

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

Lina Cole, on behalf of herself and her eleven-year-old daughter A.C., Melissa Golpl, on behalf of herself and her fifteen-year-old son P.K., Denise Randello, on behalf of herself and her thirteen-year-old daughter A.R., Lisa Boyle Meyer, on behalf of herself and her sixteen-year-old daughter K.M., and Toby Doell-Carbone, on behalf of herself and her eleven-year-old twins M.C. and J.C.,

Plaintiffs,

-against-

Howard Zucker, in his official capacity as the Commissioner of the New York State Department of Health,

Defendant.

COMPLAINT

Plaintiffs captioned above as for their Complaint against the above-captioned Defendant allege as follows:

INTRODUCTION

1. In an effort to reduce the incidence of Human Papillomavirus (“**HPV**”), healthcare professionals have placed a substantial emphasis on administering HPV vaccines, such as Gardasil or Gardasil-9 manufactured by Merck & Co., Inc., to minor children. However, these vaccines come with significant potential adverse reactions. Government data shows that since 2007 HPV vaccines have been associated with at least 48,601 cases of adverse events, including: 300 deaths, 1,650 individuals permanently disabled, 4,168 hospitalizations, and 13,785 emergency room visits.

2. Nevertheless, in May 2016 the New York Department of Health (“**DOH**”), through the Defendant, its commissioner, promulgated a new regulation that it asserts allows healthcare professionals to administer vaccines like Gardasil or Gardasil-9 to minor children without their

parents' consent or knowledge (the "**No Consent or Knowledge Rule**"). The regulation is codified in 10 NYCRR § 23.4.

3. Plaintiffs here are not intrinsically opposed to the HPV vaccine, and their children are otherwise completely vaccinated. But, they are concerned that their children may receive the vaccine without their awareness and involvement. They are concerned that if their children experience an adverse reaction to the vaccination, they may not associate the reaction with the vaccination and may not have sufficient knowledge to properly seek treatment for their children.

4. As a result, the Plaintiffs bring this action to challenge the validity of the No Consent or Knowledge Rule to the extent it permits health care practitioners in New York State to inject Gardasil or Gardasil-9 manufactured by Merck & Co., Inc., into children without parental consent or knowledge.

5. As set forth herein, the No Consent or Knowledge Rule is invalid because 42 U.S.C. § 300aa-26, part of the National Childhood Vaccine Injury Act, requires that *before* a child is injected with any vaccine, such as Gardasil or Gardasil-9, the parent or legal guardian of such child must be provided the Vaccine Information Statement created by the Center for Disease Control for the specific vaccine. The Information Statements for Gardasil and Gardasil-9 explain, *inter alia*, who should avoid these products, the risks of a reaction, what to look for after injection and what to do if there is a serious reaction to one of these products.

6. In addition, enforcement of the No Consent Or Knowledge Rule is unconstitutional because it violates the Fourteenth Amendment of the United States Constitution, and enforcement is unlawful for that separate and distinct reason. The Supreme Court has long recognized the constitutional right of parents to be present and have a decision making role when medical procedures are being performed on their children.

7. Accordingly, this action seeks a declaration of the invalidity of the No Consent Or Knowledge Rule and a permanent injunction enjoining enforcement of this rule.

PARTIES

8. Plaintiffs are all parents with children between the ages of eleven and sixteen.

9. Plaintiff Lina Cole is a mother with an eleven-year-old daughter A.C., and is a registered nurse. They reside in Webster, New York.

10. Plaintiff Melissa Golpl is a mother with a fifteen-year-old son P.K. who has an intellectual disability. They reside in Buffalo, New York.

11. Plaintiff Denise Randello is a mother with a thirteen-year-old daughter A.R. They reside in Deer Park, New York.

12. Plaintiff Lisa Boyle Meyer is a mother with a sixteen-year-old daughter that has been severely injured by an HPV vaccine. They reside in Manhasset, New York.

