IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF CONNECTICUT

KORRINE HERLTH,

Plaintiff,

v.

MERCK & CO., INC., a New Jersey Corporation; and MERCK SHARP & DOHME CORP., a New Jersey Corporation,

Defendants.

Case No.

COMPLAINT FOR

(1) Negligence
(2) Strict Liability (Failure to Warn)
(3) Strict Liability (Manufacturing Defect)
(4) Breach of Warranty
(5) Common Law Fraud

DEMAND FOR JURY TRIAL

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COMES NOW Plaintiff, KORRINE HERLTH, who by and through counsel Baum Hedlund Aristei & Goldman, PC, and Robert F. Kennedy, Jr., alleges against defendants MERCK & CO., INC., and MERCK, SHARP AND DOHME CORPORATION, and each of them, as follows:

INTRODUCTION

1. This common-law products liability, negligence, strict liability, breach of warranty and fraud action arises out of serious and debilitating injuries, including but not limited to autonomic, neurological and heterogenous autoimmune injuries and resulting sequalae that plaintiff, Korrine Herlth ("Plaintiff"), sustained as a result of receiving the Gardasil vaccine, which was designed, manufactured, labeled, and promoted by defendants Merck & Co., Inc., and Merck, Sharp and Dohme Corporation (collectively "Merck").

PARTIES AND VENUE

2. Plaintiff, Korrine Herlth ("Herlth" or "Plaintiff"), is an adult and a resident and citizen of Connecticut.

3. Defendant Merck & Co., Inc., is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

4. Defendant Merck, Sharp and Dohme Corporation, is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

5. Defendants Merck & Co., Inc., and Merck, Sharp and Dohme Corporation shall hereinafter collectively be referred to as "Merck."

6. At all times herein mentioned, each defendant was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other defendants named herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

7. At all times herein mentioned, defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all defendants and each of them, thereby ratified those actions.

8. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between the named defendants, such that any individuality and separateness between the defendants has ceased and these defendants are the alter-ego of each other and exerted control over each other. Adherence to the fiction of the separate existence of these two named defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

9. At all times herein mentioned, the two Merck defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by patients such as Plaintiff, her parents and her medical providers. As such, the two Merck defendants are each individually, as well as jointly and severally, liable to Plaintiff for her damages.

10. The harm caused to Plaintiff resulted from the conduct of one or various combinations of the two Merck defendants, and through no fault of Plaintiff. There may be uncertainty as to which one or which combination of the two Merck defendants caused the harm. The two Merck defendants have superior knowledge and information on the subject of which one or which combination of the two defendants caused Plaintiff's injuries. Thus, the burden of proof should be upon each of the two Merck defendants to prove that the defendant has not caused the harms Plaintiff has suffered. As previously stated, the two named Merck defendants shall hereinafter and throughout this Complaint be collectively referred to as "Merck."

11. Merck is the designer, manufacturer, labeler and promoter of the Gardasil and Gardasil-9 vaccines, which are purported to be "cervical cancer vaccines" by preventing a handful of the hundreds of strains of the Human Papillomavirus ("HPV"). Merck regularly conducts and transacts business in Connecticut and has promoted Gardasil to consumers, patients, hospitals, physicians, nurses and medical professionals, including but not limited to Plaintiff, her parents and the medical facility and medical professionals who prescribed and/or injected Plaintiff with Gardasil. This Court has personal jurisdiction over Merck because defendants have sufficient minimum contacts with

Connecticut to render the exercise of jurisdiction by this Court proper.

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and the defendants are citizens of different states and the amount of controversy exceeds $75,000.00, exclusive of interest and costs.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial portion of the events and omissions giving rise to the claims asserted herein occurred in this District.

GENERAL ALLEGATIONS

I. "History Doesn't Repeat Itself, But It Often Rhymes" – Mark Twain

14. Merck traces its history back to 1668, when the original founder of the company, Friedrich Jacob Merck, bought an apothecary in Darmstadt, Germany. The company operated as a pharmacy for approximately the next 150+ years when, in 1827, Friedrich's descendant, Heinrich Emmanuel Merck, converted the company into a drug manufacturing enterprise. Merck's first products included morphine and cocaine.

15. Merck later manufactured a number of controversial products including Fosamax (a purported bone density drug that caused bone fractures), Nuvaring (a birth control device associated with life-threatening blood clots and death), and probably its most infamous drug, Vioxx (a pain medication Merck was forced to pull from the market due to its cardiovascular risks), all of which landed Merck in litigation hot water.

16. With regard to Vioxx, Merck was sued by tens of thousands of patients who alleged they suffered heart attacks and other cardiovascular injuries as a result of ingesting the blockbuster pain medication.

17. Documents unsealed during the Vioxx litigation in the early 2000s revealed a culture wherein Merck knew early on that Vioxx was linked to fatal cardiovascular adverse events but nonetheless intentionally chose to conceal these risks from the public and medical community and, instead, orchestrated a scheme to downplay the severity of the risks. Merck misrepresented the results of its clinical trials, failed to undertake the clinical trials that would reveal risks, and blacklisted medical professionals who dared to publicly criticize the safety of Vioxx. *See e.g.*, Eric J. Topol, *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF

MEDICINE 1707 (2004); Gregory D. Curfman et al., *Expression of Concern Reaffirmed*, 354 NEW ENGLAND JOURNAL OF MEDICINE 1193 (2006); Aaron S. Kesselheim et al., *Role of Litigation in Defining Drug Risks*, 17 JAMA 308 (2007); Harlan M. Krumholz et al., *What We Have Learnt From Vioxx*, 334 BRITISH MED. J. 120 (2007).

18. The British Medical Journal reported that internal documents and communications obtained from Merck during litigation revealed that Merck scientists internally acknowledged the existence of Vioxx's risks very early on: "Since the early development of [Vioxx], some scientists at Merck were concerned that the drug might adversely affect the cardiovascular system … In internal emails made public through litigation, Merck officials sought to soften the academic authors' interpretation [of the data]. The academic authors changed the manuscript at Merck's request [to make less of the apparent risk] …" Harlan M. Krumholz et al., *What We Have Learnt From Vioxx*, 334 BRITISH MED. J. 120 (2007). And, despite Merck's knowledge of the risk, Merck never conducted the necessary studies designed to evaluate cardiovascular risk. *Id.*

19. In an article published in the Journal of the American Medical Association, it was reported that Merck worked to "diminish the impact of reported cardiovascular adverse effects by not publishing adverse events and failing to include complete data on myocardial infarctions that occurred during a key clinical trial. The information came to the public attention through a subpoena 5 years after the article's publication, when [Vioxx] was already off the market." Aaron S. Kesselheim et al., *Role of Litigation in Defining Drug Risks*, 17 JAMA 308 (2007). The article concludes: "These case studies indicate that clinical trials and routine regulatory oversight as currently practiced often fail to uncover important adverse effects for widely marketed products. In each instance, the litigation process revealed new data on the incidence of adverse events, enabled reassessment of drug risks through better evaluation of data, and influenced corporate and regulatory behavior." *Id.*

20. It was also revealed and reported that, in order to control the public narrative that Vioxx was safe and risk free, "Merck issued a relentless series of publications…complemented by numerous papers in peer-reviewed medical literature by Merck employees and their consultants. The company sponsored countless continuing medical 'education' symposiums at national meetings in an effort to debunk the concern about adverse cardiovascular effects." Eric J. Topol, *Failing the Public Health –*

Rofecoxib, Merck, and the FDA, 351 NEW ENGLAND JOURNAL OF MEDICINE 1707 (2004). In addition, Merck "selectively targeted doctors who raised questions about [Vioxx], going so far as pressuring some of them through department chairs." Harlan M. Krumholz et al., *What We Have Learnt From Vioxx*, 334 BRITISH MED. J. 120 (2007). Dr. Topol, Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, commented: "Sadly, it is clear to me that Merck's commercial interest in [Vioxx] sales exceeded its concern about the drug's potential cardiovascular toxicity." Eric J. Topol, *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF MEDICINE 1707 (2004).

21. Once Merck's misdeeds vis-à-vis Vioxx were revealed in various jury trials, Merck paid nearly $5 billion to settle the tens of thousands of personal injury actions that had been brought against it as a result of its concealment of Vioxx's cardiovascular risks. Merck paid an additional $1 billion to settle a securities class action brought by investors who had lost money when Merck's stock tanked following revelations of the drug's risks and subsequent lost sales. Merck was also forced to pay $950 million in civil and criminal fines to the Department of Justice and other governmental entities as a result of various criminal activities Merck had engaged in with respect to Vioxx.

22. In 2005, Merck pulled Vioxx from the market and was desperate to find a replacement for its previous multi-billion-dollar blockbuster.

23. Merck viewed Gardasil as the answer to the financial woes it had suffered from Vioxx. Within Merck, executives joked that HPV stood for "Help Pay for Vioxx."

24. In the aftermath of the Vioxx scandal, and seeking a replacement product, Merck's senior director of clinical research, Eliav Barr, M.D., proclaimed of Gardasil: "This is it. *This is the Holy Grail!*"

II. In Bringing Its *Holy Grail*, Gardasil, to Market, Merck Engaged in the Same Fraudulent Research and Marketing It Had Engaged in Vis-à-vis Vioxx Resulting In Patients Being Exposed to a Vaccine That is Of Questionable Efficacy and Which Can Cause Serious and Debilitating Adverse Events

25. As outlined herein, in researching, developing, and marketing its new Holy Grail, Gardasil, Merck engaged in the same unscrupulous tactics it had so infamously engaged in with Vioxx.

26. Certain Merck employees, scientists and executives involved in the Vioxx scandal were also involved with Gardasil, and it appears they employed the very same methods of manipulating science and obscuring risks as they did with Vioxx.

27. According to Merck's marketing claims, Gardasil (and, later, next-generation Gardasil 9) provided lifetime immunity to cervical and other HPV-associated cancers.

28. As discussed more fully below, whether Gardasil prevents cancer (not to mention lifetime immunity), is unproven. In fact, it may be more likely to cause cancer in those previously exposed to HPV than to prevent it.

29. Moreover, Merck knows and actively conceals the fact that Gardasil can cause a constellation of serious adverse reactions and gruesome diseases, including autoimmune diseases, and death in some recipients.

30. As a result of Merck's fraud, Gardasil today is wreaking havoc on a substantial swath of an entire generation of children and young adults on a worldwide scale.

A. Overview of the Human Papillomavirus

31. Human Papillomavirus ("HPV") is a viral infection that is passed between people through skin-to-skin contact. There are more than 200 strains of HPV, and of those, more than 40 strains can be passed through sexual contact.

32. HPV is the most common sexually transmitted disease. It is so common that the majority of sexually active people will get it at some point in their lives, even if they have few sexual partners.

33. HPV, for the most part, is benign. More than 90 percent of HPV infections cause no clinical symptoms, are self-limited, and are removed from the human body by its own immunological mechanisms and disappear naturally from the body following an infection. *See, e.g.*, Antonio C. de Freitas et al., *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC ONCOLOGY 306 (August 2012).

34. Approximately 12 to 18 of the over 200 strains of HPV are believed to be associated with cervical cancer.

35. Not every HPV infection puts one at risk for cervical cancer. Only persistent HPV

infections – not short-term or transient infections or sequential infections with different HPV types – in a limited number of cases with certain strains of the virus may cause the development of precancerous lesions. With respect to cervical cancer, these precancerous lesions are typically diagnosed through Pap smears and then removed through medical procedures. However, when undiagnosed, they may in some cases progress to cervical cancer in some women. Other risk factors, such as smoking, are also associated with cervical cancer. *See* Antonio C. de Freitas et al., *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC ONCOLOGY 305 (August 2012). Infection with certain types of HPV are also associated with other diseases, such as genital warts.

36. Public health officials have long recommended the Pap test (also known as Pap Smear), which detects abnormalities in cervical tissue, as the most effective frontline public health response to the disease.

37. Since its introduction, cervical cancer screening through the Pap test has reduced the rates of cervical cancer in developed countries by up to 80 percent. *Id.*

38. Incidences of cervical cancer have been declining dramatically worldwide as countries have implemented Pap screening programs.

39. New cases of cervical cancer in the U.S. affect approximately 0.8 percent of women in their lifetime. *See Cancer Stat Facts: Cervical Cancer,* NIH, at https://seer.cancer.gov/statfacts/html/cervix.html. For those who are diagnosed, cervical cancer is largely treatable, with a five-year survival rate of over 90 percent when the cancer is caught early. *See* Antonio C. de Freitas et al., *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC ONCOLOGY 305 (August 2012)

40. Although the incidence of cervical cancer was in rapid decline as a result of the implementation of routine testing and screening, including the Pap test and various DNA testing measures, Merck sought to fast-track a vaccine onto the market to prevent infection from four types of HPV (only two of which are associated with cancer).

B. Overview of the Gardasil Vaccine and Its Fast-Tracked Approval

41. While there are over 200 types of the HPV virus, only 12 to 18 currently are considered potentially associated with cervical cancer. Merck's original Gardasil vaccine claimed to prevent

infections from four strains (HPV Strain Types 6, 11, 16 and 18) and only two of those (Types 16 and 18) were associated with cervical cancer.

42. Under Food and Drug Administration ("FDA") requirements, to obtain approval for marketing a vaccine, the manufacturer must conduct studies to test the effectiveness and safety of the vaccine. Once FDA approval is obtained, the manufacturer has a duty to perform any further scientific and medical investigation as a reasonably prudent manufacturer would perform, and to engage in any necessary post-marketing pharmacovigilance related to the product.

43. The FDA approved Gardasil on June 8, 2006, after granting Merck fast-track status and speeding the approval process to a six-month period, leaving unanswered material questions relating to its effectiveness and safety as well as when and to whom the Gardasil vaccine ought to be administered.

44. Merck failed, during the preapproval processing period and thereafter, to disclose (to the FDA and/or the public), material facts and information relating to the effectiveness and safety of Gardasil, as well as to whom the vaccine should or should not be administered.

45. Merck failed to perform in the preapproval processing period and thereafter, scientific and medical investigations and studies relating to the safety, effectiveness, and need for the Gardasil vaccine as either required by and under FDA directives and regulations, and/or those which a prudent manufacturer should have conducted unilaterally.

46. In June 2006, after the FDA's fast-tracked review, Gardasil was approved for use in females ages nine through 26 for the purported prevention of cervical cancer, and almost immediately thereafter, the Advisory Committee on Immunization Practices ("ACIP"), a committee within the Centers for Disease Control ("CDC"), recommended Gardasil for routine vaccination of adolescent girls ages 11 and 12 years old, but also allowed it to be administered to girls as young as nine years old.

47. On October 16, 2009, the FDS approved Gardasil for use in boys ages nine through 26 for the prevention of genital warts caused by HPV types 6 and 11.

48. Subsequently, Merck sought approval for Gardasil 9 (containing the same ingredients as Gardasil, but in higher quantities), which purportedly guarded against five additional HPV strains

currently associated with cervical cancer (HPV Types 31, 33, 45, 52 and 58) than the original Gardasil, for a total of nine strains.

49. The FDA approved Gardasil 9 in December 2014 for use in girls ages nine through 26 and boys ages nine through 15 for the purported prevention of cervical, vaginal, and anal cancers. Presently, Gardasil 9 has been approved for and is being promoted by Merck to males and females who are between nine and 45 years of age, with an emphasis by Merck on marketing to pre-teen children and their parents.

50. With little evidence of efficacy, FDA also recently approved, on an accelerated basis, Gardasil 9 for prevention of oropharyngeal and other head and neck cancers.

51. After the approval of the Gardasil 9 vaccine, the original Gardasil vaccine was phased out of the U.S. Market, and the original Gardasil vaccine is no longer available for sale in the United States.

52. According to data from the National Cancer Institute's ("NCI") Surveillance, Epidemiology and End Results Program ("SEER"), the incidence of deaths from cervical cancer prior to Gardasil's introduction in the United States had been steadily declining for years and, in 2006, was 2.4 per 100,000 women or approximately 1 in every 42,000 women. The currently available rate is essentially unchanged, 2.2 per 100,000 women, based on data through 2017.

53. The median age of death from cervical cancer is 58, and teenagers (who are the target population of Gardasil) essentially have zero risk of dying from cervical cancer.

54. Merck purchased fast-track review for Gardasil and Gardasil 9 under the Prescription Drug User Fee Act ("PDUFA"). Fast-track is a process designed to facilitate the development of drugs, and to expedite their review, in order to treat serious conditions and fill an unmet medical need.

