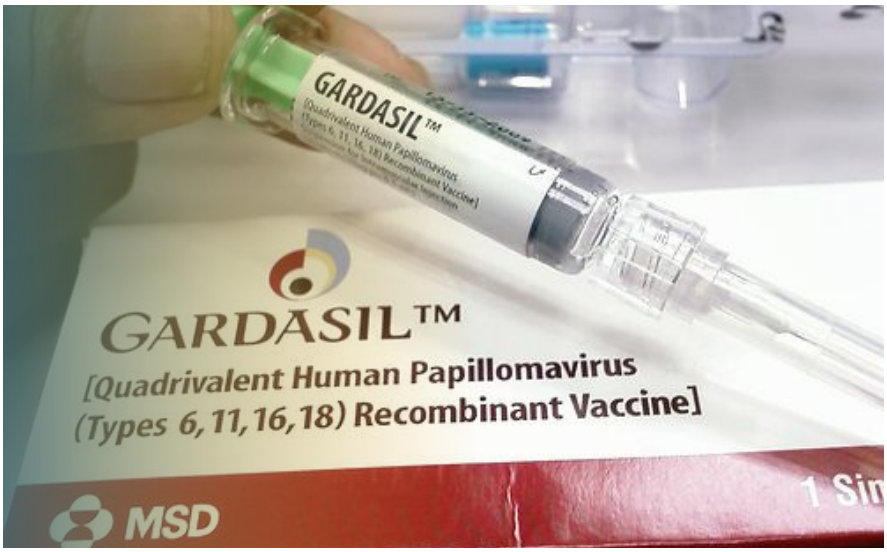
FEBRUARY 23, 2023

VOTE NO ON CALIFORNIA ASSEMBLY BILL 659

Assembly Bill 659, AKA the "Cancer Prevention Act" would require all 8th through 12th grade students in California to be vaccinated with GARDASIL, a vaccine that has not been proven to prevent cancer and has many serious and documented risks.



California Assembly Bill 659, also known as the "Cancer Prevention Act," seeks to add the vaccine Gardasil to the list of vaccines required to attend school in California for children in grades 8 to 12.The bill was introduced on February 9, 2023, by Assembly members Cecilia Aguiar-Curry (D, HD-4), Blanca Rubio (D, HD-48), Laura Friedman (D, HD-43), Ash Kalra (D, HD-27), Liz Ortega (D, HD-20), Diane Papan (D, HD-21)), Wendy Carillo (D, HD-51), and Senator Scott Wiener (D, HD-11).

The bill may be heard in committee as early as March 14, 2023.

Why Vote NO on AB 659

- Gardasil, manufactured and marketed by Merck, received fast-tracked FDA approval, leaving many unanswered questions about its safety and efficacy.

- The integrity of Merck's studies of Gardasil have been called into question by numerous members of the scientific community.

- Whether Gardasil prevents cancer (not to mention lifetime immunity) is unproven because the studies were not designed to test this hypothesis.

- The risk of developing cancer from HPV is extremely rare.

- Gardasil can cause serious and debilitating adverse reactions, including but not limited to a myriad of autoimmune diseases, autonomic dysfunction, including postural orthostatic tachycardia syndrome (POTS) and orthostatic intolerance (OI), premature ovarian failure (POF, which can cause infertility), Guillain-Barre syndrome, encephalopathy, and other serious injuries, including death.

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FACTS ABOUT HPV AND GARDASIL

• Gardasil is the only vaccine on the market in the United States for prevention of only nine of the over 200 strains of the human papillomavirus (HPV).

• HPV is so common, most sexually active people will get it at some point in their lives. Studies have also reported that 30% of children under age 10 have already been exposed to HPV through skin-to-skin contact or in the birth canal. Flora Bacopoulou et al., Genital HPV in Children and Adolescents: Does Sexual Activity Make a Difference? 29 JOURNAL OF PEDIATRIC & ADOLESCENT GYNECOLOGY 228 (June 2016).