13. Plaintiff Toby Doell-Carbone is a mother with eleven-year-old twin boys M.C. and J.C. Ms. Doell-Carbone is a registered nurse whose duties included vaccinating patients. They reside in Ontario, New York. (All children whose initials are provided above shall be referred to herein as “their children.”)

14. Defendant Howard Zucker is the Commissioner of the New York State Department of Health (the “**DOH**”).

JURISDICTION AND VENUE

15. This Court has original subject matter jurisdiction to adjudicate the claims asserted herein because the claims arise under the Constitution, laws or treaties of the United States, within the meaning of 28 U.S.C. § 1331.

16. Venue is proper within this District pursuant to 28 U.S.C. § 1391(a) because the defendant Mr. Zucker's office is located in Albany, New York, where he performs his official duties.

FACTS

A. Gardasil and Gardasil-9 Are the Only HPV Vaccines Available in the United States

17. The term Human Papillomavirus refers to a class of viruses which can be transmitted, among other ways, through sexual contact. There are over 148 known strains of HPV. In some circumstances, the HPV virus can cause people to develop certain cancers, such as cervical cancer.

18. Currently there are two vaccines for HPV licensed and sold in the United States, Gardasil and Gardasil-9 manufactured by Merck & Co., Inc., which are intended to protect against four strains and nine strains of HPV, respectively.

19. Previously GlaxoSmithKline Biologicals also produced an HPV vaccine called Cervarix. However, GlaxoSmithKline has recently withdrawn Cervarix from the United States vaccine market.

20. Gardasil and Gardasil-9 are recommended to be given in two or three injections over a multi-month period. It is recommended that the vaccine be administered to children between the ages of 11 and 12, through it can be given to children as young as 9 and older children who have not yet contracted the virus.

21. The HPV vaccine is intended to be administered before a child is sexually active because, according to Merck, "Gardasil 9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity."

B. DOH's New Regulation Permits Healthcare Practitioners to Administer the HPV Vaccine Without Parental Knowledge or Consent

22. In May 2016, the DOH put into effect a new regulation, the No Consent Or Knowledge Rule, which it claims permits healthcare practitioners in New York to administer an HPV vaccine to minors without the consent or knowledge of their parent or guardian.

23. New York Public Health Law, Section 2305(2), enacted in substance in 1972, permits a healthcare provider to “diagnose, treat or prescribe for a person under the age of twenty-one years without the consent or knowledge of the parents or guardian of said person, where such person is *infected* with a sexually transmitted disease, or has been *exposed to infection* with a sexually transmitted disease.” (emphasis added.) Thus, by enacting this Section, the Legislature made the policy decision that the exigent need to treat a child for a sexually transmitted disease that the child either had contracted or had been exposed to, outweighed a parent’s right to participate in the decision making process for their children’s medical care.

24. Pursuant to this statute, the DOH in 2016 created the No Consent Or Knowledge Rule as part of its recent addition of Section 23.4 to Title 10 of the New York Codes, Rules and Regulations (“NYCRR”). That new section provides in relevant part:

When a health care provider diagnoses, treats or prescribes for a minor, without the consent or knowledge of a parent or guardian as permitted by section 2305 of the Public Health Law, neither medical nor billing records shall be released or in any manner be made available to the parent or guardian of such minor without the minor patient’s permission. *In addition to being authorized in accordance with section 2305 of the Public Health Law to diagnose, treat or prescribe for a person under the age of 18 years without the consent or knowledge of the parent or guardian of such person where the individual is infected with a sexually transmitted disease, or has been exposed to infection with a sexually transmitted disease, health care practitioners may (as authorized by their scope of practice)*

render medical care related to other sexually transmitted diseases without the consent or knowledge of the parent or guardian.

10 NYCRR § 23.4 (emphasis added).

25. The emphasized language above goes beyond the narrow exception to parental consent created in PHL § 2305. The emphasized language for the first time permits medical professionals to provide care to minors, including performing medical procedures, with regard to a myriad of potential sexually transmitted diseases. Unlike PHL § 2305, which limited care to acute circumstances where a minor had either contracted or been exposed to a disease, the DOH's new Section 23.4 allows professionals to provide care, including preventative care, for any sexually transmitted disease, regardless of whether the minor had yet had any contact with the disease.

