- Versus 15-Month-Old Infants Born to Mothers in the Measles Vaccine Era, Pediatrics, 93(6): 939-943, 1994.

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.

Distributed by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

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

uspi-v205c-i-2006r009

EXHIBIT 4

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.

15 REFERENCES

1. CDC: General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 55(No. RR-15): 1-47, 2006.
2. Weibel, R.E.; et al.: Live Attenuated Varicella Virus Vaccine. Efficacy Trial in Healthy Children. N Engl J Med. 310(22): 1409-1415, 1984.
3. Arbeter, A.M.; et al.: Varicella Vaccine Trials in Healthy Children. A Summary of Comparative and Follow-up Studies. Am J Dis Child. 138: 434-438, 1984.
4. Weibel, R.E.; et al.: Live Oka/Merck Varicella Vaccine in Healthy Children. Further Clinical and Laboratory Assessment. JAMA. 254(17): 2435-2439, 1985.
5. Chartrand, D.M.; et al.: New Varicella Vaccine Production Lots in Healthy Children and Adolescents. Abstracts of the 1988 Inter-Science Conference Antimicrobial Agents and Chemotherapy: 237(Abstract #731).
6. Johnson, C.E.; et al.: Live Attenuated Varicella Vaccine in Healthy 12- to 24-Month-Old Children. Pediatrics. 81(4): 512-518, 1988.
7. Gershon, A.A.; et al.: Immunization of Healthy Adults with Live Attenuated Varicella Vaccine. J Infect Dis. 158(1): 132-137, 1988.
8. Gershon, A.A.; et al.: Live Attenuated Varicella Vaccine: Protection in Healthy Adults Compared with Leukemic Children. J Infect Dis. 161: 661-666, 1990.
9. White, C.J.; et al.: Varicella Vaccine (VARIVAX) in Healthy Children and Adolescents: Results From Clinical Trials, 1987 to 1989. Pediatrics. 87(5): 604-610, 1991.
10. Rynn L, Cragan J, Correa A. Update on Overall Prevalence of Major Birth Defects Atlanta, 1978-2005. CDC MMWR. 57(01): 1-5, January 11, 2008.
11. American College of Obstetricians and Gynecologists Frequently Asked Questions: Miscarriage and Molar Pregnancy, 2011.
12. Galea, S.; et al.: The Safety Profile of Varicella Vaccine: A 10-Year Review. J Infect Dis. 197(S2): 165-169, 2008.
13. Hammerschlag, M.R.; et al.: Herpes Zoster in an Adult Recipient of Live Attenuated Varicella Vaccine. J Infect Dis. 160(3): 535-537, 1989.
14. Guess, H.A.; et al.: Population-Based Studies of Varicella Complications. Pediatrics. 78(suppl): 723-727, 1986.
15. Kuter, B.J.; et al.: Ten Year Follow-up of Healthy Children who Received One or Two Injections of Varicella Vaccine. Pediatr Infect Dis J. 23: 132-37, 2004.
16. Kuter, B.J.; et al.: Oka/Merck Varicella Vaccine in Healthy Children: Final Report of a 2-Year Efficacy Study and 7-Year Follow-up Studies. Vaccine. 9: 643-647, 1991.

17. Bernstein, H.H.; et al.: Clinical Survey of Natural Varicella Compared with Breakthrough Varicella After Immunization with Live Attenuated Oka/Merck Varicella Vaccine. Pediatrics. 92(6): 833-837, 1993.

18. Wharton, M.: The Epidemiology of Varicella-zoster Virus Infections. Infect Dis Clin North Am. 10(3):571-581, 1996.

19. White, C.J. et al.: Measles, Mumps, Rubella, and Varicella Combination Vaccine: Safety and Immunogenicity Alone and in Combination with Other Vaccines Given to Children. Clin Infect Dis. 24(5): 925-931, 1997.

20. Reuman, P.D.; et al.: Safety and Immunogenicity of Concurrent Administration of Measles-Mumps-Rubella-Varicella Vaccine and PedvaxHIB® Vaccines in Healthy Children Twelve to Eighteen Months Old. Pediatr Infect Dis J. 16(7): 662-667, 1997.

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.

Dist. by: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

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

uspi-v210-i-ref-1702r911

EXHIBIT 5

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:

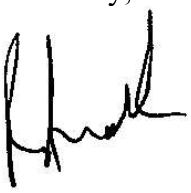
This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 9, 2020, for 'documentation sufficient to reflect any case(s) of transmission of Hepatitis B in an elementary, 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 6

Request for Review of
Denied Medical Exemption Request

Date:_____

Parent Name:_____

Address: _____ E-mail Address: _____

City:_____State:_____Zip:_____ Phone:_____

Child's Name: _____ Date of Birth:_____/_____/_____

Child's Age: _____ County of School: _____

Date of Immunization Health Officer Exemption Request Denial:_____

Below: Please explain what you feel the State Health Officer should consider as the basis for reversing the decision of the Immunization Health Officer. (Attach additional information as necessary)

Parent Signature: _____ Date:_____
(May be typed for E-mail)

May be sent by **Mail:** **West Virginia Department of Health and Human Resources**
Bureau for Public Health
Attention: State Health Officer
350 Capitol Street Room 702, Charleston, WV 25301

or **Fax:** **(304)-558-1035**

or **E-mail:** **vaccineexemption@wv.gov**

EXHIBIT 7

rom: Stacy Marteney [redacted]
Sent: Tuesday, April 2, 2024 8:59:27 AM
To: Krystle Perry <[redacted]
Subject: Re: vaccinations

Unfortunately, there is still not a religious exemption available.

