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14
15 **UNITED STATES DISTRICT COURT**
16 **NORTHERN DISTRICT OF TEXAS – FORTH WORTH DIVISION**

17 **MADELINE A. COUNTS**
18
19 Plaintiff,
20
21 v.
22 **MERCK & CO., INC., and**
23 **MERCK SHARP & DOHME CORP,**
24
25 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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1 COMES NOW Plaintiff, MADELINE A. COUNTS, who by and through counsel MORGAN
2 & MORGAN., and alleges against defendants MERCK & CO., INC., and MERCK, SHARP AND
3 DOHME CORPORATION, and each of them, as follows:

4 **INTRODUCTION**

5 1. This common-law products liability, negligence, strict liability, breach of warranty and
6 fraud action arises out of serious and debilitating injuries, including but not limited to autonomic,
7 neurological and heterogenous autoimmune injuries and resulting sequelae that plaintiff, Madeline A.
8 Counts (“Plaintiff”), sustained as a result of receiving injection(s) of the Gardasil vaccine, which was
9 manufactured, labeled, and promoted by defendants Merck & Co., Inc., and Merck, Sharp and Dohme
10 Corporation (collectively “Merck”).

11 **PARTIES AND VENUE**

12 2. Plaintiff, Madeline A. Counts (“Counts” or “Plaintiff”), is an adult and a resident and
13 citizen of Texas.

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

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

18 5. Defendants Merck & Co., Inc., and Merck, Sharp and Dohme Corporation shall
19 hereinafter collectively be referred to as “Merck.”

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

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

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

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

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

21 11. Merck is the manufacturer, labeler and promoter of the Gardasil and Gardasil-9
22 vaccines, which are purported to be "cervical cancer vaccines" and "anal cancer vaccines" by
23 preventing a handful of the hundreds of strains of the Human Papillomavirus ("HPV"). Merck
24 regularly conducts and transacts business in Texas and has promoted Gardasil to consumers, patients,
25 hospitals, physicians, nurses and medical professionals, including but not limited to Plaintiff, and the
26 medical facility and medical professionals who prescribed and/or injected Plaintiff with Gardasil.
27 This Court has personal jurisdiction over Merck because defendants have sufficient minimum
28 contacts with Texas to render the exercise of jurisdiction by this Court proper.

1 12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.
2 §1332(a) because Plaintiff and the defendants are citizens of different states and the amount of
3 controversy exceeds \$75,000.00, exclusive of interest and costs.

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

6 **GENERAL ALLEGATIONS**

7 **I. “History Doesn’t Repeat Itself, But It Often Rhymes” – Mark Twain**

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

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

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

21 17. Documents unsealed during the Vioxx litigation in the early 2000s revealed a culture
22 wherein Merck knew early on that Vioxx was linked to fatal cardiovascular adverse events but
23 nonetheless intentionally chose to conceal these risks from the public and medical community and,
24 instead, orchestrated a scheme to downplay the severity of the risks. Merck misrepresented the results
25 of its clinical trials, failed to undertake the clinical trials that would reveal risks, and blacklisted
26 medical professionals who dared to publicly criticize the safety of Vioxx. *See e.g.*, Eric J. Topol,
27 *Failing the Public Health – Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF
28 MEDICINE 1707 (2004); Gregory D. Curfman et al., *Expression of Concern Reaffirmed*, 354 NEW

1 ENGLAND JOURNAL OF MEDICINE 1193 (2006); Aaron S. Kesselheim et al., *Role of Litigation in*
2 *Defining Drug Risks*, 17 JAMA 308 (2007); Harlan M. Krumholz et al., *What We Have Learnt From*
3 *Vioxx*, 334 BRITISH MED. J. 120 (2007).

4 18. The British Medical Journal reported that internal documents and communications
5 obtained from Merck during litigation revealed that Merck scientists internally acknowledged the
6 existence of Vioxx's risks very early on: "Since the early development of [Vioxx], some scientists at
7 Merck were concerned that the drug might adversely affect the cardiovascular system ... In internal
8 emails made public through litigation, Merck officials sought to soften the academic authors'
9 interpretation [of the data]. The academic authors changed the manuscript at Merck's request [to
10 make less of the apparent risk] ..." Harlan M. Krumholz et al., *What We Have Learnt From Vioxx*,
11 334 BRITISH MED. J. 120 (2007). And, despite Merck's knowledge of the risk, Merck never
12 conducted the necessary studies designed to evaluate cardiovascular risk. *Id.*

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

23 20. It was also revealed and reported that, in order to control the public narrative that Vioxx
24 was safe and risk free, "Merck issued a relentless series of publications...complemented by numerous
25 papers in peer-reviewed medical literature by Merck employees and their consultants. The company
26 sponsored countless continuing medical 'education' symposiums at national meetings in an effort to
27 debunk the concern about adverse cardiovascular effects." Eric J. Topol, *Failing the Public Health –*
28 *Rofecoxib, Merck, and the FDA*, 351 NEW ENGLAND JOURNAL OF MEDICINE 1707 (2004). In addition,

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

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

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

17 23. Gardasil was viewed as the answer to the financial woes Merck had suffered from
18 Vioxx.

19 24. Indeed, some have euphemistically noted that HPV stood for “Help Pay for Vioxx.”

20 25. In the aftermath of the Vioxx scandal, and seeking a replacement product, Merck’s
21 senior director of clinical research, Eliav Barr, M.D., proclaimed of Gardasil: “This is it. *This is the*
22 *Holy Grail!*”

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

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

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

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

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

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

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

14 **A. Overview of the Human Papillomavirus**

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

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

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

26 35. Approximately 12 to 18 of the over 200 strains of HPV are believed to be associated
27 with cervical cancer, and approximately six of the strains are believed to be associated with anal
28 cancer.

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

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

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

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

17 40. New cases of cervical cancer in the U.S. affect approximately 0.8 percent of women in
18 their lifetime. *See Cancer Stat Facts: Cervical Cancer*, NIH, at
19 <https://seer.cancer.gov/statfacts/html/cervix.html>. For those who are diagnosed, cervical cancer is
20 largely treatable, with a five-year survival rate of over 90 percent when the cancer is caught early. *See*
21 Antonio C. de Freitas et al., *Susceptibility to cervical cancer: An Overview*, 126 GYNECOLOGIC
22 ONCOLOGY 305 (August 2012). Anal cancer is even more rare, and according to the current data,
23 approximately 0.2 percent of people will be diagnosed with anal cancer in their lifetime.

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

28 \\\

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

1 **B. Overview of the Gardasil Vaccine and Its Fast-Track Approval**
2 42. While there are over 200 types of the HPV virus, only 12 to 18 types currently are
3 considered potentially associated with cervical or anal cancer. Merck’s original Gardasil vaccine
4 claimed to prevent infections from four strains (HPV Strain Types 6, 11, 16 and 18) and only two of
5 those (Types 16 and 18) were associated with cervical and anal cancer.

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

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

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

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

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

28 48. On October 16, 2009, the FDA approved Gardasil for use in boys ages nine through 26

1 for the prevention of genital warts caused by HPV types 6 and 11, and in December 2010, it approved
2 Gardasil for the purported prevention of anal cancer in males and females ages nine through 26.

3 49. Subsequently, Merck sought approval for Gardasil 9 (containing the same ingredients as
4 Gardasil, but in higher quantities), which purportedly guarded against five additional HPV strains
5 currently associated with cervical cancer and anal cancer (HPV Types 31, 33, 45, 52 and 58) than the
6 original Gardasil, for a total of nine strains.

7 50. The FDA approved Gardasil 9 in December 2014, for use in girls ages nine through 26
8 and boys ages nine through 15 for the purported prevention of cervical, vaginal, and anal cancers.
9 Presently, Gardasil 9 has been approved for and is being promoted by Merck to males and females
10 who are between nine and 45 years of age, with an emphasis by Merck on marketing to pre-teen
11 children and their parents. With little evidence of efficacy, the FDA also recently approved, on an
12 accelerated basis, Gardasil 9 for prevention of oropharyngeal and other head and neck cancers.

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

16 52. According to data from the National Cancer Institute's ("NCI") Surveillance,
17 Epidemiology and End Results Program ("SEER"), the incidence of deaths from cervical cancer prior
18 to Gardasil's introduction in the United States had been steadily declining for years and, in 2006, was
19 2.4 per 100,000 women or approximately 1 in every 42,000 women. The currently available rate is
20 essentially unchanged, 2.2 per 100,000 women, based on data through 2017.

21 53. The median age of death from cervical cancer is 58, and death from anal cancer is 66,
22 and teenagers (who are the target population of Gardasil) essentially have zero risk of dying from
23 cervical or anal cancer.