26. The DOH provided its reason for enacting such a sweeping new rule in its Notice of Adoption for the regulation: "Human Papilloma Virus (HPV) represents the first vaccine-preventable sexually transmitted disease with vaccination protecting adolescents from . . . HPV infection. Section 23.4 permits health care providers to prescribe and administer HPV vaccine to sexually active minors during confidential sexual and reproductive health care visits without consent or knowledge of the parent or guardian."¹ In other words, the DOH is explicit that it enacted Section 23.4 in order to allow healthcare providers to administer Gardasil and Gardasil-9 to minors without their parent's consent or knowledge.

C. Federal Law Requires Informed Consent be Provided to the Minor's Legal Representative Prior to Vaccinating the Minor

27. Under Federal law a healthcare professional must provide a legal representative of a child with certain written materials prior to injecting such child with any vaccine, like Gardasil

¹ See https://regs.health.ny.gov/sites/default/files/pdf/recently_adopted_regulations/2016-05-18_sexually_transmitted_diseases.pdf

and Gardasil-9. These written materials disclose important information, including who should not receive the vaccine, who should delay receiving the vaccine, the risks of injecting these products, and what a parent should look for and do after their injection if a serious reaction occurs.

28. In the 1980s many pharmaceutical companies announced they would cease producing vaccines due to their liability from the injuries their vaccines were causing. In response, Congress passed the National Childhood Vaccine Injury Act of 1986 (the “**NCVIA**”), codified at 42 U.S.C. §§ 300aa-1 - 300aa-34, to shield pharmaceutical companies from financial liability for injuries caused by vaccines they manufacture and to ensure that individuals receiving the vaccines are properly informed about the vaccines.

29. The NCVIA includes a subsection entitled “Assuring A Safer Childhood Vaccination Program In The United States” codified at 42 U.S.C. §§ 300aa-25 – 300aa-28. Pursuant to this sub-section, the Secretary of Health and Human Services (“**HHS**”) is required to “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.” 42 U.S.C. § 300aa-26(a). “The information in such materials shall be based on available data and information, shall be presented in understandable terms and 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 National Vaccine Injury Compensation Program, and (4) such other relevant information as may be determined by the Secretary.” 42 U.S.C. § 300aa-26(c). In response, the Secretary of HHS has developed a Vaccine Information Statement (“**VIS**”) for each vaccine listed on the Vaccine Injury Table, including for Gardasil and Gardasil-9.

30. Title 42 U.S.C. § 300aa-26(d), entitled “Health care provider duties” provides 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 [VIS] ... supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.” For the purposes of the foregoing section, “The term ‘legal representative’ means a parent or an individual who qualifies as a legal guardian under State law.” 42 U.S.C. § 300aa-33.

31. In addition to requiring that parents receive information, the NCVIA also established the National Vaccine Injury Compensation Program (the “VICP”) to compensate individuals who are injured by vaccines on the Vaccine Injury Table. Claims of vaccine injuries must be made to the VICP, which is part of the United States Court of Federal Claims. 42 U.S.C. § 300aa-11. The respondent in these claims is the HHS. *Id.* Petitioners in the VICP typically must still prove causation and there is a maximum recovery of \$250,000 for death and for pain and suffering. 42 U.S.C. § 300aa-15(a)(2)-(4). In the ten years preceding 2016, over \$1.6 billion has been paid for vaccine injuries by the VICP. Each VIS statement includes a description of the VICP, and instructions on how to learn more about the program, including an admonition that there are time limits for filing a claim in the VICP.

32. The HPV vaccines Gardasil and Gardasil-9 were added to the Vaccine Injury Table on February 1, 2007. HHS has issued a VIS for Gardasil and a VIS for Gardasil-9, which it updated in December 2016. (81 FR 23299.)