55. Anxious to get Gardasil onto the market as soon as possible following the Vioxx debacle, Merck sought fast-track approval even though there already existed a highly effective and side-effect free intervention, Pap smears, with no evidence that Gardasil was potentially superior to Pap smears in preventing cervical cancer.

56. In fact, the clinical trials Merck undertook did not even examine Gardasil's potential to prevent cancer, rather, the trials only analyzed whether Gardasil could prevent potential precursor

conditions, i.e., HPV infections and cervical interepithelial neoplasia ("CIN") lesions graded from CIN1 (least serious) to CIN3 (most serious), the vast majority of which resolve on their own without intervention. CIN2 and CIN3 were the primary surrogate endpoints studied.

57. According to the FDA, whether a condition is "serious" depends on such factors as "survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one."

58. As previously discussed, over 90 percent of HPV infections and the majority of cervical dysplasia resolve without intervention.

59. However, Merck presented misleading data to the FDA suggesting that CIN2 and CIN3 inexorably result in cancer.

60. Federal law allows fast-track approval when there is no existing intervention to treat the targeted disease or where the proposed treatment is potentially superior to an existing treatment.

61. Merck knows (and knew) that Gardasil and Gardasil 9 are far less effective than Pap tests in preventing cervical cancer.

62. In order to obtain FDA approval, Merck designed and conducted a series of fraudulent Gardasil studies and then influenced the votes of the FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC") and the CDC's Advisory Committee on Immunization Practices ("ACIP") to win both an FDA license and a CDC/ACIP approval and recommendation that all 11 and 12 year old girls should be vaccinated with Gardasil.

63. That ACIP "recommendation" was, effectively, a mandate to doctors to sell Merck's very expensive vaccine, thereby compelling parents of American children as young as nine years old to buy this expensive product. With ACIP's recommendation, Merck was emboldened to build demand through direct-to-consumer advertising and door-to-door marketing to doctors, and, with the ACIP's blessing of the vaccine, circumvented the need to create a traditional market for the product.

64. Julie Gerberding, then the Director of CDC, obligingly ushered the Gardasil vaccine through CDC's regulatory process manifestly ignoring clear evidence that Gardasil's efficacy was unproven and that the vaccine was potentially dangerous.

65. Merck, shortly thereafter, rewarded Gerberding by naming her President of Merck

Vaccines in 2010.

66. In addition to the revolving regulatory/industry door (wherein the Director of CDC who approved the vaccine is subsequently employed by the manufacturer as a high-level executive to oversee the commercial success of the vaccine she previously approved), it is also worth noting some of the other conflicts of interest that exist within governmental agencies in relation to the facts surrounding Gardasil. Scientists from the National Institute of Health ("NIH"), which is a division of the United States Department of Health and Human Services ("HHS"), discovered a method of producing "virus-like-particles" ("VLPs") that made creation of the Gardasil vaccine possible. The NIH scientists' method of producing VLPs was patented by the Office of Technology Transfer ("OTT"), which is part of the NIH, and the licensing rights were sold to Merck (for manufacture of Gardasil). Not only does the NIH (and, in effect, the HHS) receive royalties from sales of Gardasil, but the scientists whose names appear on the vaccine patents can receive up to $150,000 per year (in perpetuity). Accordingly, the Gardasil patents have earned HHS, NIH and the scientists who invented the technology millions of dollars in revenue.

67. Moreover, members of ACIP have been allowed to vote on vaccine recommendations even if they have financial ties to drug companies developing similar vaccines. According to a 2000 U.S. House of Representatives investigation report, the majority of the CDC's eight ACIP committee members had conflicts of interest. The Chairman of ACIP served on Merck's Immunization Advisory Board and a number of the other ACIP members had received grants, salaries, or other forms of remuneration from Merck.

C. Merck Engaged in Disease Mongering and False Advertising to Enhance Gardasil Sales

68. Both prior to and after the approval of Gardasil, Merck engaged in unscrupulous marketing tactics designed to overemphasize both the risks associated with HPV and the purported efficacy of Gardasil to scare the public into agreeing to mass vaccinations of the Gardasil vaccine.

69. Prior to Merck's aggressive marketing campaign, there was no HPV public health emergency in high-resource countries, such as the United States.

70. Most women had never heard of HPV. The NCI's 2005 Health Information National

Trends Survey ("HINTS") found that, among U.S. women 18 to 75 years old, only 40 percent had heard of HPV. Among those who had heard of HPV, less than half knew of an association between HPV and cervical cancer. Furthermore, only four percent knew that the vast majority of HPV infections resolve without treatment.

71. The stage was set for Merck to "educate" the public about HPV, cervical cancer, and Gardasil, all to Merck's advantage.

72. Merck preceded its rollout of Gardasil with years of expensive disease awareness marketing. Merck ran "Tell Someone" commercials, designed to strike fear in people about HPV and cervical cancer – even ominously warning that you could have HPV and not know it. The commercials could not mention Gardasil, which had not yet been approved by FDA, but did include Merck's logo and name. Critics of Merck's pre-approval advertising and promotion called it "deceptive and dishonest." While Merck claims the promotion was part of public health education, critics complained that this "education" was designed to sell Gardasil and build the market for the vaccine. *See* Angela Zimm and Justin Blum, *Merck Promotes Cervical Cancer Shot by Publicizing Viral Cause*, BLOOMBERG NEWS, May 26, 2006.

73. A year before obtaining licensing for its vaccine, Merck engaged in a major offensive in "disease branding" to create a market for its vaccine out of thin air. *See* Beth Herskovits, *Brand of the Year*, PHARMEXEC.COM, February 1, 2007 at http://www.pharmexec.com/brand-year-0.

74. Merck also engaged in a relentless propaganda campaign aimed at frightening and guilting parents who failed to inoculate their children with Gardasil.

75. In addition to paid advertising, Merck worked with third parties to "seed" an obliging media with terrifying stories about cervical cancer in preparation for Merck's Gardasil launch.

76. Prior to the FDA's 2006 approval of Gardasil, the mainstream media – under direction of Merck and its agents – dutifully reported alarming cervical cancer stories, accompanied by the promotion of an auspicious vaccine.

77. Merck intended its campaign to create fear and panic and a public consensus that "good mothers vaccinate" their children with Gardasil. According to Merck propagandists, the only choice was to "get the vaccine immediately" or "risk cervical cancer."

78. Merck aggressively and fraudulently concealed the risks of the vaccine in broadcast materials and in propaganda that it disseminated in the United States.

79. Merck sold and falsely promoted Gardasil knowing that, if consumers were fully informed about Gardasil's risks and dubious benefits, almost no one would have chosen to vaccinate.

80. Merck negligently and fraudulently deprived parents and children of their right to informed consent.

81. One of Merck's television campaigns, conducted in 2016, shamelessly used child actors and actresses, implicitly dying of cancer, looking straight into the camera and asking their parents whether or not they knew that the HPV vaccine could have protected them against the HPV virus that caused them to develop their cancers. Each actor asked the following question: "Did you know? Mom? Dad?" See "Mom, Dad, did you know?" commercial: https://www.ispot.tv/ad/Ap1V/know-hpv-hpv-vaccination. Merck spent $41 million over two months on the campaign. The ads said nothing about potential side effects. Merck also distributed pamphlets via U.S. mail to doctors ahead of the ad's release to encourage them to share it with their patients:

82. Merck's fraudulent message was that cervical cancer is a real-life killer of young women, notwithstanding the fact that the average age for development of cervical cancer is 50 years old, the cancer is virtually nonexistent in women under 20.

83. Other television marketing campaigns Merck launched (including advertising that Plaintiff's mother saw and relied upon in advance of consenting to her daughter's Gardasil injections)

falsely proclaimed that Gardasil was a "cervical cancer vaccine" and that any young girl vaccinated with Gardasil would become "one less" woman with cervical cancer. The "One Less" marketing campaign portrayed Gardasil as if there were no question as to the vaccine's efficacy in preventing cervical cancer, and it disclosed none of Gardasil's side effects.

84. Merck marketed Gardasil with the most aggressive campaign ever mounted to promote a vaccine, spending more on Gardasil advertising than any previous vaccine advertising campaign.

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D. Merck Used Scare Tactics and Provided Financial Incentives to Legislatures to Attempt to make the Gardasil Vaccine Mandatory for All School Children

85. An ACIP recommendation of a vaccine, adopted by individual states, opens the door to mandates affecting as many as four million children annually.

86. With Gardasil costing $360 for the original three-dose series (exclusive of the necessary doctor's visits) and Gardasil 9 now priced at $450 for two doses (again, not including the cost of doctor's visits), Merck stood to earn billions of dollars per year, in the US alone, with little marketing costs.

87. Prior to Gardasil's approval in 2006, Merck was already targeting political figures to aid in the passage of mandatory vaccination laws.

88. As early as 2004, a group called Women in Government ("WIG") started receiving funding from Merck and other drug manufacturers who had a financial interest in the vaccine.

89. With the help of WIG, Merck aggressively lobbied legislators to mandate Gardasil to all sixth-grade girls. *See* Michelle Mello *et al.*, *Pharmaceutical Companies' Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AMERICAN J PUBLIC HEALTH 893 (May 2012).

90. In 2006, Democratic Assembly leader Sally Lieber of California introduced a bill that would require all girls entering sixth grade to receive the Gardasil vaccination. Lieber later dropped the bill after it was revealed there was a possible financial conflict of interest.

91. Prior to the introduction of the bill, Lieber met with WIG representatives. In an interview, the President of WIG, Susan Crosby, confirmed that WIG funders have direct access to state legislators, in part through the organization's Legislative Business Roundtable, of which WIG

funders are a part. *See* Judith Siers-Poisson, *The Gardasil Sell Job*, in CENSORED 2009: THE TOP 25 CENSORED STORIES OF 2007-08, 246 (Peter Philips ed. 2011).

92. Dr. Diane Harper, a medical doctor and scientist who was hired as a principal investigator on clinical trials for Gardasil gave an interview for an article on the HPV vaccines and WIG in 2007. Harper, who had been a major presenter at a WIG meeting in 2005, stated that "the Merck representative to WIG was strongly supporting the concept of mandates later in the WIG meetings and providing verbiage on which the legislators could base their proposals."

93. WIG was one of dozens of "pay to play" lobby groups that Merck mobilized to push HPV vaccine mandates.

94. Another group, the National Association of County and City Health Officials (NACCHO), was also pushing HPV vaccine mandates in all 50 states.

95. To that end, Merck made large contributions to political campaigns and legislative organizations. By February 2007, 24 states and the District of Columbia had introduced mandate legislation.

96. Several states passed laws allowing preteen children as young as age 12 to "consent" to vaccination with an HPV vaccine without parental consent or knowledge.

97. One New York state county offered children free headphones and speakers to encourage them to consent to the Gardasil vaccine. *See* Mary Holland *et al.*, THE HPV VACCINE ON TRIAL: SEEKING JUSTICE FOR A GENERATION BETRAYED 131 (2018).

98. Merck funneled almost $92 million to Maryland's Department of Health between 2012 and 2018 to promote Gardasil in Maryland schools, in a fraudulent campaign that paid school officials to deliberately deceive children and parents into believing Gardasil was mandatary for school attendance. Josh Mazer, *Maryland should be upfront about HPV vaccinations for children*, CAPITAL GAZETTE, August 14, 2018, at https://www.capitalgazette.com/opinion/columns/ac-ce-column-mazer-20180814-story.html.

E. Merck Pushed Gardasil Using Trusted Doctors and Third-Party Front Groups

99. In order to mobilize "third-party credibility" to push Gardasil, Merck gave massive donations to dozens of nonprofit groups to "educate" the public via "education grants." For example,

a disclaimer on American College of Obstetricians and Gynecologists' Immunization for Women website stated that "[t]his website is supported by an independent educational grant from Merck and Sanofi Pasteur US."

100. Merck offered influential doctors (also known as "key opinion leaders") $4,500 for every Gardasil lecture they gave.

101. Among the allegedly independent organizations Merck recruited to push Gardasil were the Immunization Coalition, the Allegheny County Board of Health, the Eye and Ear Foundation, the Jewish Healthcare Foundation, the American Dental Association, the American College of Obstetricians and Gynecologists, and the American Cancer Society.

F. Merck Has Systematically Misrepresented the Efficacy of Gardasil By Advertising that Gardasil Prevents Cervical Cancer When There Are No Clinical Studies to Support This False Claim

102. Merck faced a daunting problem in convincing regulators, doctors, and the public to accept the Gardasil vaccine.

103. Merck recommends the vaccine for children aged 11 to 12 years old, to provide protection against a disease that, in the United States, is not generally diagnosed until a median age of 50. Moreover, in those rare instances of death, the median age is 58.

104. There are no studies proving that Gardasil prevents cancer.

105. Because it can take decades for a persistent HPV infection to proceed to development of cervical cancer, and because cervical cancer is so rare, a true efficacy study would require decades and likely hundreds of thousand – if not millions – of trial participants to demonstrate that eliminating certain HPV infections would actually prevent the development of cervical cancer.

106. Merck did not want to invest the time or money necessary to perform testing that would prove that its vaccine actually worked to prevent cervical cancer.

107. Instead, Merck persuaded regulators to allow it to use "surrogate endpoints" to support its theory that the HPV vaccines would be effective in preventing cervical cancer.

108. The clinical trials therefore did not test whether HPV vaccines prevent cervical or other cancers. Instead, Merck tested the vaccines against development of certain cervical lesions, which some researchers suspect are precursors to cancer, although the majority of these lesions – even the

most serious – regress on their own. *See, e.g.*, Jin Yingji et al., *Use of Autoantibodies Against Tumor-Associated Antigens as Serum Biomarkers for Primary Screening of Cervical Cancer*, 8 ONCOTARGET 105425 (Dec. 1, 2017); Philip Castle et al., *Impact of Improved Classification on the Association of Human Papillomavirus With Cervical Precancer*, 171 AMERICAN JOURNAL OF EPIDEMIOLOGY 161 (Dec. 10, 2009); Karoliina Tainio et al., *Clinical Course of Untreated Cervical Intraepithelial Neoplasia Grade 2 Under Active Surveillance: Systematic Review and Meta-Analysis*, 360 BRIT. MED. J. k499 (Jan. 16, 2018).

109. The Department of Health and Human Services (HHS), which oversees the FDA and which also stood to make millions of dollars on the vaccine from patent royalties, allowed the use of Merck's proposed surrogate endpoints.

110. The surrogate endpoints chosen by Merck to test the efficacy of its HPV vaccine were cervical intraepithelial neoplasia (CIN) grades 2 and 3 and adenocarcinoma in situ.

111. Merck used these surrogate endpoints even though it knew that these precursor lesions are common in young women under 25 and rarely progress to cancer.

112. At the time FDA approved the vaccine, Merck's research showed only that Gardasil prevented certain lesions (the vast majority of which would have resolved on their own without intervention) and genital warts – not cancer itself, and only for a few years at that.

113. The use of these surrogate endpoints allowed Merck to shorten the clinical trials to a few years and gain regulatory approvals of the vaccines without any evidence the vaccines would prevent cancer in the long run.

114. Merck's own lawyers told its marketing department that it was illegal for the company to market the vaccine as preventing cervical cancer, and that the company could only claim that Gardasil suppressed colonization by certain HPV types.

115. Merck's marketers ignored this advice.

116. Merck's advertisements assert that the HPV vaccine prevents cervical cancer. For example, in a presentation to medical doctors, Merck proclaimed: "Every year that increases in coverage [of the vaccine] are delayed, another 4,400 women will go on to develop cervical cancer." The presentation goes on to tell doctors that women who do not get the vaccine will go on to develop

cancer.

117. Merck's foundational theory that HPV alone causes cervical cancer, while dogmatically asserted, is not proven.

118. Research indicates that cervical cancer is a multi-factor disease with persistent HPV infections seeming to play a role, along with many other environmental and genetic factors, including smoking cigarettes or exposure to other toxic smoke sources, long-term use of oral contraceptives, nutritional deficiencies, multiple births (especially beginning at an early age), obesity, inflammation, and other factors. Not all cervical cancer is associated with HPV types in the vaccines and not all cervical cancer is associated with HPV at all.

119. Despite the lack of proof, Merck claimed that Gardasil could eliminate cervical cancer and other HPV-associated cancers.

120. However, *Merck knows* that the Gardasil vaccines cannot eliminate all cervical cancer or any other cancer that may be associated with HPV.

121. Even assuming the Gardasil vaccine is effective in preventing infection from the four to nine vaccine-targeted HPV types, the results may be short term, not guaranteed, and ignore the 200 or more other types of HPV not targeted by the vaccine, and some of which already have been associated with cancer.