Stacy Marteney, NBCT

Virtual Learning Coordinator

Upshur County Schools

[redacted] ext [redacted]

Book a meeting: Book time with Stacy Marteney

Book time to meet with me

From: Krystle Perry <[redacted]>
Sent: Monday, April 1, 2024 3:41 PM
To: Stacy Marteney <[redacted]>
Subject: Re: vaccinations

Can we do a religious exemption for Kendall Perry to attend virtual school?

Get Outlook for iOS

From: Stacy Marteney <[redacted]>
Sent: Wednesday, January 3, 2024 2:06:12 PM
To: Krystle Perry <[redacted]>
Subject: Re: vaccinations

yes

Stacy Marteney, NBCT

Virtual Learning Coordinator

Upshur County Schools

304-472-5480 ext 1029

Book a meeting: Book time with Stacy Marteney

have received this email in error, please notifythe sender immediately and delete this email from your system.

Book time to meet with me

From: Krystle Perry <[redacted]>
Sent: Wednesday, January 3, 2024 2:02 PM
To: Stacy Marteney <[redacted]s>
Subject: Re: vaccinations

[EXTERNAL SENDER]: Do not click links, open attachments or reply to this email unless you recognize the sender and know the content is safe.

Will you be in the office at 3?

Get Outlook for iOS

From: Stacy Marteney <smartene@k12.wv.us>
Sent: Wednesday, January 3, 2024 10:40:24 AM
To: Krystle Perry <AnthonysGirl8161@hotmail.com>
Subject: vaccinations

Following up on our phone call: Kendall needs her Dtap, polio, MMR, and Varicella. Please let me know by Monday what you decide.

Stacy Marteney, NBCT

Virtual Learning Coordinator

Upshur County Schools

[redacted] ext [redacted]

[redacted] a meeting: Book time with Stacy Marteney

EXHIBIT 8

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 9

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]

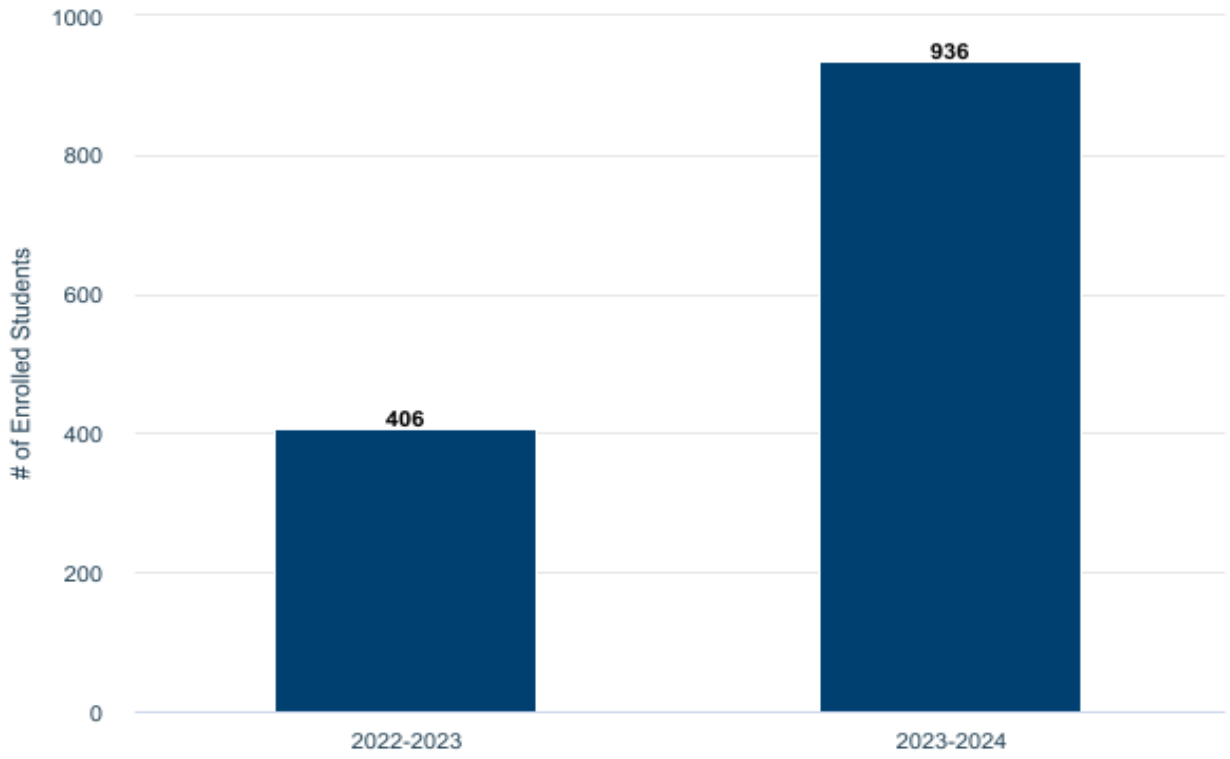
[redacted]

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 10

From: Sarah Wills [redacted]
Sent: Tuesday, April 16, 2024 11:45 AM
To: S&G Information Request Staff [redacted]
Cc: Christine Miller [redacted]
Subject: Fw: FOIA Request - IR#10010ZZ

Dear Sir or Madam,

Please find our answers below for the attached FOIA request. If you need anything else, please let us know.