33. Therefore, under Federal law, a healthcare professional must provide the VIS and appropriate supplemental explanations to the legal representative of a child prior to injecting the

child with Gardasil or Gardasil-9, and any child injured by the vaccine can typically only seek redress through the VICP.

D. HPV Vaccines Have Known Serious Adverse Reactions

34. Gardasil and Gardasil-9 can cause serious adverse reactions.

35. The VISs for Gardasil and Gardasil-9 provide warnings regarding who should avoid or delay this product in sections titled “Some people should not get HPV vaccine or should wait” and “Some people should not get this vaccine,” respectively. The VISs for Gardasil and Gardasil-9 also provide disclosure regarding the risks of these products as well as a section entitled “What if there is a serious reaction?” including describing “What should I look for?” and “What should I do?” In these sections, the VIS describes what symptoms can result from an adverse reaction to the vaccine, including those which can occur “hours after the vaccination,” and what to do if these symptoms arise.

36. The VIS for Gardasil and Gardasil-9 also advise parents of the Vaccine Adverse Events Reporting System (“VAERS”) operated by HHS and co-sponsored by the CDC and FDA. Health care providers report adverse reactions to the VAERS on a voluntary basis, and as such it is estimated to capture only a small fraction of serious adverse events and typically only captures acute reactions. Nevertheless, since 2007, VAERS has received reports of 48,601 cases of adverse events following injection of an HPV vaccine, including: 300 deaths, 1,650 permanently disabled, 4,168 hospitalized, and 13,785 emergency room visits.

37. The VIS for Gardasil and Gardasil-9 also informs parents of the Vaccine Injury Compensation Program.

38. Furthermore, Merck’s package insert for Gardasil and Gardasil-9 provide the following partial list of adverse events following injection of Gardasil or Gardasil-9: death, autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy,

pulmonary embolus, pancreatitis, asthenia, autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, urticarial, arthralgia, myalgia, acute disseminated encephalomyelitis, guillain-barre syndrome, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-clonic movements and other seizure-like activity) sometime resulting in falling with injury, and transverse myelitis.

E. Plaintiffs' Children Are Not Capable of Making Informed Decisions Regarding HPV Vaccinations

39. There is no question that parents have a constitutional due process right to make decisions concerning medical procedures for their children. Likewise, children have the right to have their parents make medical decisions for them. A parent's authority in a family legally rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions. Absent evidence of abuse or neglect, parents are presumed to act in their children's best interests, and normally there is no reason for the State to inject itself into the private realm of the family to further question a parent's ability to make appropriate decisions about their child's medical care.

40. Furthermore, a parent's Fourteenth Amendment liberty interest in familial association includes the parent's right to be present while his or her child is receiving medical attention, and the child has a corresponding right to the love, comfort, and reassurance of his or her parent while he or she receives medical care.

41. Plaintiffs are committed parents who, like most parents, carefully oversee the medical treatment of their children. Plaintiffs believe that they or their husbands are aware of and have been present for all medical procedures performed on their children. Likewise, Plaintiffs want to know and be present when their children undergo any medical procedure in the future, including receiving a vaccine.