122. Even assuming these vaccine-targets are the types solely responsible for 100 percent of cervical cancer – which they are not – the vaccines have not been followed long enough to prove that Gardasil protects girls from cancer that would strike them 40 years later.

123. Under Merck's hypothetical theory, the reduction of pre-cancerous lesions should translate to fewer cases of cervical cancer in 30 to 40 years.

124. Cervical cancer takes decades to develop and there are no studies that prove the Gardasil vaccines prevent cancer.

125. In January 2020, a study from the UK raised doubts about the validity of the clinical trials in determining the vaccine's potential to prevent cervical cancer. The analysis, carried out by researchers at Newcastle University and Queen Mary University of London, revealed many methodological problems in the design of the Phase 2 and 3 trials, leading to uncertainty regarding

understanding the effectiveness of HPV vaccination. *See* Claire Rees et al., *Will HPV Vaccine Prevent Cancer?* J. OF THE ROYAL SOC. OF MED. 1-15 (2020).

126. As Dr. Tom Jefferson of the Centre for Evidence-Based Medicine pointed out: "The reason for choosing vaccination against HPV was to prevent cancer but there's no clinical evidence to prove it will do that."

127. Gardasil has never been proven to prevent cervical or any other kind of cancer.

128. Yet Merck has marketed the Gardasil vaccines as if there is no question regarding their efficacy at preventing cervical cancer. In reality, they are at best protective against only four to nine of the over 200 strains of the human papillomavirus.

G. The Gardasil Vaccines Contain Numerous Hazardous Ingredients, Including At Least One Ingredient Merck Failed to Disclose to Regulators and the Public

i. Gardasil Contains A Toxic Aluminum Adjuvant

129. To stimulate an enhanced immune response that allegedly *might possibly* last for 50 years, Merck added to the Gardasil vaccine a particularly toxic aluminum-containing adjuvant – Amorphous Aluminum Hydroxyphosphate Sulfate ("AAHS").

130. Aluminum is a potent neurotoxin that can result in very serious harm.

131. The original Gardasil vaccine contains 225 micrograms of AAHS and Gardasil 9 contains 500 micrograms of AAHS.

132. Federal law requires that manufacturers cannot add adjuvants to vaccines that have not been proven safe. 21 C.F.R. § 610.15(a).

133. AAHS has never been proven safe. AAHS is a recent proprietary blend of aluminum and other unknown ingredients developed by Merck and used in Merck vaccines, including Gardasil. Prior vaccines have used a different aluminum formulation.

134. Peer-reviewed studies show that aluminum binds to non-vaccine proteins, including the host's own proteins, or to latent viruses, triggering autoimmune and other serious conditions. See Darja Kanduc, *Peptide Cross-reactivity: The Original Sin of Vaccines*, 4 FRONTIERS IN BIOSCIENCE 1393 (June 2012).

135. Aluminum, including AAHS, has been linked to scores of systemic side effects

including, but not limited to: impairing cognitive and motor function; inducing autoimmune interactions; increasing blood brain barrier permeability; inducing macrophagic myofascitis in muscle; blocking neuronal signaling; interrupting cell-to-cell communications; corrupting neuronal-glial interactions; interfering with synaptic transmissions; altering enzyme function; impairing protein function; fostering development of abnormal tau proteins; and altering DNA.

ii. Merck Lied About a Secret DNA Adjuvant Contained in The Gardasil Vaccines

136. Merck has repeatedly concealed or incorrectly identified Gardasil ingredients to the FDA and the public.

137. Merck lied both to the FDA and the public about including a secret and potentially hazardous ingredient, HPV LI-DNA fragments, in Gardasil. These DNA fragments could act as a Toll-Like Receptor 9 ("TLR9") agonist – further adjuvanting the vaccine and making it more potent. Merck used this hidden adjuvant to prolong the immunological effects of the vaccine, but illegally omitted it from its list of substances and ingredients in the vaccine.

138. Dr. Sin Hang Lee has opined that, without adding the TLR9 agonist, Gardasil would not be immunogenic. The DNA fragments bound to the AAHS nanoparticles act as the TLR9 agonist in both Gardasil and Gardasil 9 vaccines, creating the strongest immune-boosting adjuvant in use in any vaccine.

139. On multiple occasions, Merck falsely represented to the FDA and others, including regulators in other countries, that the Gardasil vaccine did not contain viral DNA, ignoring the DNA fragments.

140. This DNA adjuvant is not approved by the FDA and Merck does not list it among the ingredients as federal law requires. See 21 C.F.R. § 610.61(o) (requiring that adjuvants be listed on biologics' labeling). Even if not an adjuvant, the DNA fragments should have been listed because they represent a safety issue. 21 C.F.R. §610.61(n).

141. It is unlawful for vaccine manufacturers to use an experimental and undisclosed adjuvant.

142. When independent scientists found DNA fragments in every Gardasil vial tested, from all over the world, Merck at first denied, and then finally admitted, the vaccine does indeed include

HPV L1-DNA fragments.

143. Tellingly, Merck entered into a business arrangement with Idera Pharmaceuticals in 2006 to explore DNA adjuvants to further develop and commercialize Idera's toll-like receptors in Merck's vaccine program.

144. To this day, the Gardasil package inserts do not disclose that DNA fragments remain in the vaccine.

145. Dr. Lee also found HPV DNA fragments from the Gardasil vaccine in post-mortem spleen and blood samples taken from a young girl who died following administration of the vaccine. *See* Sin Hang Lee, *Detection of Human Papillomavirus L1 Gene DNA Fragments in Postmortem Blood and Spleen After Gardasil Vaccination—A Case Report*, 3 ADVANCES IN BIOSCIENCE AND BIOTECHNOLOGY 1214 (December 2018).

146. Those fragments appear to have played a role in the teenager's death.

147. The scientific literature suggests there are grave and little-understood risks attendant to injecting DNA into the human body.

iii. Gardasil Contains Borax

148. Gardasil contains sodium borate (borax). Borax is a toxic chemical and may have long-term toxic effects.

149. Merck has performed no studies to determine the impact of injecting borax into millions of young children or adults.

150. Sodium borate is known to have adverse effects on male reproductive systems in rats, mice, and dogs. Furthermore, borax causes increased fetal deaths, decreased fetal weight, and increased fetal malformations in rats, mice, and rabbits.

151. The European Chemical Agency requires a "DANGER!" warning on borax and states that borax "may damage fertility or the unborn child."

152. The Material Safety Data Sheet ("MSDS") for sodium borate states that sodium borate "[m]ay cause adverse reproductive effects" in humans.

153. The FDA has banned borax as a food additive in the United States, and yet allows Merck to use it in the Gardasil vaccine without any proof of safety.

iv. Gardasil Contains Polysorbate 80

154. Gardasil contains Polysorbate 80.

155. Polysorbate 80 crosses the blood-brain barrier.

156. Polysorbate 80 is used in drugs to open up the blood brain barrier in order to allow the active ingredients in a drug to reach the brain and to elicit the intended response. It acts as an emulsifier for molecules like AAHS and aluminum enabling those molecules to pass through resistive cell membranes.

157. Polysorbate 80 is associated with many health injuries, including, anaphylaxis, infertility and cardiac arrest.

158. Polysorbate 80 was implicated as a cause, possibly with other components, of anaphylaxis in Gardasil recipients in a study in Australia. *See* Julia Brotherton et al., *Anaphylaxis Following Quadrivalent Human Papillomavirus Vaccination*, 179 CANADIAN MEDICAL ASSOC. J. 525 (September 9, 2008). Merck never tested Polysorbate 80 for safety in vaccines.

v. Gardasil Contains Genetically Modified Yeast

159. Gardasil contains genetically modified yeast.

160. Studies have linked yeast with autoimmune conditions. *See, e.g.*, Maurizo Rinaldi et al., *Anti-Saccharomyces Cerevisiae Autoantibodies in Autoimmune Diseases: from Bread Baking to Autoimmunity*, 45 CLINICAL REVIEWS IN ALLERGY AND IMMUNOLOGY 152 (October 2013).

161. Study participants with yeast allergies were excluded from Gardasil clinical trials.

162. Merck has performed no studies to determine the safety of injecting yeast into millions of children and young adults.

H. As it Did in Vioxx, In Designing and Conducting Its Clinical Trials for Gardasil, Merck Concealed Risks to Falsely Enhance the Safety Profile of Gardasil

163. Merck engaged in wholesale fraud during its safety and efficacy clinical studies.

164. In order to obtain its Gardasil license, Merck designed its studies purposefully to conceal adverse events and exaggerate efficacy.

165. Merck sold Gardasil to the public falsely claiming that pre-licensing safety tests proved it to be effective and safe.

166. In fact, Merck's own pre-licensing studies showed Gardasil to be of doubtful efficacy and dangerous.

167. The dishonesty in the clinical tests has led many physicians to recommend the vaccination, under false assumptions.

168. The clinical trials clearly demonstrated that the risks of both Gardasil and Gardasil 9 vastly outweigh any proven or theoretical benefits.

169. Merck deliberately designed the Gardasil protocols to conceal evidence of chronic conditions such as autoimmune diseases, menstrual cycle problems, and death associated with the vaccine during the clinical studies.

170. Merck employed deceptive means to cover up injuries that study group participants suffered.

171. In early 2018, Lars Jørgensen, M.D., Ph.D. and Professor Peter Gøtzsche, M.D. (then with the Nordic Cochrane Centre), and Professor Tom Jefferson, M.D. of the Centre for Evidence-Based Medicine published a study indexing all known industry and non-industry HPV vaccine clinical trials and were disturbed to find that regulators such as the FDA and EMA (European Medicines Agency) assessed as little as half of all available clinical trial results when approving the HPV vaccines. Lars Jørgensen et al., *Index of the Human Papillomavirus (HPV) Vaccine Industry Clinical Study Programmers and Non-Industry Funded Studies: a Necessary Basis to Address Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEWS (January 18, 2018).

172. Per the indexing study discussed above, Merck appears to have kept a number of its clinical trial results secret. Moreover, it appears that Merck reported only those findings that support its own agenda.

173. Three separate reviews of the Gardasil vaccine by the Cochrane Collaboration found that the trial data were "largely inadequate."

174. According to Dr. Tom Jefferson, "HPV [vaccine] harms have not been properly studied."

175. In 2019, numerous medical professionals published an article in the British Medical Journal outlining the flaws and incomplete nature of the publications discussing Merck's Gardasil

clinical trials. The authors issued a "call to action" for independent researchers to reanalyze or "restore the reporting of multiple trials in Merck's clinical development program for quadrivalent human papillomavirus (HPV) vaccine (Gardasil) vaccine." Peter Doshi et al., *Call to Action: RIAT Restoration of Previously Unpublished Methodology in Gardasil Vaccine Trials*, 346 BRIT. MED. J. 2865 (2019). The authors explained that the highly influential publications of these studies, which formed the basis of Gardasil's FDA approval, "incompletely reported important methodological details and inaccurately describe the formulation that the control arm received, necessitating correction of the record." *Id.* The authors explained that, while the publications claimed the clinical trials of Gardasil were "placebo-controlled," "participants in the control arm of these trials did not receive an inert substance, such as saline injection. Instead, they received an injection containing [AAHS], a proprietary adjuvant system that is used in Gardasil to boost immune response." *Id.*

176. The researchers further opined that "the choice of AAHS-containing controls complicates the interpretation of efficacy and safety results in trials … We consider the omission in journal articles, of any rationale for the selection of AAHS-containing control, to be a form of incomplete reporting (of important methodological details) and believe the rationale must be reported. We also consider that use of the term 'placebo' to describe an active comparator like AAHS inaccurately describes the formulation that the control arm received, and constitutes an important error that requires correction." *Id.*

177. The authors pointed out that Merck's conduct "raises ethical questions about trial conduct as well" and that they and other scientists would need to review the Gardasil clinical trial raw data, in order to be able to analyze the safety and adverse event profile of Gardasil meaningfully and independently. *Id.*

i. Small Clinical Trials

178. Although nine to 12-year-olds are the primary target population for HPV vaccines, Merck used only a small percentage of this age group in the clinical trials. Protocol 018 was the only protocol comparing children receiving a vaccine to those who did not. In that study, Merck looked at results of fewer than 1,000 children 12 and younger for a vaccine targeting billions of boys and girls in that age group over time. In Protocol 018, 364 girls and 332 boys (696 children) were in the

vaccine cohort, while 199 girls and 173 boys (372 children) received a non-aluminum control.

179. The small size of this trial means that it was incapable of ascertaining all injuries that could occur as a result of the vaccine.

ii. Merck Used a Highly Toxic "Placebo" to Mask Gardasil Injuries

180. Instead of comparing health outcomes among volunteers in the Gardasil study group to health outcomes among volunteers receiving an inert placebo, Merck purposefully used a highly toxic placebo as a control in order to conceal Gardasil's risks in all trials using comparators with the exception of Protocol 018, where only 372 children received a non-saline placebo containing everything in the vaccine except the adjuvant and antigen.

181. Comparing a new product against an inactive placebo provides an accurate picture of the product's effects, both good and bad. The World Health Organization ("WHO") recognizes that using a toxic comparator as a control (as Merck did here) creates a "methodological disadvantage." WHO states that "it may be difficult or impossible to assess the safety" of a vaccine when there is no true placebo.

182. Merck deliberately used toxic "placebos" in the control group, in order to mask harms caused by Gardasil to the study group.

183. Instead of testing Gardasil against a control with a true inert placebo, Merck tested its vaccine in almost all clinical trials against its highly neurotoxic aluminum adjuvant, AAHS.

184. Merck gave neurotoxic aluminum injections to approximately 10,000 girls and young women participating in Gardasil trials, to conceal the dangers of Gardasil vaccines.

185. Merck never safety tested AAHS before injecting it into thousands of girls and young women in the control groups and the girls and young women were not told they could receive an aluminum "placebo." Merck told the girls that they would receive either the vaccine or a safe inert placebo.

186. Merck violated rules and procedures governing clinical trials when it lied to the clinical study volunteers, telling them that the placebo was an inert saline solution – when in reality the placebo contained the highly neurotoxic aluminum adjuvant AAHS.

187. AAHS provoked terrible injuries and deaths in a number of the study participants when

Merck illegally dosed the control group volunteers with AAHS.

188. Since the injuries in the Gardasil group were replicated in the AAHS control group, this scheme allowed Merck to falsely conclude that Gardasil's safety profile was comparable to the "placebo."

189. The scheme worked and enabled Merck to secure FDA licensing.

190. Merck lied to the FDA when it told public health officials that it had used a saline placebo in Protocol 018.

191. There was no legitimate public health rationale for Merck's failure to use a true saline placebo control in the original Gardasil clinical trials. At that time, no other vaccine was yet licensed for the four HPV strains Gardasil was intended to prevent.

192. A small handful of girls in a subsequent Gardasil 9 trial group, may have received the saline placebo, but only after they had already received three doses of Gardasil for the Gardasil 9 trial.

iii. Merck Used Exclusionary Criteria to Further Conceal Gardasil Risks

193. Merck also manipulated the Gardasil studies by excluding nearly half of the original recruits to avoid revealing the effects of the vaccine on vulnerable populations.

194. After recruiting thousands of volunteers to its study, Merck excluded all women who had admitted to vulnerabilities that might be aggravated by the vaccine such as abnormal Pap tests or women with a history of immunological or nervous system disorders.

195. Women could also be excluded for "[a]ny condition which in the opinion of the investigator might interfere with the evaluation of the study objectives."

196. Merck's protocol had exclusion criteria for subjects with allergies to vaccine ingredients including aluminum (AAHS), yeast, and the select enzymes. For most of these ingredients, there are limited resources for the public to test for such allergies in advance of being vaccinated.

197. Merck excluded anyone with serious medical conditions from the Gardasil clinical trials, even though CDC recommends the Gardasil vaccine for everyone, regardless of whether or not they suffer from a serious medical condition.

198. Merck sought to exclude from the study all subjects who might be part of any subgroup

that would suffer injuries or adverse reactions to any of Gardasil's ingredients.

199. The study exclusion criteria are not listed as warnings on the package inserts and the package insert for Gardasil only mentions an allergy to yeast or to a previous dose of Gardasil as a contraindication, rather than an allergy to any other component. Nonetheless, for most of the ingredients, it is almost impossible to determine if such an allergy exists prior to being vaccinated and Merck does not recommend allergy testing before administering the vaccine.