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

27 55. Anxious to get Gardasil onto the market as soon as possible following the Vioxx
28 debacle, Merck sought fast-track approval even though there already existed a highly effective and

1 side-effect free intervention, Pap smears, with no evidence that Gardasil was potentially superior to
2 Pap smears in preventing cervical cancer.

3 56. In fact, the clinical trials Merck undertook did not even examine Gardasil’s potential to
4 prevent cancer, rather, the trials only analyzed whether Gardasil could prevent potential precursor
5 conditions, i.e., HPV infections and cervical interepithelial neoplasia (“CIN”) lesions graded from
6 CIN1 (least serious) to CIN3 (most serious), the vast majority of which resolve on their own without
7 intervention. CIN2 and CIN3 were the primary surrogate endpoints studied. Likewise, the clinical
8 trials from Gardasil did not examine Gardasil’s potential to prevent anal cancer, rather, the trials
9 similarly only look at anal intraepithelial neoplasia (“AIN”) lesions graded 1 through 3, and the
10 Gardasil 9 studies did not even include any studies concerning the efficacy of Gardasil in preventing
11 anal lesions.

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

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

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

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

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

23 62. In order to obtain FDA approval, Merck designed and conducted a series of fraudulent
24 Gardasil studies and then influenced the votes of the FDA’s Vaccines and Related Biological Products
25 Advisory Committee (“VRBPAC”) and the CDC’s Advisory Committee on Immunization Practices
26 (“ACIP”) to win both an FDA license and a CDC/ACIP approval and recommendation that all 11 and
27 12 year old girls should be vaccinated with Gardasil.

28 63. That ACIP “recommendation” was, effectively, a mandate to doctors to sell Merck’s

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

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

8 65. Merck, shortly thereafter, rewarded Gerberding by naming her President of Merck
9 Vaccines in 2010.

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

23 67. Moreover, members of ACIP have been allowed to vote on vaccine recommendations
24 even if they have financial ties to drug companies developing similar vaccines. According to a 2000
25 U.S. House of Representatives investigation report, the majority of the CDC's eight ACIP committee
26 members had conflicts of interest. The Chairman of ACIP served on Merck's Immunization Advisory
27 Board and a number of the other ACIP members had received grants, salaries, or other forms of
28 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. <http://www.pharmexec.com/brand-year-0>

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

75. In addition to paid advertising, Merck worked with third parties to "seed" an obliging

1 media with terrifying stories about cervical cancer in preparation for Merck’s Gardasil launch.

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

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

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

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

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

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



1 82. Merck’s fraudulent message was that cervical cancer and anal cancer were real-life
2 killers of young men and women, notwithstanding the fact that the average age for development of
3 cervical cancer is 50 years old, average age of development of anal cancer is 60 years old and that the
4 cancer is virtually nonexistent in men and women under 20.

5 83. Other television marketing campaigns Merck launched falsely proclaimed that Gardasil
6 was a “cervical cancer vaccine” and that any young girl vaccinated with Gardasil would become “one
7 less” woman with cervical cancer. The “One Less” marketing campaign portrayed Gardasil as if there
8 were no question as to the vaccine’s efficacy in preventing cervical cancer, and it disclosed none of
9 Gardasil’s side effects.

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

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

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

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

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

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

24 89. With the help of WIG, Merck aggressively lobbied legislators to mandate Gardasil to all
25 sixth-grade girls. *See Michelle Mello et al., Pharmaceutical Companies’ Role in State Vaccination*
26 *Policymaking: The Case of Human Papillomavirus Vaccination*, 102 AMERICAN J PUBLIC HEALTH
27 893 (May 2012).

28 90. Dr. Diane Harper, a medical doctor and scientist who was hired as a principal

1 investigator on clinical trials for Gardasil gave an interview for an article on the HPV vaccines and
2 WIG in 2007. Harper, who had been a major presenter at a WIG meeting in 2005, stated that “the
3 Merck representative to WIG was strongly supporting the concept of mandates later in the WIG
4 meetings and providing verbiage on which the legislators could base their proposals.”

5 91. WIG was one of dozens of “pay to play” lobby groups that Merck mobilized to push
6 HPV vaccine mandates.

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

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

12 94. Several states passed laws allowing preteen children as young as age 12 to “consent” to
13 vaccination with an HPV vaccine without parental consent or knowledge.

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

17 96. Merck funneled almost \$92 million to Maryland’s Department of Health between 2012
18 and 2018 to promote Gardasil in Maryland schools, in a fraudulent campaign that paid school officials
19 to deliberately deceive children and parents into believing Gardasil was mandatory for school
20 attendance. Josh Mazer, *Maryland should be upfront about HPV vaccinations for children*, CAPITAL
21 GAZETTE, August 14, 2018, at [https://www.capitalgazette.com/opinion/columns/ac-ce-column-mazer-](https://www.capitalgazette.com/opinion/columns/ac-ce-column-mazer-20180814-story.html)
22 [20180814-story.html](https://www.capitalgazette.com/opinion/columns/ac-ce-column-mazer-20180814-story.html).

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

24 97. In order to mobilize “third-party credibility” to push Gardasil, Merck gave massive
25 donations to dozens of nonprofit groups to “educate” the public via “education grants.” For example,
26 a disclaimer on American College of Obstetricians and Gynecologists’ Immunization for Women
27 website stated that “[t]his website is supported by an independent educational grant from Merck and
28 Sanofi Pasteur US.”

1 98. Merck offered influential doctors (also known as “key opinion leaders”) \$4,500 for
2 every Gardasil lecture they gave.

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

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

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

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

15 102. There are no studies proving that Gardasil prevents cancer.

16 103. Because it can take decades for a persistent HPV infection to proceed to development of
17 cervical or anal cancer, and because cervical and anal cancers are so rare, a true efficacy study would
18 require decades and likely hundreds of thousand – if not millions – of trial participants to demonstrate
19 that eliminating certain HPV infections would actually prevent the development of cervical and anal
20 cancer.

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

23 105. Instead, Merck persuaded regulators to allow it to use “surrogate endpoints” to support
24 its theory that the HPV vaccines would be effective in preventing cervical and anal cancer.

25 106. The clinical trials therefore did not test whether HPV vaccines prevent cervical, anal or
26 other cancers. Instead, Merck tested the vaccines against development of certain cervical lesions,
27 which some researchers suspect are precursors to cancer, although the majority of these lesions – even
28 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*

1 ONCOTARGET 105425 (Dec. 1, 2017); Philip Castle et al., *Impact of Improved Classification on the*
2 *Association of Human Papillomavirus With Cervical Precancer*, 171 AMERICAN JOURNAL OF
3 EPIDEMIOLOGY 161 (Dec. 10, 2009); Karoliina Tainio et al., *Clinical Course of Untreated Cervical*
4 *Intraepithelial Neoplasia Grade 2 Under Active Surveillance: Systematic Review and Meta-Analysis*,
5 360 BRIT. MED. J. k499 (Jan. 16, 2018).

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

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

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

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

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

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

24 113. Merck's foundational theory that HPV alone causes cervical and anal cancer, while
25 dogmatically asserted, is not proven.

26 114. Research indicates that cervical and anal cancer is a multi-factor disease with persistent
27 HPV infections seeming to play a role, along with many other environmental and genetic factors,
28 including smoking cigarettes or exposure to other toxic smoke sources, long-term use of oral

1 contraceptives, nutritional deficiencies, multiple births (especially beginning at an early age), obesity,
2 inflammation, and other factors. Not all cervical and anal cancer is associated with HPV types in the
3 vaccines and not all cervical and anal cancer is associated with HPV at all.

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

6 116. However, *Merck knows* that the Gardasil vaccines cannot eliminate all cervical and anal
7 cancer or any other cancer that may be associated with HPV.

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

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

15 119. Under Merck’s hypothetical theory, the reduction of pre-cancerous lesions should
16 translate to fewer cases of cervical and anal cancer in 30 to 40 years.

17 120. Cervical and anal cancer takes decades to develop and there are no studies that prove
18 the Gardasil vaccines prevent cancer.

19 121. In January 2020, a study from the UK raised doubts about the validity of the clinical
20 trials in determining the vaccine’s potential to prevent cervical cancer. The analysis, carried out by
21 researchers at Newcastle University and Queen Mary University of London, revealed many
22 methodological problems in the design of the Phase 2 and 3 trials, leading to uncertainty regarding
23 understanding the effectiveness of HPV vaccination. *See Claire Rees et al., Will HPV Vaccine*
24 *Prevent Cancer? J. OF THE ROYAL SOC. OF MED.* 1-15 (2020).

25 122. As Dr. Tom Jefferson of the Centre for Evidence-Based Medicine pointed out: “The
26 reason for choosing vaccination against HPV was to prevent cancer but there’s no clinical evidence to
27 prove it will do that.”