42. Plaintiffs are especially concerned about vaccinations because their children have experienced reactions to prior vaccinations, including long after the vaccines were administered. Ms. Golpl's son P.K. was rushed to the emergency room after a vaccination during which his temperature exceeded 105 degrees, he required multiple IV bags, and he developed a severe rash including across his face. On a different occasion, P.K. experienced an episode of cellulitis from a vaccine in his thigh which became severely swollen and required multiple rounds of antibiotics to treat. Ms. Doell-Carbone's eleven-year-old son had a severe acute reaction to a prior vaccine which included high fever, extreme lethargy, incessant screaming and inconsolable irritability; ultimately he suffered neurological issues as a result of his reaction. Ms. Randello's ten-year-old son J.R. experienced a severe reaction to a prior vaccine, which required active management by Ms. Randello for a number of days, and whose severity prompted her doctor to conclude that her son should not receive any further doses of that particular vaccine. Ms. Cole's son suffered a severe reaction including a seizure from a prior vaccine. Ms. Boyle Meyer's daughter had a severe serious reaction to the HPV vaccine which included being rushed to the emergency room and she has suffered intermittent and ongoing paralysis in her legs from the HPV vaccine requiring use of a wheelchair, and when not paralyzed, has ongoing weakness in her legs, impaired life functions, and ongoing severe headaches, fatigue and nausea. Ms. Boyle Meyer reported this serious adverse reaction to the CDC through VAERS and a nurse from the CDC contacted Ms. Boyle Meyer to confirm this was a known reaction to the HPV vaccine and that her daughter's reaction was related to the HPV vaccine.

43. Plaintiffs are concerned that their children do not have sufficient maturity to assist health care providers in properly evaluating the risks associated with each vaccination. Plaintiffs' children are relatively young and do not have sufficient knowledge to inform a healthcare

practitioner regarding their own medical histories, allergies, and potential contra-indications. Likewise, Plaintiffs' children do not have the mental maturity to articulate, properly recall or associate any reaction they may suffer as a result of a vaccination. For example, Ms. Golpl's fifteen-year-old son has been diagnosed with an intellectual disability and has impaired judgment and maturity; he is typically incapable of verbalizing any events, even positive ones, from his past even with repeated prompting. Ms. Golpl's son has twice suffered severe reactions after vaccination and it is untenable that her son could receive the Gardasil or Gardasil-9 without at least her being present and able to observe during the following hours and days for any reactions and assure timely and proper management of any such reaction. As a result, Plaintiffs' children have reasons to be concerned about receiving a vaccination, but do not have sufficient mental maturity to make an informed decision regarding their vaccination choices without their parents' guidance.

44. The No Consent Or Knowledge Rule implemented by Defendant prevents Plaintiffs from knowing that their child has received Gardasil or Gardasil-9 and being present during the procedure and decision making process leading to that procedure. Without knowledge that vaccines like Gardasil and Gardasil-9 have been injected into their children, Plaintiffs cannot properly manage their children's health care needs. Without Plaintiffs' involvement, their children could also receive additional unnecessary doses of Gardasil or Gardasil-9 if their children have already received this product and hence expose them to the risk of this product without any benefit. Likewise, the Rule also prevents Plaintiffs from receiving the VIS for the product; without the VIS, Plaintiffs may not be aware of the side effects and adverse reactions that they should be looking for, nor are they likely aware of the VICP.

45. As a result, Plaintiffs are extremely concerned that one or more of their children will be injected with Gardasil or Gardasil-9 without their consent or knowledge, and that they will

not have sufficient information to react in a timely fashion if their child has an adverse reaction to the vaccine.

CAUSES OF ACTION

COUNT I

42 U.S.C. § 1983

DEPRIVATION OF RIGHTS AND PRIVILEGES SECURED BY FEDERAL LAW

46. Plaintiffs incorporate the preceding paragraphs as though set forth herein.

47. The HPV vaccines Gardasil and Gardasil-9 manufactured by Merck & Co. were added to the Vaccine Injury Table on February 1, 2007, and information materials -- commonly referred to as VISs -- for these products were created by HHS as required by 42 U.S.C. 300aa-26(a).

48. Pursuant to 42 U.S.C. § 300aa-26(d), “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 pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.”

49. Hence, under Federal law, the VIS for Gardasil or Gardasil-9 supplemented with appropriate visual presentations or oral explanations must be provided to the legal representative, *i.e.*, the parent or legal guardian, of a child prior to injecting such child with Gardasil or Gardasil-9.

