

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

CHILDREN'S HEALTH DEFENSE,
a California Nonprofit corporation,

COMFORT GEOFFREY, individually
and as parent and legal guardian of S.G.,
W.G., minor children,

LEONARD ROBERTS, individually
and as parent and legal guardian of A.R.,
a minor child,

MARIA PARRILLO, individually, and as
parent and legal guardian of I.P., a
minor child,

JENNIFER MORRISSEY, individually and
as parent and legal guardian of G.M., a
minor child,

DENISE SEDJIAN, individually and as
parent and legal guardian of K.C., B.C., and
B.C., minor children,

MARIA HUBER, individually and as parent
and legal guardian of C.H., and E.H., minor
children, and

JESSICA ZARECZKY, individually and as
parent and legal guardian of L.B., minor
child,

Plaintiffs,
v.

**THE CITY OF PHILADELPHIA,
THE CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH,
AND CHERYL BETTIGOLE, M.D., M.P.H.,**
in her official capacity as Health
Commissioner for the City of Philadelphia
Department of Public Health

Defendants.

Case No. 23-cv-4228

**COMPLAINT FOR
DECLARATORY RELIEF**

COME NOW Plaintiffs Children’s Health Defense (“CHD”), a not-for-profit corporation, and Comfort Geoffrey, Leonard Roberts, Maria Parrillo, Jennifer Morrissey, Denise Sedjian, Jessica Zareczky, and Maria Huber, and individually and as parents and legal guardians of their minor children (collectively, “Plaintiff-Parents”), by and through their attorneys, to file their Complaint seeking Declaratory Relief.

I. INTRODUCTION

2. This lawsuit is not brought to debate vaccine science. Rather, the lawsuit is narrowly focused on the City of Philadelphia Department of Public Health’s minor consent regulations’ violation of state and federal law, such that declaratory relief is necessary to prevent further imminent harm to children and families. Children at the tender age of eleven (11) are simply too young to make vaccination decisions on their own. The Court must recognize and declare the regulations’ inherent illegality.

3. For more than fifteen years, the City of Philadelphia has engaged in an impermissible “wink and a nod” practice of going behind parents’ backs to vaccinate children without ensuring informed consent. This policy was thrust to the forefront during the COVID-19 pandemic, and, in fact, the City of Philadelphia promulgated specific regulations for COVID-19 shots. Philadelphia’s regulations violate both federal and Pennsylvania Commonwealth law.

4. Effective August 27, 2007, the City of Philadelphia Department of Public Health enacted “Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents (the “General Minor Consent Regulation”) (attached hereto as Ex. 1), allowing minors between the ages of eleven (11) and eighteen (18) to receive vaccinations without

parental consent, provided the minor is given a vaccine information statement (“VIS”)¹ for the vaccine being administered.² This regulation does not and never has provided guidance on what constitutes “informed consent” by a minor and does not require written informed consent. Also, this regulation absolves the vaccine administrator of liability when this undefined so-called consent has been given, whether recorded or not.

5. On May 14, 2021, in response to the COVID-19 outbreak and the availability of unlicensed COVID-19 vaccines produced under an Emergency Use Authorization (“EUA”), The City of Philadelphia Department of Public Health enacted a regulation titled “Emergency Regulation for the Control and Prevention of COVID-19 Supplementing the Regulation Governing the Immunization and Treatment of Newborns, Children, and Adolescents (Vaccine Information Statements)” (the “COVID-19 Minor Consent Regulation”) (attached hereto as Ex. 2). The General Minor Consent Regulation and the COVID-19 Minor Consent Regulation are referred to herein collectively as the “Minor Consent Regulations.”

6. This action seeks necessary declaratory relief to prevent imminent harm to children and families from the Minor Consent Regulations.

7. In particular, the COVID-19 Minor Consent Regulation is an “emergency regulation” enacted in response to the COVID-19 outbreak and availability of COVID-19 vaccines. However, Defendants have ignored that the President of the United States, Joseph Biden, Jr., **declared the COVID-19 emergency over in May 2023** (the emergency ended in Pennsylvania in 2021, shortly after the COVID-19 Minor Consent Regulation was enacted).

¹ See Exhibit 1, 4(b).

² There is no VIS for eleven-year-olds who receive a COVID-19 vaccine.

Based on the language of the COVID-19 Minor Consent Regulation, the Defendants intend for its operation to continue in perpetuity and, notably, in the absence of any emergency.

8. Both Minor Consent Regulations permit vaccination of children as young as eleven years old without parental knowledge, consent, or permission. Vaccinating minor children without knowledge or consent of their parents or legal guardians violates parental constitutional rights to direct their child's upbringing and disregards valid religious and philosophical exemptions obtained under Pennsylvania law. These regulations raise troubling issues of informed consent, freedom of religion, parental rights, and due process, implicating both the United States Constitution and the Constitution of the Commonwealth of Pennsylvania and other federal and Commonwealth laws.

9. The Minor Consent Regulations remove parents from critical decision making that is an integral part of the family unit and that safeguards a child's well-being. By taking down the protective guardrails of parental consent, the Minor Consent Regulations violate federal and Commonwealth laws and put children at serious risk of harm.

10. Parents are in the best position to make important health, education, and other decisions for their minor children, including vaccination decisions, because they can consider their child's unique biological makeup, their child's individual as well as familial medical history, their family's faith, and lifestyle.

11. By contrast, most – if not all – minor children are too young to know or accurately recall details of their own health history or family health history and to understand the importance of this information, to fully understand and weigh the risks and benefits of vaccination, and to offer true informed consent, and in particular, consent free from coercion. Moreover, most – if not all – children do not appreciate that if they are injured by a vaccine, they

cannot sue the vaccine manufacturer for vaccines on the CDC's childhood schedule or, of particular relevance here, the complicated requirements in seeking compensation in the Vaccine Injury Compensation Program (the "VICP") for most vaccines administered to children or the futility of trying to obtain any compensation under the Countermeasures Injury Compensation Program (the "CICP") for a COVID-19 vaccine injury.

12. The Minor Consent Regulations eviscerate Plaintiff-Parents' federally protected right to receive critical information regarding vaccines before their child receives an injection to not only inform them of risks regarding each vaccine but also to advise them of their right to file a claim and seek compensation in the VICP under the National Childhood Vaccine Injury Act of 1986 (the "NCVIA"), 42 USCS § 300aa-1, *et seq.*, in the event of injury by childhood vaccines or under the CICP for COVID-19 vaccines under section 319 of the Public Health Service Act.

13. The National Childhood Vaccine Injury Act of 1986 requires a health care provider administering a vaccine to a child to provide the child's parent or other legal representatives a copy of information "presented in understandable terms [that] shall include – (1) a concise description of the benefits of the vaccine; (2) a concise description of the risks associated with the vaccine; (3) a statement of the availability of the [VICP]; and, (4) such other relevant information as may be determined by the Secretary." 42 USCS § 300aa-26(c)-(d). A VIS is particularized to each vaccine. For eleven-year-old children, for whom EUA COVID-19 vaccines are authorized, **there is no VIS**.³

14. It is critical that parents are informed before their child receives a vaccine so they can be on alert for any symptoms or adverse reactions following vaccine administration, but also due to the short window of time in which to seek compensation in the VICP or the CICP for any

³ See Exhibits 5 and 6.

injuries. The Minor Consent Regulations impermissibly make an end run around federally guaranteed parental rights to be informed before vaccination and take away the very remedy that Congress provided in the VICP and the CICP.