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

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

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

6 **i. Gardasil Contains A Toxic Aluminum Adjuvant**

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

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

11 127. The original Gardasil vaccine contains 225 micrograms of AAHS and Gardasil 9
12 contains 500 micrograms of AAHS.

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

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

18 130. Peer-reviewed studies show that aluminum binds to non-vaccine proteins, including the
19 host’s own proteins, or to latent viruses, triggering autoimmune and other serious conditions. See
20 Darja Kanduc, *Peptide Cross-reactivity: The Original Sin of Vaccines*, 4 FRONTIERS IN BIOSCIENCE
21 1393 (June 2012).

22 131. Aluminum, including AAHS, has been linked to scores of systemic side effects
23 including, but not limited to: impairing cognitive and motor function; inducing autoimmune
24 interactions; increasing blood brain barrier permeability; inducing macrophagic myofascitis in muscle;
25 blocking neuronal signaling; interrupting cell-to-cell communications; corrupting neuronal-glial
26 interactions; interfering with synaptic transmissions; altering enzyme function; impairing protein
27 function; fostering development of abnormal tau proteins; and altering DNA.

28 \\\

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

1
2 132. Merck has repeatedly concealed or incorrectly identified Gardasil ingredients to the
3 FDA and the public.

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

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

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

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

20 137. It is unlawful for vaccine manufacturers to use an experimental and undisclosed
21 adjuvant.

22 138. When independent scientists found DNA fragments in every Gardasil vial tested, from
23 all over the world, Merck at first denied, and then finally admitted, the vaccine does indeed include
24 HPV L1-DNA fragments.

25 139. Tellingly, Merck entered into a business arrangement with Idera Pharmaceuticals in
26 2006 to explore DNA adjuvants to further develop and commercialize Idera’s toll-like receptors in
27 Merck’s vaccine program.

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

1 the vaccine.

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

7 142. Those fragments appear to have played a role in the teenager’s death.

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

10 **iii. Gardasil Contains Borax**

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

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

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

18 147. The European Chemical Agency requires a “DANGER!” warning on borax and states
19 that borax “may damage fertility or the unborn child.”

20 148. The Material Safety Data Sheet (“MSDS”) for sodium borate states that sodium borate
21 “[m]ay cause adverse reproductive effects” in humans.

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

24 **iv. Gardasil Contains Polysorbate 80**

25 150. Gardasil contains Polysorbate 80.

26 151. Polysorbate 80 crosses the blood-brain barrier.

27 152. Polysorbate 80 is used in drugs to open up the blood brain barrier in order to allow the
28 active ingredients in a drug to reach the brain and to elicit the intended response. It acts as an

1 emulsifier for molecules like AAHS and aluminum, enabling those molecules to pass through resistive
2 cell membranes.

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

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

9 **v. Gardasil Contains Genetically Modified Yeast**

10 155. Gardasil contains genetically modified yeast.

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

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

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

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

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

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

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

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

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

164. The clinical trials clearly demonstrated that the risks of both Gardasil and Gardasil 9

1 vastly outweigh any proven or theoretical benefits.

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

5 166. Merck employed deceptive means to cover up injuries that study group participants
6 suffered.

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

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

18 169. Three separate reviews of the Gardasil vaccine by the Cochrane Collaboration found
19 that the trial data were “largely inadequate.”

20 170. According to Dr. Tom Jefferson, “HPV [vaccine] harms have not been properly
21 studied.”

22 171. In 2019, numerous medical professionals published an article in the British Medical
23 Journal outlining the flaws and incomplete nature of the publications discussing Merck’s Gardasil
24 clinical trials. The authors issued a “call to action” for independent researchers to reanalyze or
25 “restore the reporting of multiple trials in Merck’s clinical development program for quadrivalent
26 human papillomavirus (HPV) vaccine (Gardasil) vaccine.” Peter Doshi et al., *Call to Action: RIAT*
27 *Restoration of Previously Unpublished Methodology in Gardasil Vaccine Trials*, 346 BRIT. MED. J.
28 2865 (2019). The authors explained that the highly influential publications of these studies, which

1 formed the basis of Gardasil’s FDA approval, “incompletely reported important methodological
2 details and inaccurately describe the formulation that the control arm received, necessitating
3 correction of the record.” *Id.* The authors explained that, while the publications claimed the clinical
4 trials of Gardasil were “placebo-controlled,” “participants in the control arm of these trials did not
5 receive an inert substance, such as saline injection. Instead, they received an injection containing
6 [AAHS], a proprietary adjuvant system that is used in Gardasil to boost immune response.” *Id.*

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

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

18 **i. Small Clinical Trials**

19 174. Although nine to 12-year-olds are the primary target population for HPV vaccines,
20 Merck used only a small percentage of this age group in the clinical trials. Protocol 018 was the only
21 protocol comparing children receiving a vaccine to those who did not. In that study, Merck looked at
22 results of fewer than 1,000 children 12 and younger for a vaccine targeting billions of boys and girls
23 in that age group over time. In Protocol 018, 364 girls and 332 boys (696 children) were in the
24 vaccine cohort, while 199 girls and 173 boys (372 children) received a non-aluminum control.

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

27 **ii. Merck Used a Highly Toxic “Placebo” to Mask Gardasil Injuries**

28 176. Instead of comparing health outcomes among volunteers in the Gardasil study group to

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

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

10 178. Merck deliberately used toxic “placebos” in the control group, in order to mask harms
11 caused by Gardasil to the study group.

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

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

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

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

23 183. AAHS provoked terrible injuries and deaths in a number of the study participants when
24 Merck illegally dosed the control group volunteers with AAHS.

25 184. Since the injuries in the Gardasil group were replicated in the AAHS control group, this
26 scheme allowed Merck to falsely conclude that Gardasil’s safety profile was comparable to the
27 “placebo.”

28 185. The scheme worked and enabled Merck to secure FDA licensing.

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

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

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

8 **iii. Merck Used Exclusionary Criteria to Further Conceal Gardasil
9 Risks**

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

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

15 191. Women could also be excluded for “[a]ny condition which in the opinion of the
16 investigator might interfere with the evaluation of the study objectives.”

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

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

23 194. Merck sought to exclude from the study all subjects who might be part of any subgroup
24 that would suffer injuries or adverse reactions to any of Gardasil’s ingredients.

25 195. The study exclusion criteria are not listed as warnings on the package inserts and the
26 package insert for Gardasil only mentions an allergy to yeast or to a previous dose of Gardasil as a
27 contraindication, rather than an allergy to any other component. Nonetheless, for most of the
28 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.

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

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

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

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

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

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

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

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

28 203. 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,

1 lymphatic, cardiac, gastrointestinal, immune, musculoskeletal, reproductive, neurological and
2 psychological conditions, chronic illnesses such as thyroiditis, arthritis and multiple sclerosis, and
3 conditions requiring surgeries. *See, e.g.,* Nancy B. Miller, *Clinical Review of Biologics License*
4 *Application for Human Papillomavirus 6, 11, 16, 18 LI Virus Like Particle Vaccine (S. cerevisiae)*
5 *(STN 125126 GARDASIL), manufactured by Merck, Inc.* at 393-94 (Table 302) (June 8, 2006).

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

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

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

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

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

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

21 209. Abbreviated reporting periods were part of Merck’s deliberate scheme to conceal
22 chronic conditions such as autoimmune or menstrual cycle problems, and premature ovarian failure,
23 all of which have been widely associated with the vaccine, but would be unlikely to show up in the
24 first 14 days following injection.

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

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

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

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

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

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

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

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

16 218. During its Gardasil clinical trials, Merck failed to adequately capture and properly code
17 adverse events and symptoms, including but not limited to adverse events and symptoms that were
18 indicative of autoimmune or neurological injuries, including but not limited to POTS and CRPS, so as
19 to prevent the medical community, regulators and patients from learning about these adverse events
20 and to avoid the responsibility of having to issue appropriate warnings concerning these adverse
21 events.

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

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

29 220. Gardasil's most important clinical trial was Protocol 018. The FDA considered

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

6 221. Merck lied to regulators, to the public and to subjects in its clinical trials by claiming
7 that the Protocol 018 “placebo” group received an actual saline or inert placebo.

8 222. When the FDA approved Gardasil, it described the Protocol 018 control as a “true
9 saline placebo.”

10 223. The FDA declared that the Protocol 018 trial was “of particular interest” because Merck
11 used a true saline placebo instead of the adjuvant as a control.

12 224. Merck told regulators that it gave a “saline placebo” to only one small group of
13 approximately 600 nine to 15-year-old children.

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

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

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

23 228. Only 29 percent of the vaccinated children and 31 percent of control recipients in
24 Protocol 018 reported new illnesses from Day 1 through Month 12, compared to an alarming 49.6
25 percent of those vaccinated and 49 percent of AAHS controls in the “pooled group” (composed of
26 some 10,000 young women and with the other participants combined) from Day 1 only through
27 Month 7 (not 12). Because the pooled group also included Protocol 018, even those numbers may not
28 be accurate with respect to those who received either a vaccine with a full dose of AAHS or those who

1 received an AAHS control.