200. Instead of testing the vaccine on a population representative of the cross-section of humans who would receive the approved vaccine, Merck selected robust, super-healthy trial participants, who did not reflect the general population, in order to mask injurious effects on all the vulnerable subgroups that now receive the vaccine. Therefore, the population tested in the clinical trials was a much less vulnerable population than the population now receiving Gardasil.

iv. Merck Deceived Regulators and The Public by Classifying Many Serious Adverse Events, Which Afflicted Nearly Half of All Study Participants, As Coincidences

201. Because Merck did not use a true placebo, determining which injuries were attributable to the vaccine and which were attributable to unfortunate coincidence was entirely within the discretion of Merck's paid researchers.

202. In order to cover up and conceal injuries from its experimental vaccine, Merck, during the Gardasil trials, employed a metric, "new medical conditions," that allowed the company to dismiss and fraudulently conceal infections, reproductive disorders, neurological symptoms, and autoimmune conditions, which affected a troubling 50 percent of all clinical trial participants.

203. Merck's researchers systematically dismissed reports of serious adverse events from 49 percent of trial participants in order to mask the dangers of the vaccine.

204. Instead of reporting these injuries as "adverse events," Merck dismissed practically all of these illnesses and injuries as unrelated to the vaccine by classifying them under its trashcan metric "new medical conditions" – a scheme Merck could get away with only because it used a "spiked" (poisonous) placebo, that was yielding injuries at comparable rates.

205. Merck's use of a toxic placebo allowed the company to conceal from the public an epidemic of autoimmune diseases and other injuries and deaths associated with its multi-billion-dollar

HPV vaccine.

206. Because Merck conducted its studies without a true placebo, Merck investigators had wide discretion to decide what constituted an adverse event and used that power to dismiss a wave of grave vaccine injuries, injuries that sickened half of the trial volunteers, as coincidental.

207. Almost half (49 percent) of all trial participants, regardless of whether they received the vaccine or Merck's toxic placebo, reported adverse events, including serious illnesses such as blood, lymphatic, cardiac, gastrointestinal, immune, musculoskeletal, reproductive, neurological and psychological conditions, chronic illnesses such as thyroiditis, arthritis and multiple sclerosis, and conditions requiring surgeries. *See, e.g.*, Nancy B. Miller, *Clinical Review of Biologics License Application for Human Papillomavirus 6, 11, 16, 18 L1 Virus Like Particle Vaccine (S. cerevisiae) (STN 125126 GARDASIL), manufactured by Merck, Inc.* at 393-94 (Table 302) (June 8, 2006).

v. Merck Manipulated the Study Protocols to Block Participants and Researchers from Reporting Injuries and Designed the Studies to Mask Any Long-Term Adverse Events

208. Merck adopted multiple strategies to discourage test subjects from reporting injuries.

209. Merck provided Vaccination Report Cards to a limited number of trial participants. For example, in Protocol 015, only approximately 10 percent of participants – all in the United States, despite trial sites worldwide – received Vaccination Report Cards to memorialize reactions in the first few days following injections.

210. Furthermore, the report cards only included *categories* of "Approved Injuries" mainly jab site reactions (burning, itching, redness, bruising) – leaving no room to report more serious unexplained injuries such as autoimmune diseases. In fact, they were designed for the purposes of reporting non-serious reactions only.

211. Furthermore, Merck instructed those participants to record information for only 14 days following the injection.

212. In this way, Merck foreclosed reporting injuries with longer incubation periods or delayed diagnostic horizons.

213. Abbreviated reporting periods were part of Merck's deliberate scheme to conceal chronic conditions such as autoimmune or menstrual cycle problems, and premature ovarian failure,

all of which have been widely associated with the vaccine, but would be unlikely to show up in the first 14 days following injection.

214. Merck researchers did not systematically collect adverse event data, from the trials, which were spread out over hundreds of test sites all over the world.

215. To conceal the dangerous side effects of its vaccine, Merck purposely did not follow up with girls who experienced serious adverse events during the Gardasil clinical trials.

216. Merck failed to provide the trial subjects a standardized questionnaire checklist of symptoms, to document a comparison of pre- and post-inoculation symptoms.

217. To discourage its clinicians from reporting adverse events, Merck made the paperwork reporting requirements for supervising clinicians, onerous and time-consuming, and refused to pay investigators additional compensation for filling out the paperwork.

218. Thus, Merck disincentivized researchers from reviewing participants' medical records even when the participant developed a "serious medical condition that meets the criteria for serious adverse experiences" as described in the protocol.

219. Merck granted extraordinary discretion to its researchers to determine what constituted a reportable adverse event, while incentivizing them to report nothing and to dismiss all injuries as unrelated to the vaccine.

220. Merck used subpar, subjective data collection methods, relying on participants' recollections and the biased viewpoints of its trial investigators.

221. Merck downplayed the incidence of serious injuries and used statistical gimmickry to under-report entries.

vi. Merck Deceived Regulators and the Public About Its Pivotal Gardasil Clinical Trial (Protocol 018)

222. Merck tested Gardasil and Gardasil 9 in some 50 clinical trials, each one called a "Protocol." However, results for many of these studies are not available to the public or even to the regulators licensing Gardasil. *See* Lars Jørgensen, *et al.*, *Index of the Human Papillomavirus (HPV) Vaccine Industry Clinical Study Programmers and Non-Industry Funded Studies: a Necessary Basis to Address Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEWS 8 (January 18, 2018).

223. Gardasil's most important clinical trial was Protocol 018. The FDA considered Protocol 018 the pivotal trial upon which Gardasil licensing approvals hinged, because FDA believed 1) it was the only trial where Merck used a "true saline placebo," and 2) it was the only trial with a comparator group that included girls aged 11 to 12 – the target age for the Gardasil vaccine. *See* Transcript of FDA Center For Biologics Evaluation And Research VRBPAC Meeting, May 18, 2006, at 93 (Dr. Nancy Miller).

224. Merck lied to regulators, to the public and to subjects in its clinical trials by claiming that the Protocol 018 "placebo" group received an actual saline or inert placebo.

225. When the FDA approved Gardasil, it described the Protocol 018 control as a "true saline placebo."

226. The FDA declared that the Protocol 018 trial was "of particular interest" because Merck used a true saline placebo instead of the adjuvant as a control.

227. Merck told regulators that it gave a "saline placebo" to only one small group of approximately 600 nine to 15-year-old children.

228. In fact, Merck did not give even this modest control group a true saline placebo, but rather, the group members were given a shot containing "the carrier solution" – a witch's brew of toxic substances including polysorbate 80, sodium borate (borax), genetically modified yeast, L-histidine, and possibly a fragmented DNA adjuvant.

229. The only components of Gardasil the control group did not receive were the HPV antigens and the aluminum adjuvant.

230. Despite the witches' brew of toxic chemicals in the carrier solution, those children fared much better than any other study or control group participants, all of whom received the AAHS aluminum adjuvant.

231. Only 29 percent of the vaccinated children and 31 percent of control recipients in Protocol 018 reported new illnesses from Day 1 through Month 12, compared to an alarming 49.6 percent of those vaccinated and 49 percent of AAHS controls in the "pooled group" (composed of some 10,000 young women and with the other participants combined) from Day 1 only through Month 7 (not 12). Because the pooled group also included Protocol 018, even those numbers may not

be accurate with respect to those who received either a vaccine with a full dose of AAHS or those who received an AAHS control.

232. Few of the participants in the Protocol 018 control group got systemic autoimmune diseases, compared to 2.3 percent (1 in every 43) in the pooled group. In a follow-up clinical review in 2008, the FDA identified three girls in the carrier-solution group with autoimmune disease. Based on the number of girls in the placebo group as stated in the original 2006 clinical review, fewer than 1 percent of girls in the carrier solution group reported autoimmune disease.

233. In order to further deceive the public and regulators, upon information and belief, Merck cut the dose of aluminum adjuvant in half when it administered the vaccine to the nine to fifteen-year-old children in its Protocol 018 study group.

234. As a result, this group showed significantly lower "new medical conditions" compared to other protocols.

235. Upon information and belief, Merck pretended that the vaccinated children in the Protocol 018 study group received the full dose adjuvant by obfuscating the change in formulation in the description.

236. Upon information and belief, Merck had cut the adjuvant in half, knowing that this would artificially and fraudulently lower the number of adverse events and create the illusion that the vaccine was safe.

237. Upon information and belief, Merck lied about this fact to the FDA.

238. The data from that study therefore do not support the safety of the Gardasil formulation since Merck was not testing Gardasil but a far less toxic formulation.

239. Upon information and belief, Merck was testing a product with only half the dose of Gardasil's most toxic component.

240. Upon information and belief, this is blatant scientific fraud, which continues to this day because this is the study upon which current vaccine safety and long-term efficacy assurances are based.

241. As set forth above, upon information and belief, Merck's deception served its purpose: Only 29 percent of the vaccinated children in Protocol 018 reported new illness, compared to an

alarming 49.6 percent in the pooled group to receive the full dose adjuvant in the vaccine.

I. Contrary to Merck's Representations, Gardasil May Actually Cause and Increase the Risk of Cervical and Other Cancers

242. Gardasil's label states, "Gardasil has not been evaluated for potential to cause carcinogenicity or genotoxicity." The Gardasil 9 label states: "GARDASIL9 has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility."

243. Peer-reviewed studies, including CDC's own studies, have suggested that the suppression of the HPV strains targeted by the Gardasil vaccine may actually open the ecological niche for replacement by more virulent strains. *See* Fangjian Guo et al., *Comparison of HPV prevalence between HPV-vaccinated and non-vaccinated young adult women (20–26 years)*, 11 HUMAN VACCINES & IMMUNOTHERAPEUTICS 2337 (October 2015); Sonja Fischer et al., *Shift in prevalence of HPV types in cervical cytology specimens in the era of HPV vaccinations*, 12 ONCOLOGY LETTERS 601 (2016); J. Lyons-Weiler, *Biased Cochrane Report Ignores Flaws in HPV Vaccine Studies, and Studies of HPV Type Replacement*, (May 18, 2018). In other words, Gardasil may increase the chances of getting cancer.

244. In short, the Gardasil vaccines, which Merck markets as anti-cancer products, may themselves cause cancer or mutagenetic changes that can lead to cancer.

245. Merck concealed from the public data from its clinical trials indicating that the vaccines enhance the risk of cervical cancers in many women.

246. Merck's study showed that women exposed to HPV before being vaccinated were 44.6 percent more likely to develop cancerous lesions compared to unvaccinated women, even within a few years of receiving the vaccine.

247. In other words, Merck's studies suggest that its HPV vaccines may cause cancer in women who have previously been exposed to HPV, particularly if they also have a current infection.

248. In some studies, more than 30 percent of girls show evidence of exposure to HPV before age ten, from casual exposures, unwashed hands or in the birth canal. Flora Bacopoulou et al., *Genital HPV in Children and Adolescents: Does Sexual Activity Make a Difference?*, 29 JOURNAL OF PEDIATRIC & ADOLESCENT GYNECOLOGY 228 (June 2016).

249. Even in light of the data demonstrating that Gardasil can increase the risk of cancer in girls who previously have been exposed to HPV, in order to increase profits, Merck's Gardasil labels and promotional material do not inform patients and medical doctors of this important risk factor.

250. Some clinical trial participants have developed cancer, including cervical cancer.

251. Numerous women have reported a sudden appearance of exceptionally aggressive cervical cancers following vaccination.

252. Cervical cancer rates are climbing rapidly in all the countries where Gardasil has a high uptake.

253. An Alabama study shows that the counties with the highest Gardasil uptakes also had the highest cervical cancer rates.

254. After the introduction of HPV Vaccine in Britain, cervical cancer rates among young women aged 25 to 29 have risen 54 percent.

255. In Australia, government data reveals there has been a sharp increase in cervical cancer rates in young women following the implementation of the Gardasil vaccine. The most recent data reveal that, 13 years after Gardasil was released and pushed upon teenagers and young adults, there has been a 16% increase in 25- to 29-year-olds, and a 30 percent increase in 30 to 34 year-old girls contracting cervical cancer – corroborating the clinical trial data that Gardasil may *increase* the risk of cervical cancer, particularly in patients who had previous HPV infections. Meanwhile, rates are decreasing for older women (who have not been vaccinated).

256. In addition to the belief that Gardasil may create and open an ecological niche for replacement by more virulent strains of HPV, resulting in the increase of cervical cancers as outlined above, in light of Merck's false advertising that Gardasil prevents cervical cancer, young women who have received Gardasil are foregoing regular screening and Pap tests in the mistaken belief that HPV vaccines have eliminated all their risks.

257. Cervical screening is proven to reduce the cases of cervical cancer, and girls who have taken the vaccine are less likely to undergo cervical screenings.

258. Data show that girls who received HPV vaccines before turning 21 are far less likely to get cervical cancer screening than those who receive the vaccines after turning 21.

259. The cervical screening is more cost effective than vaccination alone or vaccination with screening.

260. Therefore, Pap tests, which detect cervical tissue abnormalities, and HPV DNA testing are the most effective frontline public health response to cervical health.

J. Merck has Concealed the Fact that Gardasil Induces and Increases the Risk of Autoimmune Diseases, and Other Injuries, Including But Not Limited to, Postural Orthostatic Tachycardia Syndrome, Chronic Fatigue Syndrome, Neuropathy, Fibromyalgia and Dysautonomia

261. Gardasil induces and increases the risk of autoimmune disease.

262. Gardasil has been linked to a myriad of autoimmune disorders, including but not limited, to: Guillain–Barré syndrome ("GBS"), postural orthostatic tachycardia syndrome ("POTS"), Orthostatic Intolerance ("OI"), chronic inflammatory demyelinating polyneuropathy ("CDIP"), small fiber neuropathy ("SNF"), systemic lupus erythematosus ("SLE"), immune thrombocytopenic purpura ("ITP"), multiple sclerosis ("MS"), acute disseminated encephalomyelitis ("ADEM"), antiphospholipid syndrome ("APS"), transverse myelitis, rheumatoid arthritis, interconnective tissue disorder, autoimmune pancreatitis ("AIP") and autoimmune hepatitis.

263. Gardasil has also been linked to a myriad of diseases and symptoms that are associated with induced-autoimmune disease, including for example, fibromyalgia, dysautonomia, premature ovarian failure, chronic fatigue syndrome ("CFS"), chronic regional pain syndrome ("CRPS"), cognitive dysfunction, migraines, severe headaches, persistent gastrointestinal discomfort, widespread pain of a neuropathic character, encephalitis syndrome, autonomic dysfunction, joint pain, and brain fog.

264. In a 2015 textbook, VACCINES AND AUTOIMMUNITY, edited by Dr. Yehuda Shoenfeld, the father of autoimmunology research, and many of the world's leading autoimmunity experts, the scientists concluded that Gardasil can cause autoimmune disorders because of the vaccine's strong immune stimulating ingredients. *See* Lucija Tomljenovic & Christopher A. Shaw, *Adverse Reactions to Human Papillomavirus Vaccines*, VACCINES & AUTOIMMUNITY 163 (Yehuda Shoenfeld et al. eds., 2015).

265. Medical experts have opined that the mixture of adjuvants contained in vaccines, in

particular in the Gardasil vaccines, is responsible for post-vaccination induced autoimmune diseases in select patients. The risks have become so prolific that medical experts have coined a new umbrella syndrome – Autoimmune/Inflammatory Syndrome Induced by Adjuvants ("ASIA") to refer to the spectrum of immune-mediated diseases triggered by an adjuvant stimulus contained in vaccines, such as aluminum. See e.g., YEHUDA SHOENFELD ET AL, EDS., VACCINES & AUTOIMMUNITY 2 (2015)

266. Indeed, even in animal studies, it has been revealed that aluminum adjuvants can induce autoimmune disease in tested animals. By way of example, in a series of studies conducted by Lluís Luján, DVM, Ph.D., and his colleagues, it was revealed that sheep injected with aluminum-containing adjuvants commonly come down with severe autoimmune diseases and other adverse reactions.

267. Specific to the Gardasil vaccines, which contain adjuvants, including, amorphous aluminum hydroxyphosphate sulfate (AAHS) and the previously undisclosed HPV L1 gene DNA fragments, a number of mechanisms of action have been outlined (as discussed *infra*) as to how Gardasil induces autoimmune disease in select patients.

268. Given the number of HPV strains that exist, a great part of the human population has HPV, however, HPV by itself is generally not immunogenic, and generally does not evoke immune responses. Indeed, HPV shares a high number of peptide sequences with human proteins, so that the human immune system generally does not react against HPV in order to not harm self-proteins. Immunotolerance thus generally blocks reactions against HPV in order to avoid autoimmune attacks against the human proteins.

269. To induce anti-HPV immune reactions, Merck added various adjuvants, including amorphous aluminum hydroxyphosphate sulfate (AAHS), to the Gardasil vaccine. Adjuvants, such as aluminum, are inflammatory substances that hyperactivate the immune system. Adjuvants are thus the "secret sauce" used by Merck to hyperactivate the immune system and make HPV immunogenic.