15. Additionally, the Minor Consent Regulations conflict with Pennsylvania law requiring parental consent for vaccinations by pharmacists because according to the **Commonwealth law, pharmacists cannot vaccinate minors without parental permission.**⁴ Thus, to the extent that pharmacists in Philadelphia vaccinate minors in the absence of parental consent, those pharmacists violate Commonwealth law.

16. Moreover, COVID-19 vaccine injuries are not covered by NCVIA or the administrative proceedings in the VICP. COVID-19 vaccine injuries are only covered under the CICP, an administrative process which, among other procedural irregularities, bars participation by attorneys representing injured claimants. The CICP is an administrative process that, as of October 21, 2023, has compensated only six claims, averaging just under \$3,000 for each for death or serious bodily injury claim.⁵

17. Not a single vaccine administered to children has ever been subjected to a true placebo (inert substance)-controlled study. It is highly unlikely that children are aware of this information or that children understand the importance of this fact.

18. Additionally, and of critical importance, COVID-19 vaccines available today in the United States for eleven-year-old children are still investigational and have not been licensed as safe and effective. Children are not capable of understanding the risks associated with a novel

⁴ 63 P.S. § 390-9.2(a)(5).

⁵ <https://www.hrsa.gov/cicp/cicp-data/table-4> (viewed October 21, 2023).

vaccine and cannot appreciate that there are no long-term studies of the safety or effectiveness of these vaccines.

19. The Philadelphia Department of Public Health leads Philadelphia’s COVID-19 response and provides services, support, and guidance for COVID-19.⁶

20. Therefore, CHD and Plaintiff-Parents seek an order of the Court, pursuant to 28 U.S.C. § 2201, declaring enforcement and implementation of the Minor Consent Regulations to be wholly unlawful, and any further concerted activities, messaging, and enticements directed to minors, including the children of Plaintiff-Parents, to be similarly unlawful.

21. Plaintiffs further seek from the Court a declaration pursuant to 28 U.S.C. § 2201 that the Minor Consent Regulations violate federal and Pennsylvania Commonwealth law⁷ and deprive Plaintiff-Parents of their right to freely exercise their religion in violation of the First Amendment of the United States Constitution and deprive the Plaintiff-Parents of their constitutional rights to direct the care and upbringing of their children, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution. Plaintiff-Parents further allege that Defendants’ Minor Consent Regulations violate Article II, Section 1 of the Pennsylvania Constitution.

22. Finally, Plaintiffs seek costs and attorneys’ fees pursuant to 42 U.S.C. § 1988, and any other and further relief that the Court deems just and proper.

⁶ <https://www.phila.gov/programs/coronavirus-disease-2019-covid-19/>

⁷ *Booth v. Bowser*, No. 21-cv-01857 (TNM), 2022 U.S. Dist. LEXIS 48877, at *54 (D.D.C. Mar. 18, 2022) (Federal court order based upon conflict preemption strikes down effectively the same bill in the District of Columbia that attempted to allow children a right to consensual vaccination. “Plaintiffs have shown that the NCVIA likely preempts the MCA. The Minor Consent Regulation is inconsistent with, directly conflicts with, and therefore fully pre-empted by the National Childhood Vaccine Injury Act (“NCVIA”), 42 U.S.C. 300aa, et seq.”).

II. JURISDICTION AND VENUE

23. This Court has original subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) because this action arises under the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States. This Court additionally has original subject matter jurisdiction under 28 U.S.C. § 1343(a)(3) (civil rights), 42 U.S.C. § 1983 (“civil action for deprivation of rights”), 42 U.S.C. § 300aa, *et seq.* (National Childhood Vaccine Injury Act of 1986), and 28 U.S.C. § 2201 (declaratory relief), and includes additional state law claims arising under the same case and controversy.

24. Venue is proper before this Court under 28 U.S.C. § 1391(e) on two independent bases: Leonard Roberts, Maria Parrillo, and Comfort Geoffrey reside in this judicial district; and the acts and omissions that gave rise to Plaintiff-Parents’ claims occurred in this judicial district.

III. PARTIES

25. Plaintiff Children’s Health Defense (hereinafter, “CHD”) is a 501(c)(3) nonprofit corporation organized under the laws of the State of California with chapters and membership throughout the United States including in the Commonwealth of Pennsylvania. CHD is an advocacy group dedicated to research, education, and litigation of, *inter alia*, governmental actions that pose a threat to the health and well-being of children. Since the World Health Organization proclaimed a COVID-19 pandemic, CHD has sharply focused on the activities of state and local governments, including the Commonwealth of Pennsylvania and the City of Philadelphia, regarding laws and regulatory measures responding to the pandemic and has closely followed government coordination with special interests, including pharmaceutical manufacturers, to maximize the number of children receiving Covid-19 vaccines, and to monitor the merits and bases for imposition of pandemic response measures.

26. Plaintiff Comfort Geoffrey is a citizen of the United States of America, a member of CHD, and a resident of Philadelphia, Pennsylvania. Ms. Geoffrey is the biological mother of S.G. and W.G. who are 13 and 11 years old, respectively, and who reside with Ms. Geoffrey in Philadelphia and are home schooled.

27. Plaintiff Leonard Roberts is a citizen of the United States of America, a member of CHD, and a resident of Philadelphia, Pennsylvania. Dr. Roberts is the biological father of a minor daughter A.R., who resides with Dr. Roberts in Philadelphia, is 11 years old, and is enrolled in public school in Philadelphia.

28. Plaintiff Maria Parrillo is a citizen of the United States of America, a member of CHD, and is a resident of Philadelphia, Pennsylvania. Ms. Parrillo is the biological mother of I.P., who is 13 years old, resides with Ms. Parrillo in Philadelphia, and is home schooled.

29. Plaintiff Jessica Zareczky is a citizen of the United States of America, a member of CHD, and is a resident of Bethlehem, Pennsylvania, located approximately 60 miles north of Philadelphia. Ms. Zareczky is the biological mother of L.B., who is 15 years old, resides with Ms. Zareczky, and attends public school in Bethlehem.

30. Plaintiff Jennifer Morrissey is a citizen of the United States of America, a member of CHD, and is a resident of Merion Station, Pennsylvania, located approximately five-and-one-half miles outside of Philadelphia. Ms. Morrissey is the biological mother of G.M., who is 14 years old, resides with Ms. Morrissey, and attends private school in the district.

31. Plaintiff Denise Sadjian is a citizen of the United States of America, a member of CHD, and is a resident of New Hope, Pennsylvania, in Bucks County, located approximately forty miles outside of Philadelphia. Ms. Sedjian is the biological mother of K.C., G.C., and B.C., who are 11, 13 and 14 years of age, respectively, reside with her, and attend public school. The

father of the children lives in Philadelphia, and the children are frequently in Philadelphia as a result.

32. Plaintiff Maria Huber is a citizen of the United States of America, a member of CHD, and is a resident of New Hope, Pennsylvania, located approximately forty miles outside of Philadelphia. Ms. Huber is the biological mother of 2 minor children, E.H and C.H., 12 and 17 years of age, respectively, who reside with her and attend private school right outside the City of Philadelphia.

33. Defendant, the City of Philadelphia, is a municipal corporation of the first class of the Commonwealth of Pennsylvania under the First-Class City Home Rule Act of 1949.

34. Defendant, the City of Philadelphia Department of Public Health, is an agency of Defendant the City of Philadelphia, and is located at 1101 Market St., 13th Floor, Philadelphia, PA 19107.