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

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

10 231. As a result, this group showed significantly lower “new medical conditions” compared
11 to other protocols.

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

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

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

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

21 236. Upon information and belief, Merck was testing a product with only half the dose of
22 Gardasil’s most toxic component.

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

26 238. As set forth above, upon information and belief, Merck’s deception served its purpose:
27 Only 29 percent of the vaccinated children in Protocol 018 reported new illness, compared to an
28 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

1
2 239. Gardasil’s label states, “Gardasil has not been evaluated for potential to cause
3 carcinogenicity or genotoxicity.” The Gardasil 9 label states: “GARDASIL9 has not been evaluated
4 for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility.

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

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

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

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

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

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

27 246. Even in light of the data demonstrating that Gardasil can increase the risk of cancer in
28 girls who previously have been exposed to HPV, in order to increase profits, Merck’s Gardasil labels

1 and promotional material do not inform patients and medical doctors of this important risk factor.

2 247. Some clinical trial participants have developed cancer, including cervical cancer.

3 248. Numerous women have reported a sudden appearance of exceptionally aggressive
4 cervical cancers following vaccination.

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

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

9 251. After the introduction of HPV Vaccine in Britain, cervical cancer rates among young
10 women aged 25 to 29 has risen 54 percent.

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

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

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

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

27 256. The cervical screening is more cost effective than vaccination alone or vaccination with
28 screening.

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

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

7 258. Gardasil induces and increases the risk of autoimmune disease.

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

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

21 261. In a 2015 textbook, *VACCINES AND AUTOIMMUNITY*, edited by Dr. Yehuda Shoenfeld,
22 the father of autoimmunology research, and many of the world’s leading autoimmunity experts, the
23 scientists concluded that Gardasil can cause autoimmune disorders because of the vaccine’s strong
24 immune stimulating ingredients. *See* Lucija Tomljenovic & Christopher A. Shaw, *Adverse Reactions*
25 *to Human Papillomavirus Vaccines*, *VACCINES & AUTOIMMUNITY* 163 (Yehuda Shoenfeld et al. eds.,
26 2015).

27 262. Medical experts have opined that the mixture of adjuvants contained in vaccines, in
28 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

1 spectrum of immune-mediated diseases triggered by an adjuvant stimulus contained in vaccines, such
2 as aluminum. See e.g., YEHUDA SHOENFELD ET AL, EDS., VACCINES & AUTOIMMUNITY 2 (2015).

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

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

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

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

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

25 268. While Gardasil causes immune hyperactivation and production of anti-HPV antibodies
26 to fend off certain strains of the HPV virus, it can also result in the immune system losing its ability to
27 differentiate human proteins from foreign proteins, causing the immune system to attack the body’s
28 own proteins and organs. Because of the massive peptide commonality between HPV and human

1 proteins, the indiscriminate attack triggered by the Gardasil adjuvants will cause massive cross-
2 reactions and dangerous attacks against human proteins, leading to a number of autoimmune diseases
3 manifested throughout the different organs of the body. This process is sometimes referred to as
4 “molecular mimicry.”

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

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

26 271. Medical research has determined that certain dysautonomia diseases such as POTS and
27 OI have an autoimmune etiology. Norepinephrine, a key neurotransmitter of the sympathetic (“fight
28 or flight”) system, exerts its mechanism of action by binding to receptors located in the smooth

1 muscle of the blood vessels and various organs, including the heart. These receptors include alpha-1,
2 alpha-2, beta-1, beta-2 and beta-3 receptors and, as a group, are generally known as the adrenergic
3 receptors. The adrenergic receptors, and other receptors, including but not limited to, the ganglionic
4 and muscarinic acetylcholine receptors are believed to be affected in certain cases of POTS and OI.
5 *See e.g.*, Hongliang Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. AMERICAN
6 HEART ASSOC. e000755 (2014); Artur Fedorowski et al., *Antiadrenergic Autoimmunity in Postural*
7 *Tachycardia Syndrome*, 19 EUROPACE 1211 (2017); Mohammed Ruzieh et al., *The Role of*
8 *Autoantibodies in the Syndromes of Orthostatic Intolerance: A Systematic Review*, 51 SCANDINAVIAN
9 CARDIOVASCULAR J. 243 (2017); Shu-ichi Ikeda et al., *Autoantibodies Against Autonomic Nerve*
10 *Receptors in Adolescent Japanese Girls after Immunization with Human Papillomavirus Vaccine*, 2
11 ANNALS OF ARTHRITIS AND CLINICAL RHEUMATOLOGY 1014 (2019); William T. Gunning, *Postural*
12 *Orthostatic Tachycardia Syndrome is Associated With Elevated G-Protein Coupled Receptor*
13 *Autoantibodies*, 8 J. AMERICAN HEART ASSOC. e013602 (2019).

14 272. A variety of published medical journal articles have discussed the association between
15 Gardasil and a myriad of serious injuries and have reported on patients developing POTS, OI,
16 fibromyalgia and other symptoms of autonomic impairment following Gardasil vaccination. *See*
17 Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN
18 J. OF NEUROLOGY e52 (2010); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following*
19 *Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135 (2014); Tomomi Kinoshita
20 et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following*
21 *Immunization With Human Papillomavirus Vaccine*, 53 INTERNAL MEDICINE 2185 (2014); Louise S.
22 Brinith et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse*
23 *Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-
24 Lavin et al., *HPV Vaccination Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL
25 RHEUMATOLOGY 1981 (2015); Louise S. Brinith et al., *Is Chronic Fatigue Syndrome/Myalgic*
26 *Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma*
27 *Virus Vaccine*, 1 INT. J. OF VACCINE & VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity,*
28 *Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS

1 (2017); Rebecca E. Chandler et al., *Current Safety Concerns With Human Papillomavirus Vaccine: A*
2 *Cluster Analysis of Reports in VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al.,
3 *Autonomic Dysfunction and HPV Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and
4 Svetlana Blitshetyn, *Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and*
5 *Related Conditions*, CLINICAL AUTONOMIC RESEARCH (2019).

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

12 274. In a separate article, the same authors describe their process for extracting data from not
13 only peer-reviewed journal publications, but also unpublished data from pharmaceutical company
14 clinical study reports and trial register entries from ClinicalTrials.gov, under the assumption that
15 “more than half of all studies are never published, and the published studies’ intervention effects are
16 often exaggerated in comparison to the unpublished studies. This introduces reporting bias that
17 undermines the validity of systematic reviews. To address reporting bias in systematic reviews, it is
18 necessary to use industry and regulatory trial registers and trial data—in particular, the drug
19 manufacturers’ complete study programs.” They found that 88 percent of industry studies were solely
20 industry funded and found serious deficiencies and variability in the availability of HPV vaccine study
21 data. For example, only half of the completed studies listed on ClinicalTrials.gov posted their results.
22 The clinical study reports the authors obtained confirmed that the amount of information and data are
23 vastly greater than that in journal publications. When the authors compared the data the EMA used
24 (which was provided by GlaxoSmithKline and Merck Sharp and Dohme) to conduct their review of
25 the relationship between HPV vaccination and both POTS and CRPS, the authors found that only 48
26 percent of the manufacturers’ data were reported. According to the authors, “we find this very
27 disturbing.” Lars Jørgensen et al., *Index of the Human Papillomavirus (HPV) Vaccine Industry*
28 *Clinical Study Programmes and Non-Industry Funded Studies: A Necessary Basis to Address*

1 *Reporting Bias in a Systematic Review*, 7 SYSTEMATIC REVIEW 8 (2018).

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

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

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

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

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

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

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

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

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

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

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

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

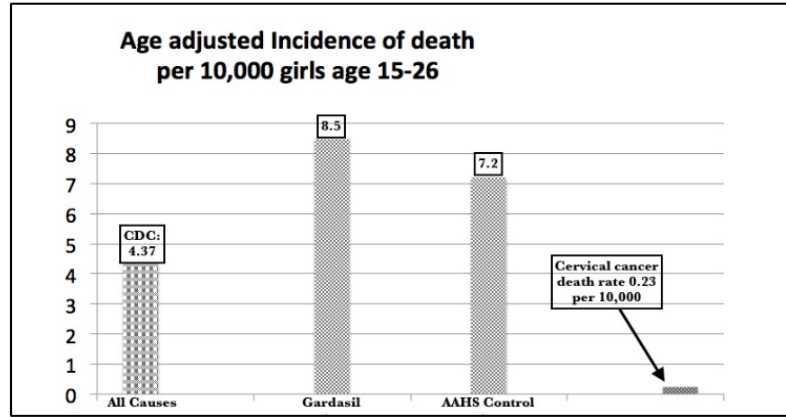
20 **L. There were an Increased Number of Deaths in the Gardasil Studies**

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

23 287. The average death rate in young women in the U.S. general population is 4.37 per
24 10,000. *See* Brady E. Hamilton et al., "Births: Provisional Data for 2016," *Vital Statistics Rapid*
25 *Release, Report No. 002*, June 2017.