• More than 90% of HPV infections cause no clinical symptoms, are self-limited, and are removed from the human body by its own immunological response. See, e.g., Antonio C. de Freitas et al., Susceptibility to cervical cancer: An Overview, 126 GYNECOLOGIC ONCOLOGY 306 (August 2012).

• Not every HPV infection puts one at risk for cervical cancer. Only persistent HPV infections (not short-term or transient infections or sequential infections with different HPV types) in a limited number of cases with certain strains of the virus may cause the development of precancerous lesions.

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

• Since its introduction, cervical cancer screening through the Pap test has reduced the rates of cervical cancer in developed countries by up to 80 percent. See Antonio C. de Freitas et al.

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

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

• Data show that young women who received HPV vaccines before turning 21 are far less likely to get cervical cancer screening than those who receive the vaccines after turning 21. Diane Harper, Leslie R. DeMars, HPV vaccines – A review of the first decade, Gynecologic Oncology, 146 (2017), 196-204, at p. 202.

Why Vote NO on AB 659

• Hundreds of young women and men across the United States are filing lawsuits against the manufacturer of Gardasil (Merck) claiming Gardasil caused them to suffer serious life altering side effects, including death.

• Several cases are pending in various California state courts, and the Judicial Panel on Multidistrict Litigation recently consolidated all federally filed Gardasil cases before one judge in North Carolina.

• The US government Vaccine Injury Compensation Program has paid out over $70 million dollars in damages for Gardasil-induced injuries and deaths.

• The potential and hypothetical benefits of Gardasil do not outweigh its risks.

• For those with an active HPV infection when vaccinated, studies have shown up to a 44.6% increased risk of developing advanced abnormal pre-cancer cells or worse.

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• New cases of cervical cancer in the U.S. affect approximately 0.8 percent of women in their lifetime. See Cancer Stat Facts: Cervical Cancer, NIH, at https://seer.cancer.gov/statfacts/html/cervix.html

• For those who are diagnosed, cervical cancer is largely treatable if caught early. See Antonio C. de Freitas et al. Anal cancer is even more rare, and according to current data, approximately 0.2 percent of people will be diagnosed with anal cancer in their lifetime.

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

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

• Merck's clinical trials of Gardasil did not test whether HPV vaccines prevent cervical, anal or other cancers. Instead, Merck tested the vaccines against development of certain lesions, which some researchers suspect are precursors to cancer, although the majority of these lesions – even the most serious – regress on their own. See, e.g., Jin Yingji et al., Use of Autoantibodies Against Tumor-Associated Antigens as Serum Biomarkers for Primary Screening of Cervical Cancer, 8 ONCOTARGET 105425 (Dec. 1, 2017); Philip Castle et al., Impact of Improved Classification on the Association of Human Papillomavirus With Cervical Precancer, 171 AMERICAN JOURNAL OF EPIDEMIOLOGY 161 (Dec. 10, 2009); Karoliina Tainio et al., Clinical Course of Untreated Cervical Intraepithelial Neoplasia Grade 2 Under Active Surveillance: Systematic Review and Meta-Analysis, 360 BRIT. MED. J. k499 (Jan. 16, 2018).

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

• The median age of death from cervical cancer is 58, and death from anal cancer is 66. Teenagers essentially have zero risk of dying from cervical or anal cancer.

• Numerous medical professionals have sharply criticized Merck's conduct of its clinical trials of Gardasil. An article published in the British Medical Journal outlines some of the flaws in Merck's Gardasil clinical trials. The authors issued a "call to action" for independent researchers to reanalyze or "restore the reporting of multiple trials in Merck's clinical development program for quadrivalent human papillomavirus (HPV) vaccine (Gardasil) vaccine." Peter Doshi et al., Call to Action: RIAT Restoration of Previously Unpublished Methodology in Gardasil Vaccine Trials, 346 BRIT. MED. J. 2865 (2019).