35. Defendant, Cheryl Bettigole, M.D., M.P.H., is named as a Defendant here in her official capacity as Health Commissioner of the City of Philadelphia Department of Public Health. Upon information and belief, Dr. Bettigole's office is located at 1101 Market St., 13th Floor, Philadelphia, PA 19107.

IV. FACTUAL AND LEGAL BACKGROUND

A. NCVIA Occupies the Field and the General Minor Consent Regulation Conflicts with NCVIA and Therefore is Unenforceable

36. The National Childhood Vaccine Injury Act provides (in pertinent part):

(b) Unavoidable adverse side effects; warnings.

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] if the injury or death resulted from side effects that were

unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 USCS § 300aa-22a(b).

37. In 1986 Congress enacted the NCVIA, which is codified at 42 U.S.C. § 300aa, *et seq.*, with a clear intent to occupy the field of law regarding the administration of childhood vaccinations and the remedies for injuries from them. The General Minor Consent Regulation must be declared unenforceable because it conflicts with and is fully pre-empted by NCVIA.

38. The NCVIA was enacted in response to a growing number of lawsuits alleging neurological damage due to vaccine injuries. It created a no-fault compensation program to stabilize the vaccine market, which was adversely affected by an increase in tort-related litigation, and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries and deaths too costly or difficult. *Breusewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

39. As the United States Supreme Court explained in *Breusewitz*, the NCVIA is based upon the premise that vaccine injury is unavoidable. *Id.* at 229-30. If a large enough number of children are vaccinated, eventually some children will be seriously injured, including severe neurological damage, or will die as a result. Congress created the National Vaccine Injury Compensation Program (the “VICP”) as part of the NCVIA to address this issue, as well as complaints that obtaining compensation for legitimate vaccine-inflicted injuries was too costly and difficult.⁸ The VICP provides financial relief and support for parents whose children were

⁸ “Design defects, in contrast, do not merit a single mention in the NCVIA or the FDA’s regulations. Indeed, the FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use. And the decision is surely not an easy one. Drug manufacturers often could trade a little less efficacy for a little more safety, but the safest design is not always the best one. Striking the right balance between safety and

injured by childhood vaccines (as well as adults injured by vaccines included on the federally recommended vaccine schedule), and since its creation has paid out over \$5 billion in compensation for vaccine injuries.

40. Under the NCVIA, “[a]s a quid pro quo, manufacturers enjoy significant tort-liability protections. Most importantly, the [NCVIA] eliminates manufacturer liability for a vaccine’s unavoidable, adverse effects.” *Id.* at 229.

41. Two types of injury claims are permitted in the VICP. First, are so called “Table” injuries. The NCVIA’s Vaccine Injury Table (the “Table”) (attached hereto as Ex. 3) lists vaccines covered by the NCVIA, describes each vaccine’s compensable adverse side effects, and indicates the short time post-vaccination, during which those adverse effects must first manifest to be considered Table injuries. The Table was intended to make possible Congress’ comprehensive regulatory scheme of fast, informal adjudication, and Table injuries are presumptively compensable. Therefore, unless the U.S. Department of Health and Human Services can prove an alternative cause of injury, Table injuries are compensated.

42. Further, other injuries (so-called “non-Table injuries”) also may be compensable, but the process to obtain compensation for non-Table injuries is more challenging. If the child’s injury is not listed on the Table, or if the injury listed on the Table does not manifest until after the short time period listed on the Table, then the petitioner bears the burden of proving causation.

43. Congress’ regulatory scheme under NCVIA is dependent on recognizing vaccine injuries in a timely manner. Not only is timely recognition important for receiving follow-up

efficacy is especially difficult with respect to vaccines, which affect public as well as individual health.” *Bruesewitz*, 562 U.S. at 237-38.

medical care, but it is also an element of proving that one is entitled to legal compensation for injuries – compensation that may be necessary for a lifetime of care.

44. As part of this comprehensive regulatory scheme, Congress has defined “legal representative” as “a parent or an individual who qualifies as a legal guardian under State law.” 42 U.S.C. § 300aa-33(2).

45. The vaccines identified in the Table are the same vaccines recommended by the United States Advisory Committee on Immunization Practices (“ACIP”) and can also be administered by authorized vaccine providers under the General Minor Consent Regulation.

B. The Role of Vaccine Information Statements

46. As part of the NCVIA, Congress mandated that the Secretary of the U.S. Department of Health and Human Services “shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.” 42 U.S.C. § 300a-26(a).

47. Congress further mandated that the Secretary develop and publish these materials in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the CDC, and the FDA. 42 U.S.C. § 300aa-26(b).⁹

48. VISs are important in recognizing and preventing vaccine injuries, which may include – among other things – severe allergic reactions, brain injury, paralysis, and death.

⁹ As noted above, the “Vaccine Information Materials” referenced in 42 U.S.C. § 300aa-26 are commonly referred to as “Vaccine Information Statements” or “Vaccine Information Sheets” (“VIS”). The terms “Vaccine Information Materials,” “Vaccine Information Statements,” and “Vaccine Information Sheets” are commonly used as interchangeable terms.

49. VISs are designed to provide parents with the minimum information needed to understand the benefits and risks of administering vaccines, so that parents can form and give informed consent. This includes information such as a list of persons who should not receive a particular vaccine, the risks of that vaccine, and adverse events to watch for.

50. The primary purpose of the VIS is to educate parents about potential “adverse events” that may result from a vaccine, which may include severe life-threatening allergic reactions, seizures, brain damage, and ultimately death. Failing to recognize vaccine adverse events in a child can result in a child not receiving immediate, necessary medical care.

51. VISs also warn parents that allergic reactions and other adverse events may be precautions and contraindications to other vaccines. Failure to timely recognize vaccine allergic reactions and other adverse events that are precautions or contraindications to other vaccines place a child at risk of serious injury or death.

52. Finally, VISs also provide parents with specific information about the VICP, applicable timelines, and how to seek compensation in the event their child suffers a vaccine injury.

53. The NCVIA requires that “[t]he information in [the VISs] shall be based on available data and information, shall be presented in understandable terms and shall include . . . such other relevant information as may be determined by the Secretary [of the U.S. Department of Health and Human Services].” 42 U.S.C. §§ 300a-26(c) and (d). In other words, the VISs may not be hyper technical – **VISs must be presented in a way that parents can understand.**

54. In sum, the information contained on the mandatory VISs is critical to advise parents of risk of, and potential prevention of, serious harm, to educate parents about potential

“adverse events”, including, but not limited to, brain injury and death, and to inform parents about the VICP in the event of injury or death.

55. As part of the NCVIA’s comprehensive regulatory scheme, Congress has mandated that “each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed” by the Secretary. 42 U.S.C. § 300a-26(d).

56. As part of this comprehensive regulatory scheme, Congress has mandated that the Secretary’s informational materials “shall be provided prior to the administration of such vaccine” to a child’s parent. 42 U.S.C. § 300a-26(d).

57. Nothing in the NCVIA mandates that the VIS be written in language a child can understand and, in fact, the NCVIA simply does not contemplate that a child may be vaccinated without parental consent. Quite the opposite – the language of the NCVIA is clear that the VIS is provided to the parent who is able to offer informed consent on behalf of his or her child. Under the Minor Consent Regulations, the parent or legal guardian is removed from the equation.