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

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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: 7/9,680³⁸
 Cervical cancer mortality: 2.3 per 100,000 source: National Cancer Institute SEER Cancer Statistics Review 2015³⁹

289. 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).

290. Merck dismissed all deaths as coincidences.

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

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

293. 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

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

295. Many Gardasil survivors will have lifelong handicaps.

296. 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.

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

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

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

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

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

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

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

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

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

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

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

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

13 **i. In Light of Gardasil’s Serious and Debilitating Adverse Events, the
14 Japanese Government Rescinded Its Recommendation that Girls
15 Receive Gardasil**

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

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

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

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

312. 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

1 pain and the vaccination.”

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

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

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

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

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

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

15 319. These were developments that Merck was extremely anxious to suppress.

16 320. Merck hired the think tank, the Center for Strategic and International Studies (“CSIS”)
17 and Professor Heidi Larson of the Vaccine Confidence Project in London, to assess the reasons for the
18 Japanese situation. The overall conclusion was that the symptoms the girls were suffering from were
19 psychogenic in nature and were a result of rumors spread online. In essence, Merck blamed the
20 victims for the Gardasil-induced adverse events in Japan.

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

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

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

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

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

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

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

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

21 326. The report alleges that Merck (through PATH, to whom it supplied vaccines) and the
22 Gates Foundation resorted to subterfuge that jeopardized the health and well-being of thousands of
23 vulnerable Indian children. The parliamentary report makes clear that the clinical trials could not have
24 occurred without Merck corrupting India’s leading health organizations. *Id.*

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

 328. 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

1 windfall of profits had they been successful in getting the HPV vaccine included in the universal
2 immunization program of the country... This [conduct] is a clear-cut violation of the human rights of
3 these girls and adolescents.” *Id.*

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

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

14 331. In April 2017, the Indian government blocked the Gates Foundation from further
15 funding of the Public Health Foundation of India and other non-governmental organizations,
16 effectively barring them from influencing India’s national vaccine program. See Nida Najar, *India’s*
17 *Ban on Foreign Money for Health Group Hits Gates Foundation*, THE NEW YORK TIMES, April 20,
18 2017.

19 **O. Merck’s Fraud Has Paid Off Handsomely Resulting in Over \$3 Billion in**
20 **Gardasil Sales Annually**

21 332. Merck’s corruption and fraud in researching, testing, labeling, and promoting Gardasil
22 have paid off handsomely.

23 333. Presently, two doses of Gardasil 9 typically cost about \$450, plus the cost of two office
24 visits.

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

26 335. The HPV vaccine is the most expensive vaccine on the market.

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

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

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

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

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

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

9 **III. Madeline A. Counts Sustained Autoimmune Disease, Autonomic Dysfunction and
10 Other Serious Injuries, as A Result of Her Gardasil Injection**

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

14 342. Plaintiff was 13 years old when she received her first dosage of Gardasil on June 21,
15 2017.

16 343. Plaintiff's mother, Courtney Counts, agreed to her daughter receiving the Gardasil
17 injection(s) after having been exposed to marketing by Merck, that Gardasil is safe, and that Gardasil
18 prevents "certain cancers". Plaintiff's mother relied upon Merck's ubiquitous representations
19 concerning the safety and efficacy of the Gardasil vaccine, in consenting to her daughter's Gardasil
20 vaccination(s).

21 344. Prior to receiving her Gardasil injection(s), Plaintiff had no autoimmune diseases, and
22 no autonomic issues.

23 345. On June 21, 2017, Plaintiff's health care provider in Alabaster, Alabama recommended
24 that Plaintiff receive the Gardasil vaccine, which was stated as a safe and effective vaccine for
25 preventing cervical cancer. In light of the doctor's recommendations, as well as Merck's relentless
26 marketing and advertising messages, to which Plaintiff's mother had been exposed concerning the
27 safety and efficacy of Gardasil, Plaintiff's mother consented to Plaintiff being injected with the
28 "cervical cancer vaccine," Gardasil.

346. By Christmas 2017, Plaintiff's mother noted manifestation of symptoms consistent with
injury of autonomic dysfunction.

1 347. As the months progressed, so did Plaintiff's injuries. She was seen by multiple
2 physicians and specialists for her complaints which now included: Postural Orthostatic Tachycardia
3 Syndrome ("POTS"), paralysis, neurological disorders, movement disorders, brain fog, and is unable
4 to focus her eyes. Plaintiff has uncontrollable tremors during which she has little to no control over
5 her movement. Her symptoms of POTS include seizures, fatigue, fainting, paralysis, blurred vision,
6 chronic nausea, and headache. Plaintiff could not walk for a period of time.

7 348. As a result of her post-Gardasil symptoms, Plaintiff was unable to engage in normal
8 activities that a normal young person would enjoy.

9 349. Based upon her chronic and severe post-Gardasil symptoms, Plaintiff has been
10 diagnosed with various medical conditions, including but not limited to, Postural Orthostatic
11 Tachycardia Syndrome ("POTS") and Autonomic Dysfunction.

12 350. As previously discussed, the medical literature has documented other patients who, like
13 Plaintiff, have suffered serious autonomic dysfunctions, and who experienced the same side effects as
14 those Plaintiff has suffered, and who were diagnosed with Gardasil-induced autonomic diseases. *See*
15 E. Israeli et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Darja Kanduc, *Quantifying the*
16 *Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS
17 AND ONCOLOGY 65 (2009); Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination*
18 *with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Darja Kanduc, *Potential Cross-Reactivity*
19 *Between HPV16 L1 Protein and Sudden Death Associated Antigens*, 9 JOURNAL OF EXPERIMENTAL
20 THERAPEUTICS AND ONCOLOGY 159 (2011); Deirdre Little et al., *Premature ovarian failure 3 years*
21 *after menarche in a 16-year-old girl following human papillomavirus vaccination*, BRIT. MED. J. CASE
22 REPORTS (2012); Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian*
23 *Failure: Another Facet of the Autoimmune Inflammatory Syndrome Induced by Adjuvants*, 70 AM. J.
24 REPRODUCTIVE IMMUNOLOGY 309 (2013); Maurizio Rinaldi et al., *Anti-Saccharomyces Cerevisiae*
25 *Autoantibodies in Autoimmune Diseases: from Bread Baking to Autoimmunity*, 45 CLINICAL REVIEWS
26 IN ALLERGY AND IMMUNOLOGY 152 (October 2013); Svetlana Blitshetyn, *Postural Tachycardia*
27 *Syndrome Following Human Papillomavirus Vaccination*, 21 EUROPEAN J. OF NEUROLOGY 135
28 (2014); Tomomi Kinoshita et al., *Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese*

1 *Girls Following Immunization With Human Papillomavirus Vaccine*, 53 INTERNAL MEDICINE 2185
2 (2014); Christopher A. Shaw et al., *Aluminum-Induced Entropy in Biological Systems: Implications*
3 *for Neurological Disease*, JOURNAL OF TOXICOLOGY (2014); Louise S. Brinth et al., *Orthostatic*
4 *Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against*
5 *Human Papilloma Virus*, 33 VACCINE 2602 (2015); Manuel Martinez-Lavin et al., *HPV Vaccination*
6 *Syndrome. A Questionnaire Based Study*, 34 J. CLINICAL RHEUMATOLOGY 1981 (2015); Louise S.
7 Brinth et al., *Is Chronic Fatigue Syndrome/Myalgic Encephalomyelitis a Relevant Diagnosis in*
8 *Patients with Suspected Side Effects to Human Papilloma Virus Vaccine*, 1 INT. J. OF VACCINE &
9 VACCINATION 3 (2015); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV*
10 *Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Rebecca E. Chandler et al.,
11 *Current Safety Concerns With Human Papillomavirus Vaccine: A Cluster Analysis of Reports in*
12 *VigiBase*, 40 DRUG SAFETY 81 (2017); Svetlana Blitshetyn et al., *Autonomic Dysfunction and HPV*
13 *Immunization An Overview*, IMMUNOLOGIC RESEARCH (2018); and Svetlana Blitshetyn, *Human*
14 *Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions*, CLINICAL
15 AUTONOMIC RESEARCH (2019); Lars Jørgensen et al., *Benefits and Harms of the Human*
16 *Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical*
17 *Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020).