For each and every Upshur County Schools public school, please provide records sufficient to show:

(1) the total number of currently enrolled students: 3.669

(2) the total number of students currently enrolled in and using the West Virginia Virtual Academy powered by K12: 1

(3) the number of currently enrolled students who have been enrolled for more than 30 days, and who do not have all required vaccinations: 46

(4) the number of currently enrolled students who have been granted a medical exemption to any required vaccination: 2

(5) the number of currently enrolled students who have been granted a religious exemption to any required vaccination: 0

(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: 0

Thank you,

Sarah Wills

Treasurer/CSBO

Upshur County Board of Education

102 Smithfield Street

Buckhannon, WV 26201

[redacted]

EXHIBIT 11

HARRISON COUNTY SCHOOLS

445 WEST MAIN STREET
POST OFFICE BOX 1370
CLARKSBURG, WEST VIRGINIA 26302-1370
(304) 326-7300
FAX (304) 326-7384

DORA L. STUTLER
Superintendent

BOARD OF EDUCATION
GARY M. HAMRICK, *President*
FRANK DEVONO, JR., *Vice President*
DOUGLAS K. HOGUE, *Member*
MARY FRANCES SMITH, *Member*
WILLIAM T. TUCKER, *Member*

WEST VIRGINIA FREEDOM OF INFORMATION ACT REQUEST

VIA EMAIL

April 10, 2024

Aaron Siri, Esquire
foia@sirillp.com

Re: *Unvaccinated Students (IR#10010R)*

Dear Aaron Siri:

Please allow this letter to serve as a response to your request for information under the West Virginia Freedom of Information Act ("WV FOIA") which was received by the Harrison County Board of Education (the "Board") on April 7, 2024.

For each and every Harrison County Schools public school, please provide records sufficient to show:

(1) the total number of currently enrolled students; 9,559

(2) the total number of students currently enrolled in and using the West Virginia Virtual Academy powered by K12; please contact the West Virginia Virtual Academy, do not have this information.

(3) the number of currently enrolled students who have been enrolled for more than 30 days, and who do not have all required vaccinations;
22 students total= 9 on medical exemptions and 13 on provisional enrollment with catch up vaccine schedule

(4) the number of currently enrolled students who have been granted a medical exemption to any required vaccination;
9 students with medical exemption from state health officer

(5) the number of currently enrolled students who have been granted a religious exemption to any required vaccination;
0 students with religious exemption- WV law does not allow religious exemptions.

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.
0 students

Sincerely,

Dora L. Stutler

Dora L. Stutler
Superintendent
Harrison County Schools
[redacted]

EXHIBIT 12

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Bureau for Public Health
Office of Epidemiology and Prevention Services

Bill J. Crouch
Cabinet Secretary

Ayne Amjad, MD, MPH
Commissioner & State Health Officer

REQUEST FOR MEDICAL EXEMPTION FROM COMPULSORY IMMUNIZATION FORM

(Incomplete or non-legible forms will be returned)

Name of Student:	Birth Date:
Parent/Guardian:	Phone Number:
Address of Student:	
Name of School and County:	
School Nurse and Contact Information:	
Healthcare Provider Requesting Exemption:	
Address and Phone Number of Healthcare Provider:	

Select the immunizations for which the exemption is requested:

New school entry:

- ☐ Diphtheria
- ☐ Tetanus
- ☐ Pertussis
- ☐ Polio
- ☐ Measles
- ☐ Mumps
- ☐ Rubella
- ☐ MMR
- ☐ Varicella
- ☐ Hepatitis B

7th Grade:

- ☐ Tdap Booster
- ☐ Meningococcal

12th Grade:

- ☐ Tdap Booster
- ☐ Meningococcal

Is the requested exemption:

- ☐ Permanent
- ☐ Temporary
  - o Expected duration: _____

*** Continued on Page 2 ***

Why does this child need an immunization exemption? If the request is based on a previous reaction, please attach medical records. If the child is on immunosuppressive medication, please include relevant diagnosis and duration of therapy.

Is there further information you feel is relevant to this request?

Are the vaccinations documented in this child's record in the West Virginia Statewide Immunization Information System (WVSIIS) complete?

☐ Yes
☐ No*
☐ Unsure*

*If No or Unsure, please include a copy of the child's immunization record with this request.

Requesting Healthcare Provider (Print Name) _____

Signature _____

Date _____