C. The Minor Consent Regulations Stand In Stark Contrast to Commonwealth and Federal Law Regarding Minor Decision-Making Authority and Ability

58. At issue here is whether the City of Philadelphia can promote vaccination of minors behind parents’ backs. Several Philadelphia regulations consider children under eighteen years old to be minors, though Pennsylvania law generally recognizes minors as under the age of twenty-one.¹⁰ As discussed below, laws limiting what activities minors may engage in have long-

¹⁰ The Commonwealth of Pennsylvania generally defines a minor as a “person under the age of 21 years.” 1 Pa. C.S. § 1991.

existed for the protection of children, many of whom are incapable because of age, immaturity, lack of education, etc., from making sound decisions.

59. In an 1845 decision in the matter of *Queen v Smith*, an English court established the common law “Rule of Sevens” regarding capacity to consent: (i) “minors from birth to age seven [have] no capacity,” (ii) “minors between the ages of seven and fourteen [have] a rebuttable presumption of no capacity,” (iii) “minors from age fourteen to twenty-one [have] a rebuttable presumption of capacity,” and (iv) “[t]hose over twenty-one [are] presumed to have full capacity.”¹¹

60. In Pennsylvania, individuals under eighteen generally may not receive medical treatment absent parental consent. Pursuant to 35 P.S. § 10101: “Any minor who is eighteen years of age or older, or has graduated from high school, or has married, or has been pregnant, may give effective consent to medical, dental and health services for himself or herself, and the consent of no other person shall be necessary.” Additionally demonstrating that children cannot consent to their own medical care, 11 P.S. § 2513 allows a parent to authorize another adult to consent to medical treatment for a minor child when the parent is unable to consent. Emphasizing the gravity and necessity of informed consent for a minor's medical care by a parent or other adult, the authorization given by a parent to another adult must be written and “shall be signed by the parent, legal guardian or legal custodian in the presence of and along with the contemporaneous signatures of two witnesses who are at least 18 years of age.” *Id.* at (c)(1). Further, recognizing the importance of an adult receiving a VIS, “[t]he authorization may

¹¹ *The Queen v. Smith* established the common law Rule of Sevens. Paul Arshagouni, “But I’m an Adult Now. . .Sort of,” 9 J. H EALTH CARE L.& P OL’Y 315, 332 (2006). Molly J. Walker Wilson, Legal and Psychological Considerations in Adolescents’ End-Of-Life Choices, 110 NW. U. L. REV. O NLINE 33, 40 (2015); see also *Bellotti v. Baird*, 443 U.S. 622, 622 (1979).

also include the right to act as the minor's legal representative for the purposes of receiving informational materials regarding vaccines under section 2126 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 300aa-26)..” *Id.* at (a).

61. Other existing federal and Pennsylvania laws clearly recognize the need for minors to be treated differently from adults, particularly in situations where the activity to be undertaken, the product to be consumed, or the decision to be made may be accompanied by significant risks to a minor’s health and safety that a minor might not have the capacity to fully comprehend. For example:

- a. Minors must obtain work permits in Pennsylvania before beginning work;¹²
- b. Parental permission is required to marry under age 18 in Pennsylvania;¹³
- c. Minors are normally under the jurisdiction of Juvenile Court if under 18 (with the exception of age fourteen for aggravated felonies and age fifteen for murder);¹⁴
- d. In Pennsylvania, the age of consent for sexual acts is sixteen;¹⁵
- e. To purchase alcohol, the legal minimum age is twenty-one;¹⁶
- f. In Pennsylvania, a person must be 18 to enter into an enforceable contract;¹⁷
- g. One must be sixteen to obtain a learner’s permit to obtain a driver’s license;¹⁸

¹² <https://www.education.pa.gov/Pages/Codes%20and%20Regulations/Child-Labor-Law.aspx>

¹³

<https://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2019&sessInd=0&billBody=H&billTyp=B&billNbr=0360&pn=3660>

¹⁴ <https://ojjdp.ojp.gov/sites/g/files/xyckuh176/files/pubs/tryingjuvasadult/states/pa.html>

¹⁵ <https://pcar.org/laws-policy/age-consent>

¹⁶ EB: 2012 Pa. Laws 151, §§ 2 and 29 CS: 43 Pa. Cons. Stat. § 40.2 CR: 40 Pa. Code § 5.14

¹⁷ At a minimum, individuals 18 and over can, for example, enter into contracts and sue or be sued. 23 Pa. C.S. § 5101.

- h. With very limited exceptions relating to supervision by specific adults, parental consent, and hunting, you must be eighteen in Pennsylvania to possess a firearm;¹⁹
- i. One must be at least sixteen to donate blood;²⁰
- j. One must be eighteen to purchase lottery tickets or play a lottery game;²¹
- k. One must be twenty-one to enter a casino;²²
- l. One must be eighteen to make a will in Pennsylvania;²³
- m. To purchase tobacco products, the minimum legal age is twenty-one.²⁴
- n. One must be at least seventeen (and parental consent is required at seventeen) to enlist in any branch of the active military.²⁵ Further, federal law requires nearly all-male US citizens and male immigrants, 18 through 25 (not younger), to register with Selective Service.²⁶
- o. One must be at least eighteen to serve as a juror;²⁷ and

¹⁸ <https://www.dmv.pa.gov/Driver-Services/Driver-Licensing/Pages/get-driver-license.aspx>

¹⁹ <https://www.pafoa.org/law/>

²⁰ <https://www.health.pa.gov/topics/programs/Pages/Blood-Donation.aspx>

²¹ https://lottery-pa.custhelp.com/app/answers/detail/a_id/3341/~/~should-i-allow-my-child-to-play-scratch-off-games%3F

²² <https://www.legalgamblingages.com/legal-gambling-age-for/pennsylvania.html>

²³ 20 Pa. C.S.A. §2501.

²⁴ 21 U.S.C. § 387f <https://www.health.pa.gov/topics/programs/tobacco/Pages/Act-112.aspx#:~:text=Retailers%20across%20Pennsylvania%20can%20no,under%20the%20age%20of%2021.>

²⁵ <https://www.usa.gov/join-military>

²⁶ <https://www.sss.gov/>

²⁷ <https://www.pacourts.us/Storage/media/pdfs/20220610/141011-jurydutyinpennsylvania-whatyouneedtoknow.pdf>

p. A child fourteen years and older may self-consent to mental health treatment, however the parent must be promptly notified to exercise the parent’s right of objection if in-patient mental health treatment is contemplated. 50 Pa. Stat. §§ 7201, 7204.

62. The decision to “vaccinate” is a critical decision affecting health and, unless a parent is unfit, a child’s parent or guardian should make that decision.

D. Philadelphia’s Impermissible Minor Consent Regulations Do Not Ensure Informed Consent and Eviscerate Parental Rights In Violation Of Federal and Pennsylvania Law

1. The Minor Consent Regulations Do Not Ensure Informed Consent By Young Children and Impermissibly Assume That Children May Consent To Serious Medical Treatment

63. The Minor Consent Regulations violate both federal and Commonwealth laws concerning informed consent and parental consent.

64. As shown above, Pennsylvania has traditionally, as a matter statutory and common law, recognized that children **are not equivalent to adults** and must be protected from engaging in certain activities deemed dangerous to their health and well-being or unsuitable given their lack of necessary maturity.

65. In particular, as noted above, with so much at risk, including to health, well-being, and life, a medical care provider should obtain true informed consent from a patient or – in the case of children – from a parent or guardian before treatment.