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

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

26 352. Pursuant to Section 300aa-11(a) of the National Vaccine Injury Compensation
27 Program: “No person may bring a civil action for damages against a vaccine administrator or
28 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

1 with section 300aa-16 of this title, for compensation under the Program for such injury ... and (I) the
2 United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on
3 such petition and (II) such person elects under section 300aa-21(a) to file such an action.” *See* 42
4 U.S.C. §§ 300aa-11(a)(2)(A).

5 353. Title 42, Section 300aa-16 (c) further states: “If a petition is filed under section 300aa-
6 11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be
7 stayed with respect to a civil action brought for such injury or death for the period beginning on the
8 date the Petition is filed and ending on the date...an election is made under section 300aa-21(a) of this
9 title to file the civil action ...” *See* 42 U.S.C. §§ 300aa-16(c).

10 354. In full compliance with the aforementioned federal law, Plaintiff duly filed her petition
11 with the U.S. Court of Federal Claims seeking compensation for her Gardasil vaccine-related injuries
12 under the National Vaccine Injury Compensation Program. The Order Concluding Proceedings was
13 filed on August 23, 2021.

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

20 **CAUSES OF ACTION**

21 **COUNT ONE**

22 **NEGLIGENCE**

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

25 357. Merck is the researcher, manufacturer, labeler, and promoter of the Gardasil
26 and the subsequent Gardasil 9 vaccines.

27 358. Merck marketed Gardasil to patients, including teenagers such as Plaintiff and her
28 medical providers.

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

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

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

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

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

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

26 365. As such, Merck breached its duty of reasonable care and failed to exercise ordinary care
27 in the research, development, manufacturing, testing, marketing, supply, promotion, advertisement,
28 packaging, labeling, sale, and distribution of Gardasil, in that Merck manufactured and produced a

1 defective and ineffective vaccine, knew or had reason to know of the defects and inefficacies inherent
2 in its products, knew or had reason to know that a patient's exposure to Gardasil created a significant
3 risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of
4 these defects, risks and injuries.

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

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

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

- 13 a) Manufacturing, producing, promoting, creating, researching, labeling, selling,
14 and/or distributing Gardasil without thorough and adequate pre-and post-market
15 testing and studies;
- 16 b) Manufacturing, producing, promoting, researching, labeling, selling, and/or
17 distributing Gardasil while negligently and intentionally concealing and failing
18 to accurately and adequately disclose the results of the trials, tests, and studies of
19 Gardasil, and, consequently, the lack of efficacy and risk of serious harm
20 associated with Gardasil;
- 21 c) Failing to undertake sufficient studies and conduct necessary tests to determine
22 the safety of the ingredients and/or adjuvants contained within Gardasil, and the
23 propensity of these ingredients to render Gardasil toxic, increase the toxicity of
24 Gardasil, whether these ingredients are carcinogenic or associated with
25 autoimmune diseases and other injures;
- 26 d) Negligently designing and conducting its clinical trials so as to prevent the
27 clinical trials from revealing the true risks, including but not limited to, long
28 terms risks and risks of autoimmune diseases associated with Gardasil;

- 1 e) Negligently designing and conducting its clinical trials so as to mask the true
2 risks, including but not limited to, long terms risks and risks of autoimmune
3 diseases and cancers associated with Gardasil;
- 4 f) Failing to test Gardasil against a true inert placebo and lying to the public that
5 Gardasil was tested against a placebo, when in reality, all, or nearly all, studies
6 used a toxic placebo that included the aluminum adjuvant AAHS;
- 7 g) Failing to have a sufficient number of studies for the targeted patient population
8 which included pre-teen girls (and boys) between the ages of nine and 12;
- 9 h) Not using the commercial dosage (and instead using a lower dosage of the
10 adjuvant and ingredients) in one of the key clinical trials used to obtain licensing
11 for the commercial dosage of Gardasil;
- 12 i) Using restrictive exclusionary criteria in the clinical study patient population
13 (including for example, the exclusion of anyone who had prior abnormal Pap
14 tests, who had a history of immunological or nervous system disorders, or was
15 allergic to aluminum or other ingredients), but then not revealing or warning
16 about these exclusionary criteria in the label and knowing that, for most of these
17 ingredients and allergies, there are limited resources for the public to test for
18 such allergies in advance of being vaccinated;
- 19 j) Negligently designing and conducting its trials so as to create the illusion of
20 efficacy when in reality the Gardasil Vaccines *have not* been shown to be
21 effective against preventing cervical and anal cancer;
- 22 k) Failing to use reasonable and prudent care in the research, manufacture, labeling
23 and development of Gardasil so as to avoid the risk of serious harm associated
24 with the prevalent use of Gardasil;
- 25 l) Failing to provide adequate instructions, guidelines, warnings, and safety
26 precautions to those persons who Merck could reasonably foresee would use
27 and/or be exposed to Gardasil;
- 28 m) Failing to disclose to Plaintiff and her medical providers and to the general

1 public that Gardasil is ineffective when used in patients who have previously
2 been exposed to HPV, and also failing to disclose that Gardasil
3 actually increases the risk of cervical cancer, including in any child or patient
4 who has previously been exposed to HPV;

- 5 n) Failing to disclose to Plaintiff and her medical providers and to the general
6 public that use of and exposure to Gardasil presents severe risks of cancer
7 (including cervical cancer, the very cancer it is promoted as preventing), fertility
8 problems, autoimmune diseases and other grave illnesses as alleged herein;
- 9 o) Failing to disclose to Plaintiff and her medical providers and to the general
10 public that use of and exposure to Gardasil presents severe risks of triggering
11 and increasing the risk of various autoimmune diseases, including but not
12 limited to POTS and OI;
- 13 p) Failing to disclose to Plaintiff and her medical providers and to the general
14 public that, contrary to Merck's promotion of the vaccine, Gardasil has not been
15 shown to be effective at preventing cervical cancer and that the safest and most
16 effective means of monitoring and combating cervical cancer is regular testing,
17 including Pap tests;
- 18 q) Representing that Gardasil was safe and effective for its intended use when, in
19 fact, Merck knew or should have known the vaccine was not safe and not
20 effective for its intended use;
- 21 r) Falsely advertising, marketing, and recommending the use of Gardasil, while
22 concealing and failing to disclose or warn of the dangers Merck knew to be
23 associated with or caused by the use of Gardasil;
- 24 s) Falsely promoting Gardasil as preventing cervical cancer when Merck knows
25 that it has not done any studies to demonstrate that Gardasil prevents cervical
26 cancer and, indeed, its clinical studies revealed that Gardasil actually increases
27 the risk of cervical cancer;
- 28 t) Engaging in false advertising and disease mongering by scaring parents and

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

- 8 u) Failing to disclose all of the ingredients in Gardasil, including but not limited to
9 the fact that Gardasil contains dangerous HPV L1-DNA fragments and that
10 these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist –
11 further adjuvanting the vaccine and making it more potent and dangerous;
- 12 v) Declining to make any changes to Gardasil’s labeling or other promotional
13 materials that would alert consumers and the general public of the true risks and
14 defects of Gardasil;
- 15 w) Systemically suppressing or downplaying contrary evidence about the risks,
16 incidence, and prevalence of the side effects of the Gardasil Vaccines by, inter
17 alia, orchestrating the retraction of peer-reviewed and published studies and
18 vilifying and attempting to ruin the careers of any scientists who openly question
19 Gardasil’s safety and efficacy.

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

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

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

28 372. Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or

1 had Merck via its labeling, advertisements, and promotions provided adequate and truthful warnings
2 and properly disclosed and disseminated the true risks, limitations, and lack of efficacy associated
3 with Gardasil to medical providers, patients and the public, then upon information and belief,
4 Plaintiff's medical providers would not have offered or recommended Gardasil to Plaintiff.
5 Moreover, even if after Merck's dissemination of truthful information concerning the true risks and
6 efficacy limitation of Gardasil, Plaintiff's medical providers had offered Gardasil, then upon
7 information and belief, the providers would have heeded any warnings issued by Merck and relayed
8 to Plaintiff the safety risks and efficacy limitations that Merck should have warned him about, but
9 failed to do so. Had Plaintiff been informed of the true risks and efficacy limitation concerning
10 Gardasil, either through her medical providers or through Merck's ubiquitous direct-to-consumer
11 promotional marketing, on which Plaintiff relied, then Plaintiff would never have consented to
12 Plaintiff being injected with Gardasil.

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

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

24 375. Merck's conduct, as described above, was aggravated, oppressive, fraudulent, and
25 malicious. Merck regularly risks the lives of patients, including Plaintiff, with full knowledge of the
26 limited efficacy of Gardasil and the severe and sometimes fatal dangers of Gardasil. Merck has made
27 conscious decisions to not warn, or inform the unsuspecting public, including Plaintiff, and her
28 medical providers. Merck's conduct, including its false promotion of Gardasil and its failure to issue

1 appropriate warnings concerning the severe risks of Gardasil, created a substantial risk of significant
2 harm to children and patients who were being injected with Gardasil, and therefore warrants an award
3 of punitive damages.