270. While adjuvants are added with the intent of destroying the HPV virus, they also can have the unintended result of rendering the immune system "blind" and unable to distinguish human proteins from HPV proteins – accordingly, human proteins that share peptide sequences with HPV are at risk of also being attacked by the vaccine.

271. While Gardasil causes immune hyperactivation and production of anti-HPV antibodies

to fend off certain strains of the HPV virus, it can also result in the immune system losing its ability to differentiate human proteins from foreign proteins causing the immune system to attack the body's own proteins and organs. Because of the massive peptide commonality between HPV and human proteins, the indiscriminate attack triggered by the Gardasil adjuvants will cause massive cross-reactions and dangerous attacks against human proteins, leading to a number of autoimmune diseases manifested throughout the different organs of the body. This process is sometimes referred to as "molecular mimicry."

272. In addition to "molecular mimicry," other mechanisms of action that explain how Gardasil can induce autoimmune disease are "epitope spreading," whereby invading Gardasil antigens, including the toxic aluminum adjuvant, accelerate autoimmune process by location activation of antigen presenting cells and "bystander activation," wherein antigens and the aluminum adjuvants in the Gardasil vaccine activate pre-primed autoreactive T cells, which can initiate autoimmune disease (bystander activation of autoreactive immune T cells), or where virus-specific T cells initiate bystander activation resulting in the immune system killing uninfected and unintended neighboring cells.

273. Relevant to the injuries at issue in this case, when a person is lying down, approximately one-quarter of their blood volume resides in the chest area. When the person stands up, a significant amount of that blood shifts to the lower extremities. This causes impaired return of blood flow to the heart which also reduces blood pressure. In healthy individuals, the autonomic nervous system adjusts the heartrate to counteract this effect and the hemodynamic changes are negligible. However, in individuals (such as Plaintiff) who are now suffering from dysautonomia or autonomic ailments, such as POTS, the body's ability to adjust the heartrate and compensate for the blood flow is corrupted resulting in a host of wide ranging symptoms, including but not limited to, dizziness, lightheadedness, vertigo, woozy sensation, chronic headaches, vision issues due to the loss of blood flow to the brain, light and sound sensitivity, loss of consciousness, shortness of breath, chest pain, gastrointestinal issues, body pains, insomnia, and confusion and/or difficulty sleeping. In certain cases of POTS, patients will also be diagnosed with other medical conditions, including but not limited to, chronic fatigue syndrome and fibromyalgia.

274. Medical research has determined that certain dysautonomia diseases such as POTS and OI have an autoimmune etiology. Norepinephrine, a key neurotransmitter of the sympathetic ("fight or flight") system, exerts its mechanism of action by binding to receptors located in the smooth muscle of the blood vessels and various organs, including the heart. These receptors include alpha-1, alpha-2, beta-1, beta-2, and beta-3 receptors and, as a group, are generally known as the adrenergic receptors. The adrenergic receptors, and other receptors, including but not limited to, the ganglionic and muscarinic acetylcholine receptors are believed to be affected in certain cases of POTS and OI. *See e.g.*, Hongliang Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. AMERICAN HEART ASSOC. e000755 (2014); Artur Fedorowski et al., *Antiadrenergic Autoimmunity in Postural Tachycardia Syndrome*, 19 EUROPACE 1211 (2017); Mohammed Ruzieh et al., *The Role of Autoantibodies in the Syndromes of Orthostatic Intolerance: A Systematic Review*, 51 SCANDINAVIAN CARDIOVASCULAR J. 243 (2017); Shu-ichi Ikeda et al., *Autoantibodies Against Autonomic Nerve Receptors in Adolescent Japanese Girls after Immunization with Human Papillomavirus Vaccine*, 2 ANNALS OF ARTHRITIS AND CLINICAL RHEUMATOLOGY 1014 (2019); William T. Gunning, *Postural Orthostatic Tachycardia Syndrome is Associated With Elevated G-Protein Coupled Receptor Autoantibodies*, 8 J. AMERICAN HEART ASSOC. e013602 (2019).

275. A variety of published medical journal articles have discussed the association between Gardasil and a myriad of serious injuries and have reported on patients developing POTS, OI, fibromyalgia and other symptoms of autonomic impairment following Gardasil vaccination. *See* Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135 (2014); Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization With Human Papillomavirus Vaccine,* 53 INTERNAL MEDICINE 2185 (2014); Louise S. Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-Lavin et al., *HPV Vaccination Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL RHEUMATOLOGY 1981 (2015); Louise S. Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic*

Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma Virus Vaccine, 1 INT. J. OF VACCINE & VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Rebecca E. Chandler et al., *Current Safety Concerns With Human Papillomavirus Vaccine: A Cluster Analysis of Reports in VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al., *Autonomic Dysfunction and HPV Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and Svetlana Blitshetyn, *Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions*, CLINICAL AUTONOMIC RESEARCH (2019).

276. In a 2017 review, Drs. Tom Jefferson and Lars Jørgensen criticized the European Medicines Agency ("EMA") for turning a blind eye to the debilitating autoimmune injuries, including CRPS and POTS that young women had suffered following vaccination with HPV vaccine. Tom Jefferson et al., *Human Papillomavirus Vaccines, Complex Regional Pain Syndrome, Postural Orthostatic Tachycardia Syndrome, and Autonomic Dysfunction – A Review of the Regulatory Evidence from the European Medicines Agency*, 3 INDIAN J. OF MED. ETHICS 30 (Jan. – March 2017).

277. In a separate article, the same authors describe their process for extracting data from not only peer-reviewed journal publications, but also unpublished data from pharmaceutical company clinical study reports and trial register entries from ClinicalTrials.gov, under the assumption that "more than half of all studies are never published, and the published studies' intervention effects are often exaggerated in comparison to the unpublished studies. This introduces reporting bias that undermines the validity of systematic reviews. To address reporting bias in systematic reviews, it is necessary to use industry and regulatory trial registers and trial data—in particular, the drug manufacturers' complete study programs." They found that 88 percent of industry studies were solely industry funded and found serious deficiencies and variability in the availability of HPV vaccine study data. For example, only half of the completed studies listed on ClinicalTrials.gov posted their results. The clinical study reports the authors obtained confirmed that the amount of information and data are vastly greater than that in journal publications. When the authors compared the data the EMA used (which was provided by GlaxoSmithKline and Merck Sharp and Dohme) to conduct their review of the relationship between HPV vaccination and both POTS and CRPS, the authors found that only 48

percent of the manufacturers' data were reported. According to the authors, "we find this very disturbing." Lars Jørgensen et al., *Index of the Human Papillomavirus (HPV) Vaccine Industry Clinical Study Programmes and Non-Industry Funded Studies: A Necessary Basis to Address Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEW 8 (2018).

278. Likewise, in a recently released February 2020 peer-reviewed study, researchers who analyzed the available clinical trial data for all HPV vaccines, which include the Gardasil vaccines and another HPV vaccine currently only available in Europe, concluded that "HPV vaccines increased serious nervous disorders." Lars Jørgensen et al., *Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020).

279. In addition, Jørgensen and his co-authors observed that, in reanalyzing the association between HPV vaccines and one specific autoimmune disease, POTS, the HPV vaccines were associated with a nearly two-fold increased risk of POTS. *Id.*

280. Jørgensen and his co-authors also noted many of the same shortcomings associated with the Gardasil clinical trials as have already been discussed in this Complaint, including for example, the fact that no true placebo was utilized by Merck as a comparator (i.e., the comparator/control used by Merck in the Gardasil clinical trials contained aluminum adjuvant). The researchers noted that "[t]he use of active comparators may have underestimated harms related to HPV vaccines," and that "[t]he degree of harms might therefore be higher in clinical practice than in the trials." *Id.*

281. Jørgensen and his co-authors also noted that the clinical trials revealed that Gardasil-9 induced more harms than Gardasil, which could be explained by the fact that Gardasil 9 contains more of the AAHS aluminum adjuvant (500 micrograms of AAHS in Gardasil-9 vs. 225 micrograms of AAHS in Gardasil), and this dose-response relationship further corroborates the plausible claim that the AAHS aluminum adjuvant is a culprit in causing adverse events. *Id.*

282. Other researchers, including Tomljenovic and Shaw, who have closely looked into Gardasil, have opined that risks from the Gardasil vaccine seem to significantly outweigh the as yet unproven long-term benefits. In their view, vaccination is unjustified if the vaccine carries any substantial risk, let alone a risk of death, because healthy teenagers face an almost zero percent risk of

death from cervical cancer.

K. Merck has Concealed the Fact that Gardasil Increases the Risk of Fertility Problems

283. Merck has never tested the impact of the Gardasil vaccines on human fertility.

284. Nevertheless, study volunteers reported devastating impacts on human fertility during combined trials, offering substantial evidence that the vaccine may be causing widespread impacts on human fertility, including increases in miscarriage, birth defects, premature ovarian failure, and premature menopause in girls and young women.

285. One of the serious adverse events now emerging in vaccinated girls, including teens, is premature ovarian failure. *See, e.g.*, D. T. Little and H. R. Ward, *Adolescent Premature Ovarian Insufficiency Following Human Papillomavirus Vaccination: A Case Series Seen in General Practice*, JOURNAL OF INVESTIGATIVE MEDICINE HIGH IMPACT, Case Reports 1-12 (Oct.-Dec. 2014); D. T. Little and H. R. Ward, *Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination*, BMJ CASE REPORTS (September 30, 2012).

286. Premature ovarian failure can occur after aluminum destroys the maturation process of the eggs in the ovaries.

287. Fertility has plummeted among American women following the 2006 mass introduction of the Gardasil vaccine. This is most evident in teen pregnancy statistics where numbers have more than halved since 2007.

288. The total fertility rate for the United States in 2017 continued to dip below what is needed for the population to replace itself, according to a report by the National Center of Health Statistics issued in January 2019, and the rate for women 15 to 44 fell another 2 percent between 2017 and 2018.

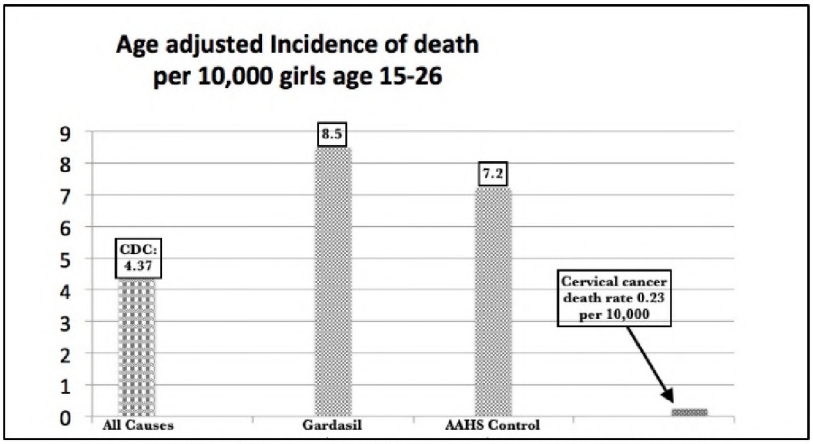
L. There were an Increased Number of Deaths in the Gardasil Studies

289. Merck's own preliminary studies predicted that Gardasil would kill and injure far more Americans than the HPV virus, prior to the introduction of the vaccine.

290. The average death rate in young women in the U.S. general population is 4.37 per 10,000. *See* Brady E. Hamilton et al., "Births: Provisional Data for 2016," *Vital Statistics Rapid*

Release, Report No. 002, June 2017.

291. The Gardasil pooled group had a death rate of 8.5 per 10,000, or almost double the background rate in the U.S.



Background CDC rate 4.37 source: National Vital Statistics Report Vol. 53 2002 page 24.[37]
Gardasil rate 8.5: 10/11,778. AAHS control rate 7.2: 7/9,680[38]
Cervical cancer mortality: 2.3 per 100,000 source: National Cancer Institute SEER Cancer Statistics Review 2015[39]

292. When Merck added in deaths from belated clinical trials, the death rate jumped to 13.3 per 10,000 (21 deaths out of 15,706).

293. Merck dismissed all deaths as coincidences.

294. The total number of deaths was 21 in the HPV vaccine group and 19 in the comparator (AAHS) groups.

295. The death rate among vaccine recipients was 13.3 per 10,000, or 133 per 100,000 (21/15,706).

296. To put this in perspective, the death rate from cervical cancer in the United States is 2.3 per 100,000 women. This means that, according to Merck's own data, a girl is 58 times more likely to die from Gardasil than from cervical cancer.

M. Post-Marketing Injuries -- The Raft of Injuries Seen in Merck's Clinical Trials Has Now Become A Population-Wide Chronic Disease Epidemic

297. By 2010, reports coming in from all over the world linked the Gardasil vaccine to bizarre and troubling symptoms.

298. Many Gardasil survivors will have lifelong handicaps.

299. The severe adverse events from the Gardasil vaccination, seen since its widespread

distribution, are similar to those injuries that Merck covered up during its clinical trials. They include autoimmune diseases, suicides, deaths, premature ovarian failures, reproductive problems, infertility, cervical cancer, sudden collapse, seizures, multiple sclerosis, strokes, heart palpitations, chronic muscle pain, complex regional pain syndrome, and weakness.

300. Other frequently reported injuries include disturbances of consciousness; systemic pain including headache, myalgia, arthralgia, back pain and other pain; motor dysfunction, such as paralysis, muscular weightiness, and involuntary movements; numbness, and sensory disturbances; autonomic symptoms including hypotension, tachycardia, nausea, vomiting, and diarrhea; respiratory dysfunction, including dyspnea, and asthma; endocrine disorders, such as menstrual disorder and hypermenorrhea; and lastly, hypersensitivity to light, heart palpitations, migraine headaches, dizziness, cognitive deficits, personality changes, vision loss, joint aches, headaches, brain inflammation, chronic fatigue, death and severe juvenile rheumatoid arthritis.

301. The data show that Gardasil is yielding far more reports of adverse events than any other vaccine. For example, Gardasil had 8.5 times more emergency room visits, 12.5 times more hospitalizations, 10 times more life-threatening events, and 26.5 more disabilities than Menactra, another vaccine with an extremely high-risk profile.

302. As of December 2019, there have been more than 64,000 Gardasil adverse events reported to the FDA's Vaccine Adverse Event Reporting System ("VAERS") since 2006.

303. Moreover, studies have shown that only approximately 1 percent of adverse events are actually reported to FDA's voluntary reporting systems, thus, the true number of Gardasil adverse events in the United States may be as high as 6.4 million incidents.

304. The Vaccine Injury Compensation Program has paid out millions of dollars in damages for Gardasil-induced injuries and deaths.

305. Gardasil now has more reported injuries than any other vaccine.

306. As of December 2019, some 10 percent of the serious injuries reported to VAERS are attributed to Gardasil and Gardasil 9.

307. The adverse events also include deaths. Parents, doctors, and scientists have reported hundreds of deaths from the Gardasil vaccine, post-marketing.

308. In order to conceal Gardasil's link to the deaths of teenagers, Merck has submitted fraudulent reports to VAERS, and posts fraudulent and misleading statements on its Worldwide Adverse Experience System.

309. For example, Merck attributed the death of a young woman from Maryland, Christina Tarsell, to a viral infection. Following years of litigation, a court determined that Gardasil caused Christina's death. There was no evidence of viral infection. Merck invented this story to deceive the public about Gardasil's safety.

310. Merck submitted fraudulent information about Christina Tarsell's death to its Worldwide Adverse Experience System and lied to the FDA through the VAERS system. Merck claimed that Christina's gynecologist had told the company that her death was due to viral infection. Christina's gynecologist denied that she had ever given this information to Merck. To this day, Merck has refused to change its false entry on its own reporting system.

N. The Gardasil Vaccines' Harms Are Not Limited to the United States, Rather the Vaccines Have Injured Patients All Over the World

311. Gardasil is used widely in the international market. Widespread global experience has likewise confirmed that the vaccine causes serious adverse events with minimal proven benefit.

312. According to the World Health Organization's Adverse Event Databases, there have been more than 100,000 serious adverse events associated with Gardasil, outside the Americas. *See* WHO Vigibase database, keyword Gardasil: http://www.vigiaccess.org.

i. In Light of Gardasil's Serious and Debilitating Adverse Events, the Japanese Government Rescinded Its Recommendation that Girls Receive Gardasil

313. In Japan, a country with a robust history of relative honesty about vaccine side effects, the cascade of Gardasil injuries became a public scandal.