50. The VIS for Gardasil or Gardasil-9 provide warnings regarding who should avoid or delay this product in sections titled “Some people should not get HPV vaccine or should wait” and “Some people should not get this vaccine,” respectively. The VISs for Gardasil and Gardasil-

9 also provide disclosure regarding the risks of these products as well as a section entitled “What if there is a serious reaction?” including describing “What should I look for?” and “What should I do?” These VISs also provide information regarding VAERS and the VICP.

51. To the extent that 10 NYCRR § 23.4 permits children to be injected with Gardasil or Gardasil-9 without parental consent or knowledge, it deprives Plaintiffs and others similarly situated of their right pursuant to 42 U.S.C. § 300aa-26 to receive a VIS for Gardasil or Gardasil-9 from the health care provider that intends to inject their child with those vaccines, along with appropriate additional information regarding those vaccines, before that health care provider performs the injection.

52. Accordingly, pursuant to 28 U.S.C. 2201 there is an actual case or controversy between the parties that requires this Court to resolve, and Plaintiffs are entitled to a declaration that 10 NYCRR § 23.4 violates Plaintiffs’ rights pursuant to 42 U.S.C. § 300aa-26 to the extent that it allows a health care provider to administer an HPV vaccine without that health care provider first giving the required VIS to the child’s parent or legal guardian supplemented with any appropriate visual presentations or oral explanations.

53. Further, Plaintiffs respectfully request that the Defendant be enjoined from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit administration of an HPV vaccine to a child without the health care provider intending to administer such vaccine first providing such child’s parent or legal guardian a VIS for such HPV vaccine supplemented with any appropriate visual presentations or oral explanations.

COUNT II
42 U.S.C. § 1983
DEPRIVATION OF RIGHTS AND PRIVILEGES SECURED BY THE CONSTITUTION
PROCEDURAL DUE PROCESS

54. Plaintiffs incorporate the preceding paragraphs as though set forth herein.

55. The Fourteenth Amendment to the United States Constitution provides, in relevant part: “No State shall . . . deprive any person of life, liberty or property without due process of law.”

56. Among other things, due process of law guarantees the citizenry that officers and bodies of the State will responsibly regulate government rules, programs and initiatives that may interfere with life, liberty or property.

57. The State may not delegate its authority to private actors unless the State proscribes clear standards to guide the conduct of said private actors, and the State exercises a reasonable degree of oversight of the private actor’s conduct.

58. Plaintiffs have liberty interest with regard to their children and the right to be present and have knowledge when their children are being injected with a product that could cause serious injury or death.

59. Gardasil and Gardasil-9 are intended to prevent HPV but also can have serious adverse reactions including permanent disabilities and death.

60. The No Consent Or Knowledge Rule improperly delegates discretion to private actors to determine when, where and how Plaintiffs’ children will be injected with Gardasil or Gardasil-9 and even requires them to withhold any knowledge of such injection from Plaintiffs.

61. The Defendant did not prescribe any standards to govern when these private actors can inject Gardasil or Gardasil-9 into Plaintiffs’ children nor any assurance that these private actors will have the knowledge that Plaintiffs have regarding their children’s medical history, allergies and possible contra-indications, nor are these private actors required to monitor Plaintiffs’ children for numerous days after injecting Gardasil or Gardasil-9 to assure no symptoms appear which would require timely attention.

62. Therefore, Plaintiffs respectfully request a declaration that the Defendant's delegation of power to private actors to inject Gardasil or Gardasil-9 into Plaintiffs' children without their consent or knowledge is a violation of the Fourteenth Amendment to the United States Constitution. Permitting the regulation to remain valid law would be an unlawful deprivation of the constitutional rights of Plaintiffs. Plaintiffs thus also respectfully request that the Defendant be enjoined from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit administration of an HPV vaccine to a child without the knowledge and consent of the child's parent.

COUNT III
42 U.S.C. § 1983
DEPRIVATION OF RIGHTS AND PRIVILEGES SECURED BY THE CONSTITUTION
SUBSTANTIVE DUE PROCESS

63. Plaintiffs incorporate the preceding paragraphs as though set forth herein.

64. Most children, even in adolescence, simply are not able to make sound judgments concerning many decisions, including their need for medical care or treatment. Recognizing this fundamental aspect of the human condition, the law presumes that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions, and therefore grants parents the constitutional right to make all significant medical decisions for their children.