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

8 **COUNT TWO**

9 **STRICT LIABILITY**

10 **(FAILURE TO WARN)**

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

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

14 379. At all times relevant to this litigation, Merck engaged in the business of researching,
15 testing, developing, manufacturing, marketing, selling, distributing, and promoting Gardasil, which is
16 defective and unreasonably dangerous to consumers, including Plaintiff, because it does not contain
17 adequate warnings or instructions concerning the dangerous characteristics of Gardasil and its
18 ingredients and adjuvants. These actions were under the ultimate control and supervision of Merck.

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

25 381. At all times relevant to this litigation, Merck had a duty to properly research, test,
26 manufacture, inspect, package, label, market, promote, sell, distribute, provide proper warnings, and
27 take such steps as necessary to ensure that Gardasil did not cause users and consumers to suffer from
28 unreasonable and dangerous risks. Merck had a continuing duty to instruct on the proper, safe use of

1 these products. Merck, as manufacturer, seller, or distributor of vaccines, is held to the knowledge of
2 an expert in the field.

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

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

10 384. Despite the fact that Merck knew or should have known that Gardasil posed a grave and
11 unreasonable risk of harm (including but not limited to increased risk of autoimmune disease, and the
12 various other Gardasil induced injuries that Plaintiff has sustained), it failed to warn of the risks
13 associated with Gardasil. The dangerous propensities of Gardasil and the carcinogenic characteristics
14 and autoimmune-inducing characteristics of Gardasil, as described in this Complaint, were known to
15 Merck, or scientifically knowable to Merck through appropriate research and testing by known
16 methods, at the time it distributed, supplied, or sold Gardasil, and not known to end users and
17 consumers, such as Plaintiff and her medical providers.

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

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

28 387. Plaintiff was injected with Gardasil in its intended or reasonably foreseeable manner

1 without knowledge of its unreasonable dangerous and inefficacious characteristics.

2 388. Plaintiff could not have reasonably discovered the defects and risks associated with
3 Gardasil before or at the time of her injection(s). Plaintiff relied upon the skill, superior knowledge,
4 and judgment of Merck.

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

10 390. The information that Merck did provide or communicate failed to contain relevant
11 warnings, hazards, and precautions that would have enabled patients, parents of patients and the
12 medical providers of patients to properly utilize, recommend or consent to the utilization of Gardasil.
13 Instead, Merck disseminated information that was inaccurate, false, and misleading and which failed
14 to communicate accurately or adequately the lack of efficacy, comparative severity, duration, and
15 extent of the serious risk of injuries associated Gardasil; continued to aggressively promote the
16 efficacy and safety of its products, even after it knew or should have known of Gardasil's
17 unreasonable risks and lack of efficacy; and concealed, downplayed, or otherwise suppressed, through
18 aggressive marketing and promotion, any information or research about the risks, defects and dangers
19 of Gardasil.

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

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

28 393. Merck is liable to Plaintiff for injuries caused by its failure, as described above, to

1 provide adequate warnings or other clinically relevant information and data regarding Gardasil, the
2 lack of efficacy and serious risks associated with Gardasil and its ingredients and adjuvants.

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

8 395. Had Merck not engaged in the negligent and fraudulent conduct alleged herein and/or
9 had Merck, via its labeling, advertisements, and promotions provided adequate and truthful warnings
10 and properly disclosed and disseminated the true risks, limitations, and lack of efficacy associated
11 with Gardasil to medical providers, patients and the public, then upon information and belief,
12 Plaintiff's medical providers would not have offered or recommended Gardasil to Plaintiff.
13 Moreover, even if after Merck's dissemination of truthful information concerning the true risks and
14 efficacy limitation of Gardasil, Plaintiff's medical providers had offered Gardasil, then upon
15 information and belief, the providers would have heeded any warnings issued by Merck and relayed to
16 Plaintiff the safety risks and efficacy limitations that Merck should have warned him about, but failed
17 to do so. Had Plaintiff been informed of the true risks and efficacy limitation concerning Gardasil,
18 through her medical providers or through Merck's ubiquitous direct-to-consumer promotional
19 marketing, on which she relied, then Plaintiff would not have consented to being injected with
20 Gardasil.

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

28 397. As a direct and proximate result of her Gardasil-induced injuries, Plaintiff has suffered

1 and continues to suffer economic losses, including considerable financial expenses for medical care
2 and treatment, and diminished income capacity and she will continue to incur these losses and
3 expenses in the future.

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

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

16 **COUNT THREE**

17 **STRICT LIABILITY**

18 **(MANUFACTURING DEFECT)**

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

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

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

26 403. Upon information and belief, the Gardasil vaccines injected into Plaintiff were defective
27 and unreasonably dangerous because they failed to comply with manufacturing specifications required
28 by the governing manufacturing protocols and also required by the regulatory agencies, including but

1 not limited to the FDA, by among other things, containing ingredients and toxins that were not
2 disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert.

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

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

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

17 407. Plaintiff and her medical providers could not reasonably have discovered the defects,
18 including the manufacturing defects, and risks associated with Gardasil before or at the time of her
19 injection(s). Plaintiff relied upon the skill, superior knowledge, and judgment of Merck.

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

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

26 410. As a proximate result of Merck's wrongful acts and Gardasil's manufacturing defects,
27 Plaintiff has suffered and continues to suffer severe and permanent physical injuries and associated
28 symptomology and has suffered severe and permanent emotional injuries, including pain and

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

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

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

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

20 **COUNT FOUR**

21 **BREACH OF EXPRESS WARRANTY**

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

24 415. Merck engaged in the business of testing, researching, manufacturing, labeling,
25 marketing, selling, distributing, and promoting Gardasil, which is defective and unreasonably
26 dangerous to consumers, including Plaintiff.

27 416. At all times relevant to this litigation, Merck expressly represented and warranted
28 through statements made in its Gardasil label, publications, television advertisements, billboards, print

1 advertisements, online advertisements and website, and other written materials intended for
2 consumers, patients, parents of minor-aged patients, medical providers and the general public, that
3 Gardasil was safe and effective at preventing cancer. Merck advertised, labeled, marketed, and
4 promoted Gardasil, representing the quality to consumers, patients, medical providers and the public
5 in such a way as to induce their purchase or use, thereby making an express warranty that Gardasil
6 would conform to the representations.

7 417. These express representations included incomplete warnings and instructions that
8 purport, but fail, to include the complete array of risks associated with Gardasil. Merck knew and/or
9 should have known that the risks expressly included in Gardasil's promotional material and labels did
10 not and do not accurately or adequately set forth the risks of developing the serious injuries
11 complained of herein. Nevertheless, Merck falsely and expressly represented that Gardasil was "safe"
12 for use by individuals such as Plaintiff, and/or that Gardasil was "effective" in preventing cancer and
13 that anyone who was vaccinated with Gardasil would be "one less" person with cancer.

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

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

- 24 a) Representing to patients and the medical community, including Plaintiff, his
25 parents and/or her medical providers that Gardasil is effective in preventing
26 cancer, including anal and cervical cancer, when Merck knew that contrary to
27 these representations (i) no clinical studies were performed to test if Gardasil
28 prevents cancer; (ii) the clinical studies confirmed that Gardasil is indeed

1 ineffective when used in patients who have previously been exposed to HPV,
2 and that Gardasil actually increases the risk of cancer in a patient who has been
3 previously exposed to HPV; and (iii) there are safer and more effective methods
4 of monitoring for and attempting to prevent cervical or anal cancer, including
5 but not limited to regular testing, such as regular Pap smears for cervical cancer,
6 and monitoring for anal cancer.

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

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

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

23 421. Plaintiff had no knowledge of the falsity or incompleteness of Merck's statements and
24 representations concerning Gardasil.

25 422. Plaintiff was exposed to and relied upon the ubiquitous promotional material and
26 representations Merck made in its direct-to-consumer advertisements and marketing materials
27 concerning the safety and efficacy of Gardasil, including: that Gardasil prevents cervical and anal
28 cancer and these cancers are prevalent (even though children rarely get cervical or anal cancer and Pap

1 tests are the best frontline defense in detecting and fighting cervical cancer); that “good mothers”
2 vaccinate their children and that Gardasil is perfectly safe. However, had Merck in these
3 advertisements not engaged in disease mongering and deception, but instead had informed him the
4 truth about the serious risks of Gardasil (as outlined in this Complaint) and its lack of efficacy, she
5 would never have consented to being injected with Gardasil, nor would Plaintiff have consented to the
6 Gardasil injection(s) had she been adequately informed about the questionable efficacy and serious
7 risks associated with Gardasil.