66. In addition to the federal and Commonwealth laws described above requiring parental consent to vaccination applicable to all Pennsylvania healthcare professionals who administer vaccines, Pennsylvania law also expressly limits the authority of pharmacists to administer vaccines to children. Pharmacists may not administer any vaccines to children four

years of age or younger. 63 P.S. § 390-9.2(a)(5).²⁸ Further, the only vaccines pharmacists may administer to children between five and eighteen years of age are influenza and COVID-19 vaccines, and the law **mandates that pharmacists obtain parental consent before administering** them. *Id.*

67. Philadelphia’s Minor Consent Regulations turn these requirements on their head. Rather than protecting children, Philadelphia’s Minor Consent Regulations let any child walk into a temporary vaccine “pop-up clinic” or elsewhere on a whim, roll up her sleeve and receive a vaccine without her parents’ knowledge and even more importantly, her parents’ protective veil of consent.

68. The Minor Consent Regulations are a house of cards built on the unsupported, unsupportable, and preposterous presumption that every Philadelphia child aged eleven and up is capable of true informed consent, knows her own medical history, her family’s medical history, can truly ascertain the potential serious risks and alleged benefits of a treatment, and can read and understand any written information – written for adults – presented to her without further explanation.

69. “Informed Consent” generally means voluntary agreement given by a person or a patient’s responsible proxy (for example, a parent) for participation in a study, immunization program, treatment regimen, invasive procedure, etc., after being informed of the purpose, methods, procedures, benefits, and risks.

²⁸ In 2022, the Commonwealth allowed many waivers expanding who could administer COVID-19 injections and under what circumstances such individuals could administer certain injectable biologics. <https://www.dos.pa.gov/Pages/COVID-19-Waivers.aspx>. (last viewed October 28, 2023)

70. The essential criteria of informed consent are that: (1) the subject has both knowledge and comprehension, (2) that consent is freely given without duress or undue influence, and (3) that the right of withdrawal at any time is clearly communicated to the patient. Other aspects of informed consent in the context of epidemiologic and biomedical research, and criteria to be met in obtaining it, are specified in International Guidelines for Ethical Review of Epidemiologic Studies (Geneva: CIOMS/WHO 1991) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO 1993).

71. When it comes to minors' informed for medical interventions, law, psychology, studies in child development, and tradition dictate that there are individual differences between children, that one size does not fit all, that dedicated time and expertise on the part of the medical professional is required to determine if an individual child, on a case by case basis, is "mature" enough, cognitively, intellectually, experientially, and emotionally under the totality of the circumstances to provide knowing and informed consent to the purported benefits and risks of, and alternatives to accepting administration of any medication, especially of an EUA or recently licensed vaccine. The Minor Consent Regulations on their face provide no guarantee that any of these crucial considerations will be fulfilled by even a competently trained "health care provider" before the injection.

72. Exhibit 1 demonstrates that beginning in 2007, Defendant Philadelphia Department of Public Health allowed minors to consent to immunization:

4(b) Minor's Consent to Immunization.²⁹ A person between the ages of 11 and 18 may authorize his or her own immunization, without the approval or consent of another person, to prevent occurrence of a reportable disease, infection, or condition, provided such person is capable of providing informed consent. A

²⁹ <https://www.phila.gov/media/20190716120557/BOH-School-and-Childcare-Immunization-Regulations-Consolidated-July-19-2019.pdf>

parent or guardian does not need to be present at the time the vaccine is administered. Written consent by the minor is not required, but documentation that the vaccine information statement (VIS) was provided to the vaccine recipient, and the publication date of the VIS, is required. The health care provider may not be sued or held liable for providing such immunization to the minor if the minor has consented to such procedures or treatment.³⁰

73. First, while the VIS is intended to be comprehensible to parents, there is no requirement that the VISs are written at a level understandable by children as young as 11 years old. For example, attached hereto as Exhibit 4 is the current COVID-19 vaccine VIS.³¹ It clearly shows that VISs are not written in language intended for children to comprehend. Further, there is no requirement that a provider ensures that the child can read and understand the VIS and has the opportunity to ask questions or seek adult guidance before receiving the vaccine.

74. While this regulation baldly requires that the child receiving the vaccine is purportedly “capable of providing informed consent,” it utterly fails to offer any guidance as to what constitutes informed consent by the minor. Nor do the Minor Consent Regulations cite to any evidence to support what appears to be a mere assumption that children – who likely lack knowledge of their individual and familial medical history and who in many instances cannot read or comprehend the VIS – can offer true informed consent. Merely handing a child a VIS is particularly troubling in a school district like Philadelphia where students’ test scores are alarmingly low: only 34% of elementary students tested at or above the proficient level for reading, and only 20% tested at or above that level for math. Similarly, only 34% of middle school students tested at or above the proficient level for reading, and a mere 19% tested at or

³⁰ <https://www.phila.gov/media/20190716120557/BOH-School-and-Childcare-Immunization-Regulations-Consolidated-July-19-2019.pdf> (at Sec. 4(b), p.6).

³¹ COVID-19 vaccines are still EUA for eleven-year-olds, and those children must be given the Fact Sheet, not the VIS

above that level for math. Finally, only 43% of high school students tested at or above the proficient level for reading, and only 32% tested at or above that level for math.^{32, 33}

75. Tragically, on top of all this, should a child who agrees to vaccination be injured as a result, the provider is insulated from liability where he or she allegedly obtained verbal “consent.” **No concrete proof of consent is required.** Indeed, because the Minor Consent Regulations explicitly do not require written consent, providers are discouraged from documenting how consent was obtained or if true informed consent was obtained at all.

76. In short, simply requiring that the child be handed a VIS is theatre masking as consent.

77. The COVID-19 Minor Consent Regulation piggybacks on this earlier regulation, but astonishingly claims that section 4(b) of the earlier General Minor Consent Regulation found that minors ages 11 and up were “typically capable of providing informed consent.” Contrary to this statement, there is no such finding in the General Minor Consent Regulation and nothing cited there or in the COVID-19 Minor Consent Regulation that supports such a far-fetched statement. (*See* Exhibit 1.)

78. As recognized above, there is no VIS for COVID-19 vaccines authorized under EUA for eleven-year-olds. Instead, a provider administering an EUA vaccine to these children should hand them a Pfizer-BioNTech fact sheet (attached hereto as Exhibit 5) or a Moderna fact sheet (attached hereto as Exhibit 6) depending on the COVID-19 vaccine administered. There is

³² <https://www.usnews.com/education/k12/pennsylvania/districts/philadelphia-city-sd-101796#:~:text=Test%20Scores%20at%20Philadelphia%20City%20School%20District&text=A%20C%2034%25%20of%20middle%20school,above%20that%20level%20for%20math.>

³³ https://cdn.philasd.org/offices/performance/Open_Data/School_Performance/District_Scorecard/DPR_SY1819_District_Scorecard_20200128.pdf

no requirement that the provider review the fact sheet³⁴ with a child before injection to ensure that the child understands it. Moreover, if anything, distinguishing and deciphering the COVID-19 fact sheet and VIS is a complex task.

79. The fact sheets are directed at the parental consent as Exhibit 5 begins with, “Your child is being offered the Pfizer-BioNTech COVID-19 vaccine ...” and Exhibit 6 begins with “Your child is being offered the Moderna COVID-19 vaccine ...” Clearly these fact sheets are not directed at, written for, or understandable by eleven-year-olds.

80. Neither of the Minor Consent Regulations provides guidance to a provider as to how to determine if a particular child is capable of understanding a VIS or a Fact Sheet for COVID-19 vaccines or is capable of providing true informed consent. Indeed, as stated above, test scores for students in Philadelphia suggest the opposite.