65. The State may not give parental decision-making authority to adult healthcare professionals, outside of an emergency or other exigent circumstances. The Fourteenth Amendment's Due Process Clause has a substantive component that provides heightened protection against government interference with certain fundamental rights and liberty interests, including parents' fundamental right to make decisions concerning the care, custody, and control of their children. There is a presumption that fit parents act in their children's best interests; there

is normally no reason for the State to inject itself into the private realm of the family to further question fit parents' ability to make the best decisions regarding their children.

66. Parents are presumed to be fit under the due process clause of the Fourteenth Amendment. Nevertheless, the No Consent Or Knowledge Rule turns this presumption on its head assuming that parents are not able to make appropriate decisions regarding the HPV vaccination.

67. In effect, the No Consent Or Knowledge Rule declares all parents in the State to be unfit to make the decision regarding when their child will be injected with the Gardasil or Gardasil-9 product, or to even know that this medical procedure has been performed on their child.

68. Therefore, Plaintiffs respectfully request a declaration that Defendant's deprivation of Plaintiffs' fundamental right to make decisions concerning the care, custody, and control of their children by permitting health care providers to inject their minor children with Gardasil or Gardasil-9 without their consent or knowledge is a violation of the Fourteenth Amendment to the United States Constitution. Permitting the regulation to remain valid law would be an unlawful deprivation of the constitutional rights of Plaintiffs. Plaintiffs thus also respectfully request that the Defendant be enjoined from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit administration of an HPV vaccine to a child without the knowledge and consent of the child's parent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment granting the following relief:

- (i) Injunction pursuant to 42 U.S.C. § 1983 and the Ex Parte Young doctrine enjoining Defendant from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit

administration of an HPV vaccine to a child without the health care provider intending to administer such vaccine first providing such child's parent or legal guardian a VIS for such HPV vaccine supplemented with any appropriate visual presentations or oral explanations;

- (ii) Declaration pursuant to 28 U.S.C. §§ 2201 and 2202, and 42 U.S.C. § 1983 and the Ex Parte Young doctrine that 10 NYCRR § 23.4 violates Plaintiffs' rights pursuant to 42 U.S.C. § 300aa-26 to the extent that it allows a health care provider to administer an HPV vaccine without that health care provider first giving the required VIS to the child's parent or legal guardian supplemented with any appropriate visual presentations or oral explanations;
- (iii) Declaration pursuant to 28 U.S.C. §§ 2201 and 2202, and 42 U.S.C. § 1983 and the Ex Parte Young doctrine that 10 NYCRR § 23.4 is an unconstitutional violation of Procedural Due Process, in violation of the Fourteenth Amendment of the United States Constitution, to the extent it permits Plaintiffs children to be injected with Gardasil or Gardasil-9 without parental consent or knowledge, and an injunction enjoining Defendant from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit administration of an HPV vaccine to a child without the knowledge and consent of the child's parent;
- (iv) Declaration pursuant to 28 U.S.C. §§ 2201 and 2202, and 42 U.S.C. § 1983 that the No Consent Or Knowledge Rule is an unconstitutional violation of Substantive Due Process, in violation of the Fourteenth Amendment of the United States Constitution, to the extent it permits Plaintiffs children to be

injected with Gardasil or Gardasil-9 without parental consent or knowledge, and an injunction enjoining Defendant from any prospective conduct, enforcement, dissemination or promotion of 10 NYCRR § 23.4 intended to encourage or permit administration of an HPV vaccine to a child without the knowledge and consent of the child's parent; and

- (v) Such other relief in favor of the Plaintiffs as the Court deems just and proper, including, without limitation, attorney's fees, costs and disbursements of the action.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury in this action of all issues so triable.

Dated: March 3, 2017

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