314. Japan's health ministry discovered adverse events reported after Gardasil were many times higher than other vaccines on the recommended schedule. These included seizures, severe headaches, partial paralysis, and complex regional pain syndrome. See Hirokuni Beppu et al., *Lessons Learnt in Japan From Adverse Reactions to the HPV Vaccine: A Medical Ethics Perspective,* 2 INDIAN J MED ETHICS 82 (April-June 2017).

315. Japanese researchers found that the adverse events rate of the HPV vaccine was as high as 9 percent, and that pregnant women injected with the vaccine aborted or miscarried 30 percent of their babies. *See* Ministry of Health, Labour and Welfare, Transcript "The Public Hearing on Adverse Events
following HPV vaccine in Japan," February 26, 2014

316. The injuries caused the Japanese government to rescind its recommendation that girls receive the HPV vaccine.

317. Japan withdrew its recommendation for Gardasil three months after it had added the vaccine to the immunization schedule, due to "an undeniable causal relationship between persistent pain and the vaccination."

318. Uptake rates for the vaccine in Japan are now under 1 percent, compared to 53.7 percent fully vaccinated teenaged girls in the United States.

319. In late 2016 Japanese industry watchdog, MedWatcher Japan issued a scathing letter faulting the WHO for failing to acknowledge the growing body of scientific evidence demonstrating high risk of devastating side effects.

320. In 2015, the Japanese Association of Medical Sciences issued official guidelines for managing Gardasil injuries post-vaccination.

321. That same year, the Japanese Health Ministry published a list of medical institutions where staffs were especially trained to treat patients who had sustained Gardasil-induced injuries.

322. The Japanese government also launched a series of special clinics to evaluate and treat illnesses caused by the Gardasil vaccines.

323. The president of the Japanese Association of Medical Sciences stated that there was no proof that the vaccines prevent cancer.

324. These were developments that Merck was extremely anxious to suppress.

325. Merck hired the think tank, the Center for Strategic and International Studies ("CSIS") and Professor Heidi Larson of the Vaccine Confidence Project in London, to assess the reasons for the Japanese situation. The overall conclusion was that the symptoms the girls were suffering from were psychogenic in nature and were a result of rumors spread online. In essence, Merck blamed the

victims for the Gardasil-induced adverse events in Japan.

ii. Denmark Has Opened Specialized Clinics Specifically Focused on Treating Gardasil-Induced Injuries, Including Gardasil-Induced Autoimmune Diseases

326. In March 2015, Denmark announced the opening of five new "HPV clinics" to treat children injured by Gardasil vaccines. Over 1,300 cases flooded the HPV clinics shortly after opening. *See* Zosia Chustecka, *Chronic Symptoms After HPV Vaccination: Danes Start Study*, MEDSCAPE (November 13, 2015).

iii. Gardasil-Induced Adverse Events Caused the Government in Colombia to Conclude that Gardasil Would No Longer Be Mandatory

327. In Colombia, more than 800 girls in the town of El Carmen de Bolivar reported reactions ranging from fainting to dizziness to paralysis in March of 2014, following vaccination with Gardasil.

328. With protests erupting across the country, the Colombian attorney general asked the Constitutional Court to rule on a lower court ruling on the outcome of a case of an injured girl.

329. In 2017, in response to an unresolved case, Colombia's constitutional court, ruled that the Colombian government could not infringe on the bodily integrity of its citizens. This decision meant that the government could not require the HPV vaccine to be mandatory.

iv. India Halted Gardasil Trials and Accused Merck of Corruption After the Death of Several Young Girls Who were Participants in the Trial

330. Seven girls died in the Gardasil trials in India coordinated by Merck and the Gates Foundation. A report by the Indian Parliament accused the Gates Foundation and Merck of conducting "a well-planned scheme to commercially exploit" the nation's poverty and powerlessness and lack of education in rural India in order to push Gardasil. *See* 72nd Report on the *Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Programme for Appropriate Technology in Health (PATH) in India* (August 2013).

331. The report alleges that Merck (through PATH, to whom it supplied vaccines) and the Gates Foundation resorted to subterfuge that jeopardized the health and well-being of thousands of vulnerable Indian children. The parliamentary report makes clear that the clinical trials could not have

occurred without Merck corrupting India's leading health organizations. *Id.*

332. The Report accused PATH, which was in collaboration with Merck, of lying to illiterate tribal girls to obtain informed consent, widespread forging of consent forms by Merck operatives, offering financial inducements to participate, and providing grossly inadequate information about potential risks. *Id.*

333. Many of the participants suffered adverse events including loss of menstrual cycles and psychological changes like depression and anxiety. According to the report: PATH's "sole aim has to been to promote the commercial interests of HPV vaccine manufacturers, who would have reaped a windfall of profits had they been successful in getting the HPV vaccine included in the universal immunization program of the country... This [conduct] is a clear-cut violation of the human rights of these girls and adolescents." *Id.*

334. A 2013 article in the *South Asian Journal of Cancer* concludes that the HPV vaccine program is unjustifiable. "It would be far more productive to understand and strengthen the reasons behind the trend of decreasing cervical cancer rates than to expose an entire population to an uncertain intervention that has not been proven to prevent a single cervical cancer or cervical cancer death to date." *See* Sudeep Gupta, *Is Human Papillomavirus Vaccination Likely to be a Useful Strategy in India?* 2 SOUTH ASIAN J CANCER 194 (October-December 2014).

335. The article goes on to say: "A healthy 16-year-old is at zero immediate risk of dying from cervical cancer, but is faced with a small, but real risk of death or serious disability from a vaccine that has yet to prevent a single case of cervical cancer... There is a genuine cause for concern regarding mass vaccination in this country." *Id.*

336. On April 2017, the Indian government blocked the Gates Foundation from further funding of the Public Health Foundation of India and other non-governmental organizations, effectively barring them from influencing India's national vaccine program. *See* Nida Najar, *India's Ban on Foreign Money for Health Group Hits Gates Foundation*, THE NEW YORK TIMES, April 20, 2017.

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O. Merck's Fraud Has Paid Off Handsomely Resulting in Over $3 Billion in Gardasil Sales Annually

337. Merck's corruption and fraud in researching, testing, labeling, and promoting Gardasil have paid off handsomely.

338. Presently, two doses of Gardasil 9 typically cost about $450, plus the cost of two office visits.

339. By comparison, the cost of the DTaP vaccine is about $25 per dose.

340. The HPV vaccine is the most expensive vaccine on the market.

341. Since approximately 1 in 42,000 American women die of cervical cancer annually, the cost of avoiding a single death is over $18 million, assuming the Gardasil vaccine is 100 percent effective.

342. In 2018, the Gardasil vaccines made $2.2 billion for Merck in the U.S. alone.

343. In 2019, Merck made $3.7 billion in worldwide revenues from the Gardasil vaccines.

344. Gardasil is Merck's most lucrative vaccine and its third-highest selling product.

345. Gardasil is crucial to Merck's overall financial health. Merck identifies Gardasil as one of its "key products," meaning that any change in Gardasil's cash flow affects the corporation as a whole.

346. Merck's 10-K financial reports note that, for example, the discovery of a previously unknown side effect, or the removal of Gardasil from the market, would hurt Merck's bottom line.

III. Korrine Herlth Sustained Autoimmune Disease, Including Postural Orthostatic Tachycardia Syndrome ("POTS"), Dysautonomia and Other Serious Injuries, as A Result of Her Gardasil Injections

A. Gardasil and Its Ingredients Caused Plaintiff's Autoimmune Disease and Other Related Injuries and Has Resulted in Her Suffering From Severe, Debilitating, Disabling and Painful Chronic Injuries

347. Plaintiff was 15 years-old when she received her first shot of Gardasil on October 2, 2013 and her second Gardasil shot on December 3, 2013.

348. Plaintiff's mother, Andrea Herlth, agreed to her daughter receiving the Gardasil injections after having been exposed to years of relentless online, in print and television marketing by Merck, that Gardasil is very safe, that Gardasil prevents cancer and that good mothers must vaccinate their teenage daughters with the Gardasil vaccine. Plaintiff's mother relied upon Merck's ubiquitous

representations concerning the safety and efficacy of the Gardasil vaccine, in consenting to her daughter's Gardasil vaccination.

349. On October 2, 2013, during a routine yearly physical examination, Plaintiff's pediatrician, Dr. Allison Whitaker, in Middletown, Connecticut, recommended that Plaintiff receive the Gardasil vaccine, which she stated was a safe and effective vaccine for preventing cervical cancer. In light of the doctor's recommendations, as well as Merck's relentless marketing and advertising messages, to which Plaintiff's mother had been exposed concerning the safety and efficacy of Gardasil, Plaintiff's mother, consented to her daughter being injected with the "cervical cancer vaccine," Gardasil.

350. Prior to receiving her Gardasil injections, Plaintiff was doing well and maintaining overall good health. Plaintiff had no autoimmune diseases, and no autonomic issues and no orthostasis. She was passionate about music and singing, she was in the school choir and traveled out of state for choir performances. At the time, Plaintiff was a vocational agriculture student, she excelled in her studies, and enjoyed spending time outdoors, taking care of farm animals, as well as her own animals at home.

351. Within one week following her second Gardasil injection on December 3, 2013, Plaintiff began experiencing dizziness and shakiness, headache, and nausea. She also noticed an increased heartbeat and felt faint and unsteady when she stood.

352. Considering these post-Gardasil symptoms, and her rapidly declining health, Plaintiff's mother did not consent to Plaintiff receiving a third shot of Gardasil.

353. As the months progressed, so did Plaintiff's injuries. She was seen by multiple physicians and specialists for her complaints which now included: daily seizures; intractable vertigo and nausea exacerbated by double vision; visual floaters; balance difficulties; fatigue; anxiety and panic attacks; convulsions; sleep apnea and sleep disturbances; depression and atypical response to antidepressants; cognitive difficulties; numbness and tingling in her lower extremities; involuntary movements and tics; weakened connective tissue and chronic joint pain; vision and hearing loss; vaginismus and endometriosis.

354. As a result of her post-Gardasil symptoms, Plaintiff was unable to engage in normal

activities that a teenager would enjoy. She no longer could participate in school and choir events in the same manner she used to prior to her Gardasil injections, her physical activities declined, she was constantly tired, dizzy, fatigued or in pain. Plaintiff's vision and cognitive abilities declined, she was taken out of school had to complete the majority of her high school classes via homebound and one-on-one tutoring. Plaintiff could no longer physically attend school in a normal fashion due to her deteriorated medical condition. Plaintiff had hopes of attending community college but was forced to defer her education due to her worsening physical condition.

355. Studies, including serum samples from June 2018, demonstrated that Plaintiff tested positive for the anti-alpha-1 adrenergic antibodies, anti-beta-2 adrenergic antibodies, anti-muscarinic cholinergic receptor 1 antibodies, anti-muscarinic cholinergic receptor 3 antibodies, and anti-muscarinic cholinergic receptor 4 antibodies. Plaintiff is at risk for anti-AT1R antibodies and anti-ETAR antibodies. The alpha-1 and beta-2 receptors are some of the same receptors that play a role in POTS and are linked to muscle and blood vessel contraction, heart rate, heart excitability and the force of heart contraction, and as previously discussed, medical research has demonstrated that certain POTS patients have autoantibodies to these receptors thus confirming the autoimmune etiology of these diseases. *See e.g.*, Hongliang Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. AMERICAN HEART ASSOC. e000755 (2014); Artur Fedorowski et al., *Antiadrenergic Autoimmunity in Postural Tachycardia Syndrome*, 19 EUROPACE 1211 (2017); Mohammed Ruzieh et al., *The Role of Autoantibodies in the Syndromes of Orthostatic Intolerance: A Systematic Review*, 51 SCANDINAVIAN CARDIOVASCULAR J. 243 (2017); Shu-ichi Ikeda et al., *Autoantibodies Against Autonomic Nerve Receptors in Adolescent Japanese Girls after Immunization with Human Papillomavirus Vaccine*, 2 ANNALS OF ARTHRITIS AND CLINICAL RHEUMATOLOGY 1014 (2019).

356. Based upon her chronic and severe post-Gardasil symptoms and adverse events as outlined above and the tests performed by her medical providers, Plaintiff has been diagnosed with various medical conditions, including but not limited to, postural orthostatic tachycardia syndrome (POTS), sinus tachycardia, chronic fatigue syndrome (CFS), mixed connective tissue disease, complex regional pain syndrome (CRPS), pediatric acute-onset neuropsychiatric syndrome (PANS), pelvic floor dysfunction, endometriosis, vaginismus, neurogenic bladder, worsened hearing loss,

progressive vision loss in both central acuity and peripheral vision, seizures and sleep apnea.

357. As previously discussed, the medical literature has documented other patients who, like Plaintiff, have suffered serious autonomic dysfunctions, and who experienced the same side effects as those Plaintiff has suffered, and who were diagnosed with Gardasil-induced autonomic diseases. *See* Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135 (2014); Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization With Human Papillomavirus Vaccine,* 53 INTERNAL MEDICINE 2185 (2014); Louise S. Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-Lavin et al., *HPV Vaccination Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL RHEUMATOLOGY 1981 (2015); Louise S. Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma Virus Vaccine*, 1 INT. J. OF VACCINE & VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Rebecca E. Chandler et al., *Current Safety Concerns With Human Papillomavirus Vaccine: A Cluster Analysis of Reports in VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al., *Autonomic Dysfunction and HPV Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and Svetlana Blitshetyn, *Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions*, CLINICAL AUTONOMIC RESEARCH (2019); Lars Jørgensen et al., *Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020).

358. Plaintiff contends that her Gardasil injection caused her to develop serious and debilitating injuries, including but not limited to autonomic, neurological, heterogenous autoimmune disease, POTS, as well as a constellation of adverse symptoms, complications, injuries, and other adverse events, many of which are alleged herein and all of which were caused by Gardasil or otherwise linked to her Gardasil-induced autoimmune disorder.

B. "It is Not Revolutions and Upheavals That Clear the Road to New and Better Days, But Revelations, Lavishness and Torments of Someone's Soul, Inspired and Ablaze." – Boris Pasternak, *After the Storm*

359. Pursuant to Section 300aa-11(a) of the National Vaccine Injury Compensation Program: "No person may bring a civil action for damages ..... against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury ... associated with the administration of a vaccine ..... unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury ... and (I) the United Stated Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition and (II) such person elects under section 300aa-21(a) to file such an action." *See* 42 U.S.C. §§ 300aa–11(a)(2)(A).

360. Title 42, Section 300aa-16 (c) further states: "If a petition is filed under section 300aa-11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the Petition is filed and ending on the date…an election is made under section 300aa-21(a) of this title to file the civil action ..." *See* 42 U.S.C. §§ 300aa–16(c).

361. In full compliance with the aforementioned federal law, Plaintiff, while still a minor, duly filed her petition with the U.S. Court of Federal Claims seeking compensation for her Gardasil vaccine-related injuries under the National Vaccine Injury Compensation Program. A judgement thereon was rendered on or about July 2, 2020 and Plaintiff duly filed her election to file a civil action on July 3, 2020.

362. Having complied with National Vaccine Injury Compensation Program administrative procedure and having duly filed her election to proceed with a civil action, Plaintiff hereby timely initiates the instant action against Merck, the manufacturer, designer and promoter of the Gardasil vaccines which caused her debilitating injuries. Through this civil action, Plaintiff seeks to hold Merck accountable for its negligent, reckless, and fraudulent conduct and she seeks full compensation from Merck for the physical and emotional injuries and harms she sustained as a result of Gardasil.

363. Moreover, by engaging in conduct that Merck knew was unsafe and likely to injure patients and by placing Gardasil's profits ahead of patient safety, Merck has engaged in the same

fraudulent, malicious and oppressive conduct it engaged in with respect to Vioxx. Plaintiff, therefore, requests that exemplary damages be assessed against Merck, so as to, once again, attempt to deter Merck and other would-be defendants from engaging in similar reprehensible conduct.

CAUSES OF ACTION

COUNT ONE

NEGLIGENCE

364. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges:

365. Merck is the researcher, designer, manufacturer, labeler, and promoter of the Gardasil and the subsequent Gardasil 9 vaccines.

366. Merck marketed Gardasil to patients, including teenagers such as Plaintiff, her parents and her medical providers.

367. Merck had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Gardasil, including the duty to take all reasonable steps necessary to research, manufacture, label, promote and/or sell a product that was not unreasonably dangerous to consumers, users, and other persons coming into contact with the product.

368. At all times relevant to this litigation, Merck had a duty to exercise reasonable care in the marketing, advertising, and sale of Gardasil. Merck's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the efficacy and risks of Gardasil and appropriate, complete, and accurate warnings concerning the potential adverse effects of Gardasil and its various ingredients and adjuvants.