8 423. As a proximate result of Merck’s wrongful acts and breaches of warranties concerning
9 the safety and efficacy of Gardasil, Plaintiff has suffered and continues to suffer severe and permanent
10 physical injuries, and associated symptomology and has suffered severe and permanent emotional
11 injuries, including pain and suffering. Plaintiff also has a substantial fear of suffering additional and
12 ongoing harms, including but not limited to now being at an increased risk of cancer, and future
13 symptoms and harms associated with her autoimmune disease and other injuries caused by Gardasil.

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

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

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

1 issues contained herein.

2 **COUNT FIVE**

3 **COMMON LAW FRAUD**

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

6 428. Merck is the researcher, manufacturer, labeler, and promoter of Gardasil.

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

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

11 431. Merck's duty of care owed to patients and medical providers included providing
12 accurate, complete, true, and correct information concerning the efficacy and risks of Gardasil in its
13 direct-to-consumer advertisements, promotional material, and labeling.

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

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

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

26 435. These express representations included incomplete warnings and instructions that
27 purport, but fail, to include the complete array of risks associated with Gardasil. By way of example
28 Merck's marketing material, including its "One Less" television and print advertisement campaign

1 (including but not limited to Gardasil posters in medical facilities and doctors' offices), which
2 Plaintiff had been exposed to, stated that Gardasil was safe, that Gardasil was effective in preventing
3 cancer, that Gardasil was a "cervical cancer vaccine," and that any young child or teenager who was
4 vaccinated with Gardasil would lead to "one less" person with cervical or anal cancer. The only safety
5 warnings Merck provided in these marketing materials was that a patient could get pain, swelling or
6 redness at injection site, fever, and/or nausea.

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

10 437. Merck knew or should have known that the risks expressly included in Gardasil's
11 promotional material and labels did not and do not accurately or adequately set forth the true and
12 complete risks of developing the serious injuries that are associated with Gardasil, as previously
13 alleged herein, and which include but are not limited to POTS, systemic adverse events, autoimmune
14 disease, increased risk of cancer, and death.

15 438. The same promises of efficacy and limited and incomplete warnings Merck relayed in
16 its direct-to-consumer advertising, were what Plaintiff's medical providers relayed to her when they
17 recommended Gardasil – i.e., that if Plaintiff got vaccinated with Gardasil, it would prevent cancer,
18 and the only risks associated with Gardasil are soreness, redness, minor pain, and a headache may
19 develop. There was no discussion about warnings.

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

1 440. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was
2 never informed by Merck, or anyone else, that Merck had not conducted the proper testing necessary
3 to demonstrate the efficacy and full safety of Gardasil.

4 441. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was
5 never informed by Merck, or anyone else, that Merck had, as alleged herein, manipulated its clinical
6 studies to mask and conceal the adverse events associated with Gardasil.

7 442. Prior to providing consent to inject Plaintiff with the Gardasil vaccine, Plaintiff was
8 never informed by Merck, or anyone else, that the Gardasil clinical trials never established that
9 Gardasil can prevent cervical or anal cancer, even though Merck in its promotional material falsely
10 represented that Gardasil was a “cervical cancer vaccine” and that a patient who received Gardasil
11 would result in “one less” woman or man getting cancer.

12 443. Merck’s representations were false, because in truth, Gardasil has not been proven to
13 prevent cervical or anal cancer and is associated with a myriad of dangerous and undisclosed risks,
14 including, but not limited to, the risk of autoimmune disease, including POTS, increased risk of
15 developing cancer, and other serious side effects. The false representations Merck made to the
16 patients, children, teenagers, the parents of children and teenagers, the medical community, including
17 to Plaintiff, included:

- 18 a) that Gardasil is effective in preventing cervical and anal cancer, when Merck
19 knew that, contrary to these representations (i) no clinical studies were
20 performed to test whether Gardasil prevents cancer; and (ii) the clinical studies
21 confirmed that Gardasil is indeed ineffective when used in patients who have
22 previously been exposed to HPV, and that Gardasil actually increases the risk of
23 cervical cancer in any child or patient who has been previously exposed to HPV;
- 24 b) that Gardasil is safe, when in reality, Gardasil causes and presents severe risks
25 of cancer (including cervical cancer, the very cancer it is promoted as
26 preventing), fertility problems, autoimmune disease, including POTS, OI, and
27 other grave illnesses;
- 28 c) false advertising and disease mongering by scaring parents into believing that

1 cervical and anal cancer were far more prevalent than it really was; that Gardasil
2 prevented cervical and anal cancer; and that Gardasil only had risks of injection
3 site pain and fever, when in reality none of these representations were true as
4 cervical cancer rates were declining in the United States due to Pap testing and
5 Gardasil has not been shown to prevent cervical or anal cancer, and indeed some
6 studies demonstrated that it actually increased the risk of cervical cancer; and
7 Gardasil was linked to a host of serious, chronic and sometimes fatal diseases,
8 including autoimmune diseases, as previously outlined in this Complaint.

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

12 445. At the time she provided her consent to the Gardasil injection(s), Plaintiff was not
13 aware of the falsity of Merck's aforementioned representations concerning the safety and efficacy of
14 Gardasil.

15 446. Plaintiff reasonably and justifiably relied upon the truth of the assurance made by
16 Merck in its direct-to-consumer marketing concerning the efficacy and safety of Gardasil (which were
17 also echoed by Plaintiff's medical providers), when she provided consent to be injected with the
18 Gardasil vaccine.

19 447. Had Merck's advertisements and promotional material, which Merck targeted to
20 teenagers and the parents of teenagers, and which Plaintiff received and on which she relied, provided
21 complete and truthful warnings and properly disclosed and disseminated the true risks, limitations and
22 lack of efficacy associated with Gardasil, then Plaintiff would not have consented to being injected
23 with Gardasil.

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

- 1 a) Failing to test Gardasil against a true inert placebo and lying to the public that
2 Gardasil was tested against a placebo, when in reality, all, or nearly all, studies
3 used a toxic placebo that included the dangerous aluminum adjuvant AAHS.
- 4 b) Failing to conduct a sufficient number of studies for the targeted patient
5 population which included pre-teen girls (and boys) between the ages of nine
6 and 12.
- 7 c) Not using the commercial dosage (and instead using a lower dosage of the
8 adjuvant and ingredients) in one of the key clinical trials, which was used to
9 obtain licensing for the commercial dosage of Gardasil;
- 10 d) Using very restrictive exclusionary criteria in the clinical study patient
11 population (including for example, exclusion of anyone who had prior abnormal
12 Pap tests, who had a history of immunological or nervous system disorders or
13 was allergic to aluminum or other ingredients), but then not revealing or
14 warning about these exclusionary criteria in the label and knowing that for most
15 of these ingredients and allergies, there are limited resources for the public to
16 test for such allergies in advance of being vaccinated;
- 17 e) Failing to disclose all of the ingredients in Gardasil, including but not limited to
18 the fact that Gardasil contains dangerous HPV L1-DNA fragments and that
19 these DNA fragments could act as a Toll-Like Receptor 9 (TLR9) agonist –
20 further adjuvanting the vaccine and making it more potent and dangerous.

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

27 450. Plaintiff could not reasonably have discovered the falsity of Merck's representations,
28 the fraudulent nature of Merck's conduct, and the defects and risks associated with Gardasil before or

1 at the time of her injection(s). Plaintiff relied upon the skill, superior knowledge, and judgment of
2 Merck, the manufacturer, labeler, and promoter of Gardasil, and they detrimentally relied upon
3 Merck's fraudulent, false, and misleading statements, omissions, and conduct.

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

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

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

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

26 **PRAYER FOR RELIEF**

27 WHEREFORE, Plaintiff, Madeline A. Counts, requests that the Court enter judgment in her
28 favor and against Merck & Co., Inc., and Merck, Sharp and Dohme Corporation (collectively

1 “Merck”) as to all causes of action, and awarding as follows:

- 2 A. For compensatory damages, in an amount exceeding this Court’s jurisdictional
3 minimum and to be proven at trial;
- 4 B. For economic and non-economic damages in an amount to be proven at trial;
- 5 C. For medical, incidental, hospital, psychological and other expenses in an amount to be
6 proven at trial;
- 7 D. For loss of earnings and earnings capacity, in an amount to be proven at trial;
- 8 E. For an award of pre-judgment and post-judgment interest as provided by law;
- 9 F. For exemplary and punitive damages against Merck;
- 10 G. For preliminary and/or permanent injunctive relief against Merck;
- 11 H. For an award providing for payment of reasonable fees, court costs, and other litigation
12 expenses as permitted by law;
- 13 I. For such other and further relief as this Honorable Court may deem just and proper.

14 **DEMAND FOR JURY TRIAL**

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

17
18 Dated: July 18, 2022

BAUM HEDLUND ARISTEI & GOLDMAN, PC

19 By: /s/ Stephanie Sherman

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