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

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FACTS ABOUT HPV AND GARDASIL

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

• Meanwhile, the medical literature has documented serious autoimmune, autonomic, and neurological dysfunction associated with Gardasil. See e.g.:

- E. Israeli et al., Adjuvants and Autoimmunity, 18 LUPUS 1217 (2009); Darja Kanduc, Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 65 (2009);
- Svetlana Blitshetyn, Postural Tachycardia Syndrome After Vaccination with Gardasil, 17 EUROPEAN J. OF NEUROLOGY e52 (2010);
- Darja Kanduc, Potential Cross-Reactivity Between HPV16 L1 Protein and Sudden Death Associated Antigens, 9 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 159 (2011);
- Deirdre Little et al., Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination, BRIT. MED. J. CASE REPORTS (2012);
- Serena Colafrancesco et al., Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune Inflammatory Syndrome Induced by Adjuvants, 70 AM. J. REPRODUCTIVE IMMUNOLOGY 309 (2013);
- Maurizo Rinaldi et al., Anti-Saccharomyces Cerevisiae Autoantibodies in Autoimmune Diseases: from Bread Baking to Autoimmunity, 45 CLINICAL REVIEWS IN ALLERGY AND IMMUNOLOGY 152 (October 2013);
- Svetlana Blitshetyn, Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination, 21 EUROPEAN J. OF NEUROLOGY 135 (2014);
- Tomomi Kinoshita et al., Peripheral Sympathetic Nerve Dysfunction in Adolescent Japanese Girls Following Immunization With Human Papillomavirus Vaccine, 53 INTERNAL MEDICINE 2185 (2014);
- Christopher A. Shaw et al., Aluminum-Induced Entropy in Biological Systems: Implications for Neurological Disease, JOURNAL OF TOXICOLOGY (2014);
- Louise S. Brinth et al., Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against Human Papilloma Virus, 33 VACCINE 2602 (2015);
- Manuel Martinez-Lavin et al., HPV Vaccination Syndrome. A Questionnaire Based Study, 34 J. CLINICAL RHEUMATOLOGY 1981 (2015);
- Louise S. Brinth et al., Is Chronic Fatigue Syndrome/Myalgic Encephalomyelitis a Relevant Diagnosis in Patients with Suspected Side Effects to Human Papilloma Virus Vaccine, 1 INT. J. OF VACCINE & VACCINATION 3 (2015);
- Jill R. Schofield et al., Autoimmunity, Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation, CLINICAL PEDIATRICS (2017);
- Ozawa et al., Suspected Adverse Effects After Papillomavirus Vaccination: A Temporal Relationship Between Vaccine Administration and the Appearance of Symptoms in Japan, Drug Saf, 1219-1229 (2017).
- Rebecca E. Chandler et al., Current Safety Concerns With Human Papillomavirus Vaccine: A Cluster Analysis of Reports in VigiBase, 40 DRUG SAFETY 81 (2017);
- Svetlana Blitshetyn et al., Autonomic Dysfunction and HPV Immunization An Overview, IMMUNOLOGIC RESEARCH (2018);
- Svetlana Blitshetyn, Human Papilloma Virus (HPV) Vaccine Safety Concerning POTS, CRPS and Related Conditions, CLINICAL AUTONOMIC RESEARCH (2019);
- Lars Jørgensen et al., Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports, 9 SYSTEMATIC REVIEWS 43 (February 2020);
- Mehlsen et al., Autoimmunity in Patients Reporting Long-term Complications After Exposure to Human Papillomavirus Vaccination, Journal of Autoimmunity 133 (2022).

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FACTS ABOUT HPV AND GARDASIL

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

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

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

• Finally, let us not forget, Merck, the manufacturer of Gardasil, is the same company that claimed its drug, Vioxx, was safe, and continued to do so for several years until it was forced to take Vioxx off the market in one of the biggest medical scandals in history. See Topol, Failing the Public Health – Rofecoxib, Merck, and the FDA, NEJM (October 31, 2004); see also Kesselheim et al, Role of Litigation in Defining Drug Risks, 17 JAMA 308 (2007) ("the litigation process revealed new data on the incidence of adverse events, enabled reassessment of drug risks through better evaluation of data, and influenced corporate and regulatory behavior.").

PLEASE VOTE NO ON ASSEMBLY BILL 659.

Compiled by the law offices of Wisner Baum LLP, who represent hundreds of Gardasil injured girls and boys.