369. At all times relevant to this litigation, Merck knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Gardasil and specifically, the serious, debilitating and potentially fatal adverse events associated with Gardasil, including but not limited to autoimmune diseases (including, but not limited to, POTS and OI), fibromyalgia, fertility complications, increased risk of cancer (including cervical cancer, which was the very cancer it was promoted as preventing) and death.

370. Accordingly, at all times relevant to this litigation, Merck knew or, in the exercise of reasonable care, should have known that use of Gardasil could cause Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

371. Merck knew or, in the exercise of reasonable care, should have known that its negligently and poorly designed clinical trials and studies were insufficient to test the true long-term safety and efficacy of Gardasil.

372. Merck also knew or, in the exercise of reasonable care, should have known that its targeted consumers and patients (who were pre-teen and teen children), the parents of these patients and the children's medical providers were unaware of the true risks and the magnitude of the risks associated with Gardasil and the disclosed and undisclosed ingredients of Gardasil.

373. As such, Merck breached its duty of reasonable care and failed to exercise ordinary care in the research, development, manufacturing, testing, marketing, supply, promotion, advertisement, packaging, labeling, sale, and distribution of Gardasil, in that Merck manufactured and produced a defective and ineffective vaccine, knew or had reason to know of the defects and inefficacies inherent in its products, knew or had reason to know that a patient's exposure to Gardasil created a significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these defects, risks and injuries.

374. Merck failed to appropriately and adequately test the safety and efficacy of Gardasil and its individual ingredients and adjuvants.

375. Despite the ability and means to investigate, study, and test its products and to provide adequate warnings, Merck has failed to do so. Indeed, Merck has wrongfully concealed information and has further made false and/or misleading statements concerning the safety and efficacy of Gardasil.

376. Merck's negligence is outlined in detail in this Complaint, and included, among other things:

a) Manufacturing, producing, promoting, creating, researching, labeling, selling, and/or distributing Gardasil without thorough and adequate pre-and post-market testing and studies;

b) Manufacturing, producing, promoting, researching, labeling, selling, and/or distributing Gardasil while negligently and intentionally concealing and failing to accurately and adequately disclose the results of the trials, tests, and studies of Gardasil, and, consequently, the lack of efficacy and risk of serious harm associated with Gardasil;

c) Failing to undertake sufficient studies and conduct necessary tests to determine the safety of the ingredients and/or adjuvants contained within Gardasil, and the propensity of these ingredients to render Gardasil toxic, increase the toxicity of Gardasil, whether these ingredients are carcinogenic or associated with autoimmune diseases and other injures;

d) Negligently designing and conducting its clinical trials so as to prevent the clinical trials from revealing the true risks, including but not limited to, long terms risks and risks of autoimmune diseases associated with Gardasil;

e) Negligently designing and conducting its clinical trials so as to mask the true risks, including but not limited to, long terms risks and risks of autoimmune diseases and cancers associated with Gardasil;

f) Failing to test Gardasil against a true inert placebo and lying to the public that Gardasil was tested against a placebo, when in reality, all, or nearly all, studies used a toxic placebo that included the aluminum adjuvant AAHS;

g) Failing to have a sufficient number of studies for the targeted patient population which included pre-teen girls (and boys) between the ages of nine and 12;

h) Not using the commercial dosage (and instead using a lower dosage of the adjuvant and ingredients) in one of the key clinical trials used to obtain licensing for the commercial dosage of Gardasil;

i) Using restrictive exclusionary criteria in the clinical study patient population (including for example, the exclusion of anyone who had prior abnormal Pap tests, who had a history of immunological or nervous system disorders, or was allergic to aluminum or other ingredients), but then not revealing or warning

about these exclusionary criteria in the label and knowing that, for most of these ingredients and allergies, there are limited resources for the public to test for such allergies in advance of being vaccinated;

j) Negligently designing and conducting its trials so as to create the illusion of efficacy when in reality the Gardasil Vaccines *have not* been shown to be effective against preventing cervical cancer;

k) Failing to use reasonable and prudent care in the research, manufacture, labeling and development of Gardasil so as to avoid the risk of serious harm associated with the prevalent use of Gardasil;

l) Failing to provide adequate instructions, guidelines, warnings, and safety precautions to those persons who Merck could reasonably foresee would use and/or be exposed to Gardasil;

m) Failing to disclose to Plaintiff, her mother, her medical providers and to the general public that Gardasil is ineffective when used in patients who have previously been exposed to HPV, and also failing to disclose that Gardasil actually increases the risk of cervical cancer, including in any child or patient who has previously been exposed to HPV;

n) Failing to disclose to Plaintiff, her mother, her medical providers and to the general public that use of and exposure to Gardasil presents severe risks of cancer (including cervical cancer, the very cancer it is promoted as preventing), fertility problems, autoimmune diseases and other grave illnesses as alleged herein;

o) Failing to disclose to Plaintiff, her mother, her medical providers and to the general public that use of and exposure to Gardasil presents severe risks of triggering and increasing the risk of various autoimmune diseases, including but not limited to POTS and OI;

p) Failing to disclose to Plaintiff, her parents, her medical providers and to the general public that, contrary to Merck's promotion of the vaccine, Gardasil has

not been shown to be effective at preventing cervical cancer and that the safest and most effective means of monitoring and combating cervical cancer is regular testing, including Pap tests;

q) Representing that Gardasil was safe and effective for its intended use when, in fact, Merck knew or should have known the vaccine was not safe and not effective for its intended use;

r) Falsely advertising, marketing, and recommending the use of Gardasil, while concealing and failing to disclose or warn of the dangers Merck knew to be associated with or caused by the use of Gardasil;

s) Falsely promoting Gardasil as preventing cervical cancer when Merck knows that it has not done any studies to demonstrate that Gardasil prevents cervical cancer and, indeed, its clinical studies revealed that Gardasil actually increases the risk of cervical cancer;

t) Engaging in false advertising and disease mongering by scaring parents and children into believing that cervical cancer is far more prevalent than it really is; that all cervical cancer was linked to HPV; that Gardasil prevented cervical cancer, when in reality none of these representations were true as cervical cancer rates were declining in the United States due to Pap testing and Gardasil has not been shown to prevent against all strains of HPV that are associated with cervical cancer and, indeed, it has never been shown to prevent cervical cancer;

u) Failing to disclose all of the ingredients in Gardasil, including but not limited to the fact that Gardasil contains dangerous HPV L1-DNA fragments and that these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist – further adjuvanting the vaccine and making it more potent and dangerous;

v) Declining to make any changes to Gardasil's labeling or other promotional materials that would alert consumers and the general public of the true risks and defects of Gardasil;

w) Systemically suppressing or downplaying contrary evidence about the risks,

incidence, and prevalence of the side effects of the Gardasil Vaccines by, inter alia, orchestrating the retraction of peer-reviewed and published studies and vilifying and attempting to ruin the careers of any scientists who openly question Gardasil's safety and efficacy.

377. Merck knew and/or should have known that it was foreseeable that patients, such as Plaintiff, would suffer injuries as a result of Merck's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Gardasil.

378. Plaintiff and her mother, and upon information and belief, her medical providers, did not know the true nature and extent of the injuries that could result from the intended use of and/or exposure to Gardasil or its adjuvants and ingredients.

379. Merck's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

380. Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or had Merck via its labeling, advertisements and promotions provided adequate and truthful warnings and properly disclosed and disseminated the true risks, limitations and lack of efficacy associated with Gardasil to medical providers, patients and the public, then upon information and belief, Plaintiff's medical providers would not have offered or recommended Gardasil to Plaintiff. Moreover, even if after Merck's dissemination of truthful information concerning the true risks and efficacy limitation of Gardasil, Plaintiff's medical providers had offered Gardasil, then upon information and belief, the providers would have heeded any warnings issued by Merck and relayed to Plaintiff and her mother the safety risks and efficacy limitations that Merck should have warned them about, but failed to do so. Had Plaintiff and her mother been informed of the true risks and efficacy limitation concerning Gardasil, either through her medical providers or through Merck's ubiquitous direct-to-consumer promotional marketing, then neither Plaintiff nor her mother would have consented to Plaintiff being injected with Gardasil.

381. As a proximate result of Merck's wrongful acts and omissions and its negligent and fraudulent testing, labeling, manufacturing, marketing and promotion of Gardasil, Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated symptomology

and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but not limited to now being at an increased risk of cancer and future symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

382. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered and continues to suffer economic losses, including considerable financial expenses for medical care and treatment, and diminished income capacity, and she will continue to incur these losses and expenses in the future.

383. Merck's conduct, as described above, was aggravated, oppressive, fraudulent, and malicious. Merck regularly risks the lives of teenagers, including Plaintiff, with full knowledge of the limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff, her mother and her medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

384. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for compensatory and punitive damages, together with interest, and costs herein incurred, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

COUNT TWO

STRICT LIABILITY

(FAILURE TO WARN)

385. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

386. Plaintiff brings this strict liability claim against Merck for failure to warn.

387. At all times relevant to this litigation, Merck engaged in the business of researching, testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting

Gardasil, which is defective and unreasonably dangerous to consumers, including Plaintiff, because it does not contain adequate warnings or instructions concerning the dangerous characteristics of Gardasil and its ingredients and adjuvants. These actions were under the ultimate control and supervision of Merck.

388. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Gardasil, and in the course of same, directly advertised or marketed the vaccine to consumers and end users, including Plaintiff, her mother and medical providers, and Merck therefore had a duty to warn of the risks associated with the reasonably foreseeable uses of Gardasil and a duty to instruct on the proper, safe use of these products.

389. At all times relevant to this litigation, Merck had a duty to properly research, test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, provide proper warnings, and take such steps as necessary to ensure that Gardasil did not cause users and consumers to suffer from unreasonable and dangerous risks. Merck had a continuing duty to instruct on the proper, safe use of these products. Merck, as manufacturer, seller, or distributor of vaccines, is held to the knowledge of an expert in the field.

390. At the time of manufacture, Merck could have provided warnings or instructions regarding the full and complete risks of Gardasil because it knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to these products.

391. At all times relevant to this litigation, Merck failed to properly investigate, study, research, test, manufacture, label or promote Gardasil. Merck also failed to minimize the dangers to children, patients, and consumers of Gardasil products and to those who would foreseeably use or be harmed by Gardasil, including Plaintiff.

392. Despite the fact that Merck knew or should have known that Gardasil posed a grave and unreasonable risk of harm (including but not limited to increased risk of autoimmune disease, and the various other Gardasil induced injuries that Plaintiff has sustained), it failed to warn of the risks associated with Gardasil. The dangerous propensities of Gardasil and the carcinogenic characteristics and autoimmune-inducing characteristics of Gardasil, as described in this Complaint, were known to

Merck, or scientifically knowable to Merck through appropriate research and testing by known methods, at the time it distributed, supplied, or sold Gardasil, and not known to end users and consumers, such as Plaintiff, her mother and medical providers.

393. Merck knew or should have known that Gardasil and its ingredients and adjuvants created significant risks of serious bodily harm to children and patients, as alleged herein, and Merck failed to adequately warn patients, parents, medical providers and reasonably foreseeable users of the risks and lack of efficacy of Gardasil. Merck has wrongfully concealed information concerning Gardasil's dangerous nature and lack of efficacy and has further made false and misleading statements concerning the safety and efficacy of Gardasil.

394. At all times relevant to this litigation, Merck's Gardasil products reached the intended consumers, handlers, and users or other persons coming into contact with these products throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Merck.

395. Plaintiff was injected with Gardasil in its intended or reasonably foreseeable manner without knowledge of its unreasonable dangerous and inefficacious characteristics.

396. Plaintiff could not have reasonably discovered the defects and risks associated with Gardasil before or at the time of her injections. Plaintiff and her mother relied upon the skill, superior knowledge, and judgment of Merck.

397. Merck knew or should have known that the warnings disseminated with Gardasil were inadequate, and failed to communicate adequate information concerning the true risks and lack of efficacy of Gardasil and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses, including injection in teenagers.

398. The information that Merck did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled patients, parents of patients and the medical providers of patients to properly utilize, recommend or consent to the utilization of Gardasil. Instead, Merck disseminated information that was inaccurate, false, and misleading and which failed to communicate accurately or adequately the lack of efficacy, comparative severity, duration, and

extent of the serious risk of injuries associated Gardasil; continued to aggressively promote the efficacy and safety of its products, even after it knew or should have known of Gardasil's unreasonable risks and lack of efficacy; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks, defects and dangers of Gardasil.

399. To this day, Merck has failed to adequately and accurately warn of the true risks of Plaintiff's injuries, including but not limited to, POTS, neuropathy, dysautonomia, and autoimmune diseases, associated with the use of and exposure to Gardasil, and has failed to warn of the additional risks that Plaintiff is now exposed to, including, but not limited to, the increased risk of cancer and other potential side effects and ailments.

400. As a result of Merck's failure to warn and false promotion, Gardasil is and was defective and unreasonably dangerous when it left the possession and/or control of Merck, was distributed by Merck, and used by Plaintiff.

401. Merck is liable to Plaintiff for injuries caused by its failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding Gardasil, the lack of efficacy and serious risks associated with Gardasil and its ingredients and adjuvants.

402. The defects in Merck's Gardasil vaccine were substantial and contributing factors in causing Plaintiff's injuries, and, but for Merck's misconduct and omissions and Gardasil's defects, including its defective labeling and false promotion, Plaintiff would not have sustained her injuries which she has sustained to date, and would not have been exposed to the additional prospective risk and dangers that are associated with Gardasil.

403. Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or had Merck, via its labeling, advertisements, and promotions provided adequate and truthful warnings and properly disclosed and disseminated the true risks, limitations, and lack of efficacy associated with Gardasil to medical providers, patients, and the public, then upon information and belief, Plaintiff's medical providers would not have offered or recommended Gardasil to Plaintiff. Moreover, even if after Merck's dissemination of truthful information concerning the true risks and efficacy limitation of Gardasil, Plaintiff's medical providers had offered Gardasil, then upon

information and belief, the providers would have heeded any warnings issued by Merck and relayed to Plaintiff and her mother the safety risks and efficacy limitations that Merck should have warned them about, but failed to do so. Had Plaintiff and her mother been informed of the true risks and efficacy limitation concerning Gardasil, either through her medical providers or through Merck's ubiquitous direct-to-consumer promotional marketing, then neither Plaintiff nor her mother would have consented to Plaintiff being injected with Gardasil.

404. As a proximate result of Merck's wrongful acts and omissions and its negligent and fraudulent testing, labeling, manufacturing, marketing and promotion of Gardasil, Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated symptomology and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but not limited to now being at an increased risk of cancer and future symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

405. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered and continues to suffer economic losses, including considerable financial expenses for medical care and treatment, and diminished income capacity, and she will continue to incur these losses and expenses in the future.

406. Merck's conduct, as described above, was oppressive, fraudulent, and malicious. Merck regularly risks the lives of teenagers, including Plaintiff, with full knowledge of the limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff, her mother, and her medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children, teenagers, and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

407. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for compensatory and punitive damages, together with interest, and costs herein incurred, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the

issues contained herein.

COUNT THREE

STRICT LIABILITY

(MANUFACTURING DEFECT)

408. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

409. Plaintiff brings this strict liability claim against Merck for manufacturing defect.

410. At all times relevant to this litigation, Merck engaged in the business of researching, testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Gardasil, which is defective and unreasonably dangerous to consumers, including Plaintiff, because of manufacturing defects, which patients, including Plaintiff, her mother and her medical providers did not expect.

411. Upon information and belief, the Gardasil vaccines injected into Plaintiff were defective and unreasonably dangerous because they failed to comply with manufacturing specifications required by the governing manufacturing protocols and also required by the regulatory agencies, including but not limited to the FDA, by among other things, containing ingredients and toxins that were not disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert.

412. Upon information and belief, and as way of example, the Gardasil injected into Plaintiff was defective and unreasonably dangerous because it failed to comply with the approved manufacturing specifications, by containing dangerous and undisclosed HPV L1-DNA fragments, and these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist, further adjuvanting the vaccine and making it more potent and dangerous than intended.

413. Upon information and belief, and as way of example, the Gardasil injected into Plaintiff was defective and unreasonably dangerous because it failed to comply with the approved manufacturing specifications, by containing dangerous and undisclosed ingredients and neurotoxins, including but not limited to, phenylmethylsulfonyl fluoride (PMSF), a toxic nerve agent that is not intended for human consumption or injection.