81. Neither of the Minor Consent Regulations requires written consent from a child. The City of Philadelphia Department of Public Health fails to provide: medical professionals any standardized guidelines or checklists regarding the child’s cognitive level, emotional maturity, knowledge of health or psychiatric conditions; any requirement that a licensed physician or nurse administer the vaccine; inquiry regarding prior vaccine history or past medical history that might reveal past or likely vaccine reactions or other health conditions including autoimmune or heart diseases; the child be returned safely home after the injection; reassurance before the child “consents” that the child knows and understands – particularly if that injection is only allowed

³⁴ Upon information and belief, the Fact Sheets are written at a 10th grade level whereas two-thirds of all American students are reading below grade level, e.g., 66% of 4th graders (9-10 years old) are reading below grade level. <https://www.ascendlearningcenter.com/blog-highlights/howmanystudents>

because of an EUA – the limitations of safety and effectiveness data, as well as her rights under state and federal law to refuse vaccination.

82. Moreover, the Minor Consent Regulations require none of the following:

- a. Any inquiry into the health and safety of the home the child comes from and what the consequences the child may face if the parents discover that their child agreed to receive a vaccine without their knowledge or consent;
- b. With respect to any vaccine, any explanation of the limitations of the vaccine;
- c. Particularly with respect to the COVID-19 vaccine, any clarification to the child that, if the child has received the vaccine out of concern that she might transmit a virus or disease to parents, grandparents, or other older people she loves, the vaccine does not work that way, and those adults will not magically be made any safer by the child receiving the vaccine; and
- d. Any provision to confirm the vaccine provider supplied information regarding any alternate interventions to the vaccine – including that no vaccination is necessary.

83. Thus, the Minor Consent Regulations sharply conflict with the federal NCVIA and Pennsylvania law, which generally require a parent's or adult guardian's written informed consent before a medical professional is allowed to perform medical-surgical procedures on a child, including, but not limited to, surgery with anesthesia; radiation or chemotherapy; administration of an experimental medication; or use an experimental device.

84. Moreover, with respect to the COVID-19 Minor Consent Regulation, given the dismantling of emergency conditions for Emergency Use Authorization, Philadelphia now lacks

any valid basis to continue enforcement of this regulation, if any basis ever existed, and which Plaintiffs contend never existed.³⁵

E. The General Minor Consent Regulation Conflicts With and is Preempted by Federal Law

85. The General Minor Consent Regulation subverts the NCVIA’s requirement that a parent receive a VIS prior to each vaccine by commanding that health providers seek consent from minors and simply hand them a VIS without determining if they can understand – or even read – the document, instead of providing these required materials to parents in seeking the parents’ consent.

86. The General Minor Consent Regulation ignores the fact that the VIS data provided to a minor may not be easily understandable by a minor, as required by the NCVIA, as the VIS for the MMR (Measles, Mumps, and Rubella) (Exhibit 7) demonstrates.

87. The language of the NCVIA is clear: parents, not children, must give consent. “Congress’ reference to “the legal representatives of any child” and then to “any other

³⁵ Putting Pennsylvania in the forefront, Governor Wolf’s final extension by amendment to his original Proclamation of Disaster Emergency formally ended on June 15, 2021, with all Covid-19-related restrictions for unvaccinated individuals, except masking mandates, ending on May 31, 2021. In further consideration of the fact that there was no longer a pandemic devastating the country, putting the health, safety and welfare of the citizens and children of the Commonwealth at risk, on June 11, 2021, Philadelphia phased out the last of its “Safer at Home” Covid-19-related restrictions; and On June 15, 2021, Pennsylvania’s Covid-19 emergency declaration formally came to end. <https://thehill.com/homenews/state-watch/558593-pennsylvania-ends-covid-19-emergency-declaration/> President Biden Announced Pending National End to Emergency in a televised interview last November, President Biden declared that “the pandemic is over.” On May 11, 2023, public and national health emergencies for Covid-19 ended. <https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html#:~:text=The%20federal%20COVID%2D19%20PHE,and%20testing%2C%20will%20remain%20available.>

individual” conveys that when the person receiving the vaccination is a child, **the VIS must be given** to the legal representative. 42 U.S.C. § 300aa-26(d).

88. Because a vaccine provider cannot comply with both the General Minor Consent Regulation and the NCVIA (as well as Commonwealth law), and because the NCVIA provides parents with federally protected rights, the General Minor Consent Regulation must be declared unenforceable and **fully pre-empted by the NCVIA**.

89. Indeed, recently, the D.C. Circuit Court in *Booth v. Bowser*, No. 21-cv-01857 (TNM), 2022 U.S. Dist. LEXIS 48877 at *55 (D.D.C. Mar. 18, 2022), found that the NCVIA pre-empted a similar law in the District of Columbia that attempted to lower the age of consent to eleven years of age for vaccinations. The *Booth* Court ordered “that Defendants, their agents, employees, and successors in office are hereby enjoined from enforcing 22-B DCMR § 600.9 (Minor Consent for Vaccinations Amendment Act of 2020 § 2) pending further order of this Court.” According to the *Booth* Court: “If Congress did not mean for the legal representative of a child to receive a VIS when his child receives a vaccine, then the phrase “the legal representatives of any child” would be superfluous. All Congress would have needed to say is that a healthcare provider should give a VIS “to any individual to whom such provider intends to administer such vaccine.” But it did not do that.” *Id.* at *28-29.

90. The Court in *Booth* recognized the DC Minor Consent Law’s irreconcilable conflict with the NCVIA. First, because parents and guardians, not minor children, make claims for compensation in the VICP, they (not their minor children) must receive the VIS and provide consent to vaccination. *See id.*; 42 U.S.C. § 300aa-11(b)(1)(A); *Booth*, 2022 U.S. Dist. LEXIS 48877 at *35-37. Second, if a regulation hides vaccination from parents and guardians and parents and guardians are denied access to a child’s accurate vaccination records, they likely

cannot make a connection between vaccination and a child's injury or death resulting from vaccination, which obviously hinders or eviscerates a parent's or guardian's ability to file a claim in the VICP. The VICP has no mechanism to toll claims until a child reaches the age of majority and has a strict three-year statute of limitations. Like the minor consent law at issue in *Booth*, the General Minor Consent Regulation here irreconcilably conflicts with the NCVIA and therefore cannot stand.

F. Parental Rights to Control Medical Decision-Making for Their Children are Constitutionally Protected and are Enshrined in Case Precedent Under Both Federal and Pennsylvania Law

91. Beyond conflict of law preemption by the NCVIA and, conflict with Commonwealth law as described above, both the Minor Consent Regulations also violate parents' fundamental right to the care, custody, and control of their own children, a right long recognized under the United States Constitution. This right specifically includes a parent's right to make fundamental medical decisions for their minor children.

92. According to the CDC and scientific studies, vaccines are capable of causing serious harm. Vaccine side effects can range from mild problems such as fever, rash and swelling of glands, to moderate problems such as joint pain, or low platelet count, to severe problems such as serious allergic reactions, deafness, long-term seizures, coma, lowered consciousness, anaphylaxis, permanent brain damage, and death. The CDC spells out the dangers and purported benefits in a list of vaccines and links to VISs.

93. The CDC admits “rates of COVID-19-associated hospitalization are currently lowest among children and adolescents ages 5-17 years....”³⁶

94. By allowing providers to vaccinate children ages eleven and older without parental consent and thus without providing parents a federally required VIS prior to each vaccination, the Minor Consent Regulations pose substantial, ongoing, and imminent medical risks to children – a risk the U.S. Congress has deemed unacceptable in the context of the NCVIA. Specifically, when a child receives a vaccination without a parent’s knowledge and consent and is harmed as a result, the parent is, in all probability, unable to recognize that the child suffered a vaccine-induced injury. Not being able to recognize the cause of an ongoing physical injury in a child because a parent has been stripped of their rights can lead to serious medical consequences for the child. If the parent has not been provided the minimum information necessary to recognize a post-vaccination adverse event, the parent may not know to seek immediate medical attention and will not be able to provide a full and relevant medical history to a treating provider.