414. At all times relevant to this litigation, Merck's Gardasil products reached the intended

consumers, handlers, and users or other persons coming into contact with these products throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Merck.

415. Plaintiff was injected with Gardasil in its intended or reasonably foreseeable manner without knowledge of its dangerous and inefficacious characteristics.

416. Plaintiff and her medical providers could not reasonably have discovered the defects, including the manufacturing defects, and risks associated with Gardasil before or at the time of her injections. Plaintiff relied upon the skill, superior knowledge, and judgment of Merck.

417. Merck is liable to Plaintiff for injuries caused as a result of its manufacturing defects.

418. The defects in Merck's Gardasil vaccine were substantial and contributing factors in causing Plaintiff's injuries, and, but for Merck's misconduct and omissions and Gardasil's defects, including but not limited to its manufacturing defects, Plaintiff would not have sustained the injuries she has sustained to date, and would not have been exposed to the additional prospective risk and dangers associated with Gardasil.

419. As a proximate result of Merck's wrongful acts and Gardasil's manufacturing defects, Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated symptomology and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but not limited to now being at an increased risk of cancer and future symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

420. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered and continues to suffer economic losses, including considerable financial expenses for medical care and treatment, and diminished income capacity, and she will continue to incur these losses and expenses in the future.

421. Merck's conduct, as described above, was oppressive, fraudulent, and malicious. Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff, and her

medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

422. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for compensatory and punitive damages, together with interest, and costs herein incurred, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

COUNT FOUR

BREACH OF EXPRESS WARRANTY

423. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

424. Merck engaged in the business of testing, researching, developing, designing, manufacturing, labeling, marketing, selling, distributing, and promoting Gardasil, which is defective and unreasonably dangerous to consumers, including Plaintiff.

425. At all times relevant to this litigation, Merck expressly represented and warranted through statements made in its Gardasil label, publications, television advertisements, billboards, print advertisements, online advertisements and website, and other written materials intended for consumers, patients, parents of minor-aged patients, medical providers, and the general public, that Gardasil was safe and effective at preventing cancer. Merck advertised, labeled, marketed, and promoted Gardasil, representing the quality to consumers, patients, medical providers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Gardasil would conform to the representations.

426. These express representations included incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with Gardasil. Merck knew and/or should have known that the risks expressly included in Gardasil's promotional material and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Merck falsely and expressly represented that Gardasil was "safe"

for use by individuals such as Plaintiff, and/or that Gardasil was "effective" in preventing cancer and that anyone who was vaccinated with Gardasil would be "one less" person with cancer.

427. The representations about Gardasil, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

428. Merck breached these warranties because, among other things, Gardasil is ineffective at preventing cancer, defective, dangerous, unfit for use, and is associated with a myriad of dangerous and undisclosed risks, including, but not limited to, the risk of autoimmune disease, including POTS, the risk of developing cervical cancer in women (even though Merck promoted it as preventing cervical cancer), and the risk of fertility problems for young girls. Specifically, Merck breached the warranties in the following ways:

a) Representing to patients and the medical community, including Plaintiff, her mother and her medical providers that Gardasil is effective in preventing cancer, including cervical cancer, when Merck knew that contrary to these representations (i) no clinical studies were performed to test if Gardasil prevents cancer; (ii) the clinical studies confirmed that Gardasil is indeed ineffective when used in patients who have previously been exposed to HPV, and that Gardasil actually increases the risk of cancer a patient who has been previously exposed to HPV; and (iii) there are safer and more effective methods of monitoring for and attempting to prevent cervical cancer, including but not limited to regular testing, such as regular Pap smears for cervical cancer, and monitoring.

b) Representing to patients and the medical community, including Plaintiff, her mother and her medical providers that Gardasil is safe, when in reality, Gardasil causes and presents serious risks of cancer, autoimmune disease, including but not limited to POTS, and other grave illnesses as outlined herein;

c) Engaging in false advertising and disease mongering by scaring parents and

children into believing that cervical cancer is far more prevalent than it really is; that all cervical cancer was linked to HPV; that Gardasil prevented cervical cancer, when in reality none of these representations were true as cervical cancer rates were declining in the United States due to Pap testing and Gardasil has not been shown to prevent against all strains of HPV that are associated with cervical cancer and indeed it has never been shown to prevent cervical cancer.

429. Merck had sole access to material facts concerning the nature of the risks and defects associated with Gardasil as expressly stated within its promotional material and labels, and Merck knew that patients and users such as Plaintiff could not have reasonably discovered the truth about the inefficacies and serious risks associated with Gardasil as alleged herein.

430. Plaintiff and her mother had no knowledge of the falsity or incompleteness of Merck's statements and representations concerning Gardasil.

431. Plaintiff's mother was exposed to the ubiquitous promotional material and representations Merck made in its direct-to-consumer advertisements and marketing materials concerning the safety and efficacy of Gardasil, including: that Gardasil prevents cervical cancer and cervical cancer is prevalent (even though children rarely get cervical cancer and Pap tests are the best frontline defense in detecting and fighting cervical cancer); that "good mothers" vaccinate their children and that Gardasil is perfectly safe. However, had Merck in these advertisements not engaged in disease mongering and deception, but instead had informed her the truth about the serious risks of Gardasil (as outlined in this Complaint) and its lack of efficacy, she would never have consented to her minor daughter being injected with Gardasil, nor would Plaintiff have consented to any of the Gardasil injections had she been adequately informed about the questionable efficacy and serious risks associated with Gardasil.

432. As a proximate result of Merck's wrongful acts and it breaches of warranties concerning the safety and efficacy of Gardasil, Plaintiff has suffered and continues to suffer severe and permanent physical injuries, and associated symptomology, and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but not limited to now being at an increased risk of

cancer, and future symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

433. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered and continues to suffer economic losses, including considerable financial expenses for medical care and treatment, and diminished income capacity, and she will continue to incur these losses and expenses in the future.

434. Merck's conduct, as described above, was oppressive, fraudulent, and malicious. Merck regularly risks the lives of children, including Plaintiff, with full knowledge of the limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

435. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for compensatory and punitive damages, together with interest, and costs herein incurred, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

COUNT FIVE

COMMON LAW FRAUD

436. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

437. Merck is the researcher, designer, manufacturer, labeler, and promoter of Gardasil.

438. Merck marketed Gardasil to and for the benefit of patients, including teenagers such as Plaintiff, her mother, and her medical providers.

439. Merck had a duty to deal honestly and truthfully with regulators, patients, consumers and medical providers in its development, testing, marketing, promotion, and sale of Gardasil.

440. Merck's duty of care owed to patients and medical providers included providing

accurate, complete, true, and correct information concerning the efficacy and risks of Gardasil in its direct-to-consumer advertisements, promotional material, and labeling.

441. At all times relevant to this litigation, Merck knew or should have known of the hazards and dangers of Gardasil and specifically, the serious, debilitating and potentially fatal adverse events associated with Gardasil, including but not limited to autoimmune diseases including, but not limited to, POTS, dysautonomia, autoimmune disease, increased risk of cancer and death.

442. At all times relevant to this litigation, Merck knew or should have known that its poorly designed clinical trials and studies were insufficient to test the true long-term safety and efficacy of Gardasil.

443. At all times relevant to this litigation, Merck expressly represented through statements it made in its publications, ubiquitous television advertisements, billboards, print advertisements, online advertisements and website, and other written materials intended for consumers, patients, parents of minor-aged patients, medical providers, and the general public, that Gardasil was safe and effective at preventing cancer.

444. These express representations included incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with Gardasil. As way of example Merck's marketing material, including its "One Less" television and print advertisement campaign (including but not limited to Gardasil posters in medical facilities and doctors' offices), which Plaintiff's mother had been exposed to, stated that Gardasil was safe, that Gardasil was effective in preventing cancer, that Gardasil was a "cervical cancer vaccine," and that any child who was vaccinated with Gardasil would lead to "one less" woman with cervical cancer. The only safety warnings Merck provided in these marketing materials was that a patient could get pain, swelling or redness at injection site, fever, and/or nausea.

445. The ubiquitous nature of these Gardasil commercials and the Gardasil marketing campaign gave the impression that cervical cancer was on the rise and more prevalent than it actually was, and that all good mothers vaccinate their children with the "cervical cancer vaccine."

446. Merck knew or should have known that the risks expressly included in Gardasil's promotional material and labels did not and do not accurately or adequately set forth the true and

complete risks of developing the serious injuries that are associated with Gardasil, as previously alleged herein, and which include but are not limited to, POTS, systemic adverse events, autoimmune disease, increased risk of cancer, and death.

447. The same promises of efficacy and limited and incomplete warnings Merck relayed in its direct-to-consumer advertising, were what Plaintiff's medical providers relayed to her when they recommended Gardasil – i.e., that if Plaintiff got vaccinated with Gardasil, it will prevent her from getting cervical cancer, and the only risks associated with Gardasil are temporary dizziness, soreness, redness, minor pain, and itching at the injection site.

448. Plaintiff's mother had been exposed to Merck's marketing material concerning Gardasil, including the aforementioned "One Less" marketing campaign and other print advertisements and posters at doctors' offices, and the representations made by Merck therein that Gardasil is effective at preventing cervical cancer, that Gardasil is safe and that its only side-effects are essentially minor injection site pain and swelling and the possible onset of a fever or nausea. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff and her mother were never informed by Merck, or anyone else, that Gardasil is linked to a host of serious debilitating and chronic adverse events including, autoimmune diseases (including, but not limited to, POTS), increased risk of cancer, and death.

449. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff and her mother were never informed by Merck, or anyone else, that Merck had not conducted the proper testing necessary to demonstrate the efficacy and full safety of Gardasil.

450. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff and her mother were never informed by Merck, or anyone else, that Merck had, as alleged herein, manipulated its clinical studies to mask and conceal the adverse events associated with Gardasil.

451. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff and her mother were never informed by Merck, or anyone else, that the Gardasil clinical trials never established that Gardasil can prevent cervical cancer, even though Merck in its promotional material to which Plaintiff's mother had been exposed, falsely represented that Gardasil was a "cervical cancer vaccine" and that a child who received Gardasil would result in "one less" woman getting cervical

cancer.

452. Merck's representations were false, because in truth, Gardasil has not been proven to prevent cervical cancer and is associated with a myriad of dangerous and undisclosed risks, including, but not limited to, the risk of autoimmune disease, including POTS, the increased risk of cancer, and other serious side effects. The false representations Merck made to the children, the parents of children, the medical community, including to Plaintiff and her mother, included:

a) that Gardasil is effective in preventing cervical cancer, when Merck knew that, contrary to these representations (i) no clinical studies were performed to test whether Gardasil prevents cancer; and (ii) the clinical studies confirmed that Gardasil is indeed ineffective when used in patients who have previously been exposed to HPV, and that Gardasil actually increases the risk of cervical cancer in any child or patient who has been previously exposed to HPV;

b) that Gardasil is safe, when in reality, Gardasil causes and presents severe risks of cancer (including cervical cancer, the very cancer it is promoted as preventing), fertility problems, autoimmune disease, including POTS, OI and other grave illnesses;

c) false advertising and disease mongering by scaring parents into believing that cervical cancer was far more prevalent than it really was; that Gardasil prevented cervical cancer; and that Gardasil only had risks of injection site pain and fever, when in reality none of these representations were true as cervical cancer rates were declining in the United States due to Pap testing and Gardasil has not been shown to prevent cervical cancer and indeed some studies demonstrated that it actually increased the risk of cervical cancer; and Gardasil was linked to a host of serious, chronic and sometimes fatal diseases, including autoimmune diseases, as previously outlined in this Complaint.

453. These representations and other similar representations were made by Merck to the public, including to Plaintiff's mother, with the intent that parents would either seek out Gardasil from their medical providers or otherwise would provide their consent when they were offered Gardasil.

454. At the time they provided their consent to the Gardasil injection, Plaintiff and her mother were not aware of the falsity of Merck's aforementioned representations concerning the safety and efficacy of Gardasil.

455. Plaintiff's mother reasonably and justifiably relied upon the truth of the assurance made by Merck in its direct to consumer marketing concerning the efficacy and safety of Gardasil (which were also echoed by Plaintiff's medical providers), when she and Plaintiff provided their consent to Plaintiff being injected with the Gardasil vaccine.

456. Had Merck's advertisements and promotional material, which Merck targeted to teenagers and the parents of teenagers, and which Plaintiff's mother received and on which she relied, provided complete and truthful warnings and properly disclosed and disseminated the true risks, limitations and lack of efficacy associated with Gardasil, then neither Plaintiff nor her mother would have consented to Plaintiff being injected with Gardasil.

457. Merck also engaged in a number of additional fraudulent activities that led to regulators, medical providers (upon information and belief, including but not limited Plaintiff's medical providers), and the general public (including directly and/or indirectly Plaintiff and her mother) to be duped into believing that Gardasil is safe and effective. These fraudulent acts are outlined in greater detail in the preceding paragraphs of this Complaint, and included, among others:

d) Failing to test Gardasil against a true inert placebo and lying to the public that Gardasil was tested against a placebo, when in reality, all, or nearly all, studies used a toxic placebo that included the dangerous aluminum adjuvant AAHS.

e) Failing to conduct a sufficient number of studies for the targeted patient population which included pre-teen girls (and boys) between the ages of nine and 12.

f) Not using the commercial dosage (and instead using a lower dosage of the adjuvant and ingredients) in one of the key clinical trials, which was used to obtain licensing for the commercial dosage of Gardasil;

g) Using very restrictive exclusionary criteria in the clinical study patient population (including for example, exclusion of anyone who had prior abnormal

Pap tests, who had a history of immunological or nervous system disorders or was allergic to aluminum or other ingredients), but then not revealing or warning about these exclusionary criteria in the label and knowing that for most of these ingredients and allergies, there are limited resources for the public to test for such allergies in advance of being vaccinated;

h) Failing to disclose all of the ingredients in Gardasil, including but not limited to the fact that Gardasil contains dangerous HPV L1-DNA fragments and that these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist – further adjuvanting the vaccine and making it more potent and dangerous.

458. Merck engaged in the above mentioned fraudulent conduct as well as the additional fraudulent conduct detailed throughout this Complaint with the intent to enhance Gardasil's safety and efficacy profile and to conceal Gardasil's serious risks and efficacy shortcomings in order to secure regulatory approval and more importantly, so as to encourage physicians and medical providers to recommend Gardasil to patients and to prepare and encourage patients to request and consent to Gardasil injections.

459. Plaintiff and her mother could not reasonably have discovered the falsity of Merck's representations, the fraudulent nature of Merck's conduct, and the defects and risks associated with Gardasil before or at the time of her injections. Plaintiff and her mother relied upon the skill, superior knowledge, and judgment of Merck, the manufacturer, labeler, and promoter of Gardasil, and they detrimentally relied upon Merck's fraudulent, false, and misleading statements, omissions, and conduct.

460. As a proximate result of Merck's fraudulent, false, and misleading statements, omissions, and conduct concerning the safety and efficacy of Gardasil, Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated symptomology and has suffered severe and permanent emotional injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and ongoing harms, including but not limited to now being at an increased risk of cancer and future symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

461. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered and continues to suffer economic losses, including considerable financial expenses for medical care and treatment, and diminished income capacity, and he will continue to incur these losses and expenses in the future.

462. Merck's conduct, as described above, was oppressive, fraudulent, and malicious. Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff and her medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant harm to children and patients who were being injected with Gardasil, and therefore warrants an award of punitive damages.

463. WHEREFORE, Plaintiff requests that the Court enter judgment in her favor for compensatory and punitive damages, together with interest, and costs herein incurred, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Korrine Herlth, requests that the Court enter judgment in her favor and against Merck & Co., Inc., and Merck, Sharp and Dohme Corporation (collectively "Merck") as to all causes of action, and awarding as follows:

A. For compensatory damages, in an amount exceeding this Court's jurisdictional minimum and to be proven at trial;

B. For economic and non-economic damages in an amount to be proven at trial;

C. For medical, incidental, hospital, psychological and other expenses in an amount to be proven at trial;

D. For loss of earnings and earnings capacity, in an amount to be proven at trial;

E. For an award of pre-judgment and post-judgment interest as provided by law;

F. For exemplary and punitive damages against Merck;

G. For preliminary and/or permanent injunctive relief against Merck;

H. For an award providing for payment of reasonable fees, court costs, and other litigation expenses as permitted by law;

I. For such other and further relief as this Honorable Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, Korrine Herlth, hereby demands a jury trial on *all* of her claims, causes of action and issues that are triable by jury.

Dated: March 30, 2021

By: /s/ ct11706

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