95. Moreover, a parent – lacking knowledge of their child’s vaccination – may not be aware of the VICP or the CICIP or be able to participate in these government-funded restitution programs, which have very circumscribed periods to make a claim (three years in the VICP and one year in the CICIP). Thus, a family may be foreclosed from funds to which they may be entitled to assist in what is often tremendously expensive care for their vaccine-injured child.

96. As a population group, children under eighteen (and particularly the youngest children at whom these regulations are directed (eleven and twelve-year-olds, for example)), are

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<https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm#:~:text=Rates%20of%20COVID%20D19%E2%80%93associated,had%20no%20underlying%20medical%20conditions.>

too young to compare and appreciate the risks and benefits of vaccination, both generally and in the applied context of patient personal and family history, particularly in the short time (if any) allotted for a vaccination during a medical visit, trip to the school nurse's office, or excursion to a local pharmacy. Indeed, physicians experienced in obtaining informed consent have reported that it is not possible for eleven-year-old children as a group to understand the risks and benefits of vaccination.³⁷

97. Children in this age range are also uniquely swayed by peer and school pressure and pressure from perceived authority figures such as doctors, nurses, and pharmacists, not to mention propaganda by the media and health agencies.

98. Parental oversight is necessary to counterbalance these influences.

99. In *Troxel v. Granville*, 530 U.S. 57 (2000), the Supreme Court of the United States recognized that one of the oldest fundamental liberty interests protected by the Constitution is the interest of parents in the care, custody, and control of their children. The *Troxel* Court acknowledged the long line of cases going back almost a century establishing parents' constitutionally protected rights in the upbringing of their children. *Id.* at 65-66 (discussing *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923); *Pierce v. Society of Sisters*, 268 U.S. 510, 534-535 (1925); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944)).

100. Many other Supreme Court decisions also recognize and uphold the fundamental right of parents to control the upbringing of their children.

³⁷ Diekema DS. Adolescent brain development and medical decision-making. *Pediatrics*. 2020;146(suppl 1):S18-S24. doi:10.1542/peds.2020-0818F (last viewed 10/21/2023).

101. In *Santosky v. Kramer*,³⁸ the Court declared that “freedom of personal choice in matters of family life is a fundamental liberty interest protected by the Fourteenth Amendment.”

102. In *Wisconsin v. Yoder*, the Court declared that “the history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. This primary role of the parents in the upbringing of their children is now established beyond debate as an enduring American tradition.”³⁹

103. As also recognized by the Supreme Court, the fundamental rights of parents are implicated when the state intervenes and substitutes its decision making for that of the parents.

104. In *Cleveland Board of Education v. LaFleur*,⁴⁰ the Court warned that “freedom of personal choice in matters of . . . family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment.”

105. In *Parham v. J.R.*,⁴¹ the Court stated that “our constitutional system long ago rejected any notion that a child is ‘the mere creature of the State,’ and, on the contrary, asserted that parents generally ‘have the right, coupled with the high duty, to recognize and prepare [their children] for additional obligations.’ Surely, this includes a ‘high duty’ to recognize symptoms of illness and to seek and follow medical advice. The law’s concept of the family rests on the presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life’s complex decisions.”

³⁸ *Santosky v. Kramer*, 455 U.S. 745, 753 (1982).

³⁹ *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972).

⁴⁰ *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 639-640 (1974).

⁴¹ *Parham v. J.R.*, 442 U.S. 584, 621 (1979).

106. Further, the fundamental right of bodily integrity has been recognized by the Supreme Court for well over a century. As the Supreme Court found in *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891), “No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.” See also *Washington v. Harper*, 494 U.S. 210, 229 (1990) (“The forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.”).

107. A fit parent’s decision with respect to the care, custody, and control of his or her child cannot be overridden by the government unless the government has a compelling interest and its actions are narrowly tailored to accomplish that compelling interest.

108. Pennsylvania law⁴² provides that “the control of one’s own person and the right of self-determination are closely guarded through the principle of informed consent, which declares that absent an emergency, medical treatment may not be imposed without a person’s permission.” Further, “the right to refuse treatment or to withdraw treatment once it has begun is a logical corollary to that principle.”⁴³

109. Of central importance here and as a recognized exception to an individual’s right to exercise medical decision making authority, minors are generally considered incompetent as a matter of law to make healthcare decisions or to consent to medical treatment.⁴⁴ Therefore,

⁴² *Commonwealth of Pa. v. Nixon*, 761 A.2d 1151, 1157 (Pa. 2000) (citing *In re Fiori*, 673 A.2d 905, 909 (Pa. 1996)) (Cappy, J., concurring).

⁴³ *Id.*

⁴⁴ *Parents United for Better Schools v. Sch. Dist. of Phila.*, 978 F. Supp. 197, 206 (E.D. Pa. 1997).

Pennsylvania parents or other duly appointed guardian must do so on their behalf since parents have the legal power and duty to make decisions for their children (until the child reaches the age of 18.)⁴⁵ Under Pennsylvania law, parents protect their children, including an “affirmative duty . . . to seek medical help when the life of a child is threatened, regardless of, and in fact despite, their religious beliefs.”⁴⁶

110. The Minor Consent Regulations disregard the importance of parents’ superior knowledge of a minor’s medical history and genetic predisposition, as well as the legal and constitutional rights Parents have to make these critical health decisions for their own children.

111. Where, as here, Plaintiff-Parents are fit with respect to the care, custody and control of their children, there is no reason, let alone a compelling state interest, to disturb parental authority.

G. Informed Consent/Refusal in Vaccination is a Fundamental Right

112. True informed consent cannot possibly be obtained with the Minor Consent Regulations at issue here. The Philadelphia Department of Public Health has provided no standards or guidelines as to information that must be conveyed to the child or to ensure that informed consent is provided (and discourages written informed consent). In fact, the Department assumes that all children age eleven and older can provide “informed consent” despite the overwhelming evidence that this simply is not true, given that the vast majority of Philadelphia students cannot perform at even grade level in fundamental skills such as reading

⁴⁵ *Nixon*, 761 A.2d at 1153.

⁴⁶ *Commonwealth of Pa. v. Foster*, 764 A.2d 1076, 1082 (Pa. Super. Ct. 2000). In *Foster*, a 2-year-old was terminally ill with renal carcinoma because his parents failed to seek medical care. They believed instead that “God would raise Patrick up and restore him to perfect health.” The Department of Human Services intervened with a restraining order, and the child survived after medical treatment. *Id.*, at 1078-80.

and math, let alone critically analyze complex medical and scientific information. Minors as young as eleven are not adults and cannot consent to an invasion of their bodily autonomy because they simply do not have the ability to assess risks and benefits on their own. Yet under the Minor Consent Regulations, behind closed doors an adult stranger can ask an eleven-year-old girl to “consent” to medical injections.

113. Moreover, the Minor Consent Regulations allow minors to receive vaccines without manufacturer liability.

114. Whether a vaccine is lifesaving, safe, effective, or is even essential for a particular child’s health is a nuanced medical and personal subject matter. Parents, and not school nurses, pop-up clinics, politicians, teachers, or any other adult – whether well-meaning or predatory – should be making these decisions for any children other than their own.

V. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

28 U.S.C. § 2201 and 42 U.S.C. § 1983

(Adoption and Enforcement of Unconstitutional Regulations that Violate Informed Consent and Deprive Parents of Federal Statutory Rights Guaranteed by the National Childhood Vaccine Injury Act of 1986, in Violation of Article VI and the Fifth and Fourteenth Amendments to the United States Constitution)

115. The allegations contained in the preceding paragraphs are hereby realleged and are incorporated by reference as if fully set forth herein.

116. Article VI, Clause 2 of the U.S. Constitution states that the Constitution and laws of the United States shall be the supreme law of the land.

117. By enacting the NCVIA, Congress expressed a clear intent to occupy the field of law as to the administration of childhood vaccinations. Congress has mandated that before a vaccine is administered to a child, the parent must receive a detailed Vaccine Information Statement (VIS) and further requires that detailed information about each vaccine—including

date of administration, the manufacturer and lot number, and the name and address of the health care provider administering the vaccine—is recorded in the child’s permanent, available health record.

118. In direct conflict with the NCVIA, the General Minor Consent Regulation allows a child to be injected without the parent’s knowledge or consent and conceals that information from the child’s parent. By depriving parents of knowledge of their children’s vaccinations, intentionally and surreptitiously stripping parents of their decision-making rights regarding the medical care of their children and placing that decision-making squarely in the hands of the government, the General Minor Consent Regulation subverts the protections of the NCVIA, and violates the Supremacy Clause (Article VI) and the Fifth and Fourteenth Amendments to the Constitution.

119. In direct conflict with the NCVIA, the General Minor Consent Regulation prevents the parent from receiving federally mandated Vaccine Injury Statements at the time the child is vaccinated (and before the vaccine is administered). By depriving parents of any knowledge that their child may be at increased risk of serious harm or death, the General Minor Consent Regulation subverts Congress’s intent to protect children. The General Minor Consent Regulation thus usurps the responsibility and authority of federal health agencies to which Congress assigned the development and publication of Vaccine Information Statements. The General Minor Consent Regulation thus violates the Supremacy Clause of Article VI and the Due Process Clause of Fifth and Fourteenth Amendments to the United States Constitution.

120. Because the General Minor Consent Regulation provides no notice to parents, parents are stripped of the opportunity to assert their rights under NCVIA. The information contained on the federally approved VISs is critical for parents to potentially prevent serious

harm and to inform parents about the VICP in the event their child is injured. By giving license to surreptitiously vaccinating children, the General Minor Consent Regulation erects barriers making it difficult if not impossible for parents like Plaintiffs to vindicate their legal rights.

121. The plain language of the General Minor Consent Regulation and other information has caused Plaintiff-Parents to fear that their children may be pressured into submitting to vaccination without their parental knowledge or consent.

122. Therefore, Plaintiffs ask this Court to declare the General Minor Consent Regulation illegal and to issue declaratory relief preventing Defendants from enforcing it.

SECOND CAUSE OF ACTION
VIOLATION OF 28 U.S.C. § 2201 and 42 U.S.C. § 1983
(Adoption and Enforcement of Unconstitutional Regulations that Deprive Parents of Their Fundamental Right to Direct the Upbringing of their Children in Violation of the Fifth and Fourteenth Amendments of the U.S. Constitution)

123. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference as if fully set forth herein.

124. As shown above, long-standing precedent from the United States Supreme Court and this Circuit clearly establish that parents have a fundamental right to direct the upbringing of their children. (*See* paragraphs 99-105 *supra*).

125. The Minor Consent Regulations do not hinge on any finding of parental unfitness. On the contrary, the Minor Consent Regulations permit authorized vaccine providers to administer vaccines to minor children without any consideration of the parents' fitness. Instead, the provider makes a nebulous and undefined "assessment" of whether a minor child can provide informed consent. The vaccinator has unfettered discretion to determine a child's alleged informed consent with no guidelines of how to determine if a child can consent and with no proof required of how the vaccinator reached his or her determination.

126. Parents must be entitled to be involved in such critical and potentially life-altering decisions as supporting by the U.S. Constitution and case law interpreting it.

127. Therefore, Plaintiffs ask this Court to declare the Minor Consent Regulations illegal and to issue declaratory relief preventing Defendants from enforcing them.

THIRD CAUSE OF ACTION
NON-DELEGATION

128. The allegations contained in the preceding paragraphs are hereby realleged and incorporated by reference as if fully set forth herein.

129. The Pennsylvania Constitution Article II, Section 1, the legislative power of the Commonwealth of Pennsylvania is vested in the General Assembly and is delegated to the municipalities only by limited grant.

130. The City, its Department of Public Health, and/or the Health Commissioner have not been delegated authority from the General Assembly to establish laws or regulations that contradict the laws of the Commonwealth.

131. The Minor Consent Regulations do not reflect the basic policy choices necessary to establish an adequate exercise of legislative power and do not include adequate standards which will guide and restrain the exercise of the delegated administrative functions. Instead, The Minor Consent Regulations illegally attempt to usurp the Commonwealth's power and place in the hands of the City's administrative agencies, or even the unelected Advisory Board, under the guise of an unavailable blanket authority, to establish their own system with no intelligible principles to guide their authority.

132. Therefore, Plaintiffs ask this Court to declare the Minor Consent Regulations illegal and to issue declaratory relief preventing Defendants from enforcing them.

VI. CONCLUSION

133. For the foregoing reasons, the Minor Consent Regulations must be declared unlawful and unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Parents respectfully request that this Court:

- A. Issue a declaratory judgment that the General Minor Consent Regulation conflicts with the National Childhood Vaccine Injury Act of 1986 thereby depriving parents and children of their statutory rights to have prior knowledge and consent before vaccines are administered to minor children;
- B. Issue a declaratory judgment that, because the General Minor Consent Regulation conflicts with the National Childhood Vaccine Injury Act of 1986, it is unconstitutional and violates the Supremacy Clause of the United States Constitution;
- C. Issue a declaratory judgment that the Minor Consent Regulations deprive parents of their fundamental right to direct the care and upbringing of their children, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States;
- D. Issue a declaratory judgment that the Minor Consent Regulations violate the non-delegation provisions of the Pennsylvania Constitution;
- E. Declare that the Minor Consent Regulations are unenforceable;
- F. Award Plaintiffs costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and
- G. Grant such other and further relief as the Court deems just and proper.

A JURY TRIAL IS HEREBY DEMANDED

Dated: November 1, 2023

Respectfully submitted,

THE LAW OFFICES OF
TRICIA S. LINDSAY

By: Tricia Lindsay
TRICIA S. LINDSAY
Counsel for Plaintiffs,
Children's Health Defense
531 E. Lincoln Ave., Ste. 5B
Mount Vernon, New York 10552
(914) 668-4908; (347) 386-4604
Tricialindsaylaw@gmail.com
Attorney@tricialindsaylaw.com

/s Mary S. Holland
MARY S. HOLLAND
(subject to admission Pro Hac Vice)
New York State Bar Number 2355618
Children's Health Defense
852 Franklin Ave, Suite 511
Franklin Lakes, NJ 07417
Tel: (202) 854-1310
mary.holland@childrenshealthdefense.org

/s Ray Flores
RAY L. FLORES II
(subject to admission Pro Hac Vice)
California State Bar Number 233643
11622 El Camino Real Suite 100
San Diego, CA 92130
Tel: (858) 367-0397
rayfloreslaw@gmail.com