WISNER WB BAUM
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March 7, 2023

Wisner Baum Position Statement in Opposition to Assembly Bill 659

We write in opposition to Assembly Bill 659 (AB 659) as lawyers representing hundreds of young women and men who have suffered serious and debilitating autoimmune injuries, including death, following HPV vaccination with Gardasil, the only HPV vaccine on the United States market at this time. AB 659 would require all 8th through 12th grade students in California to receive the Gardasil vaccine in order to attend school. We oppose the bill, not only as advocates for our clients, but because we cannot stand by, knowing what we know, while hundreds of thousands of children in California are exposed to Gardasil's risks without their (or their parents) being fully informed, and having no choice.

About Wisner Baum

Wisner Baum (formerly known as Baum Hedlund Aristei & Goldman) is an award-winning plaintiffs' law firm that has earned a reputation for successfully litigating pharmaceutical cases, holding Fortune 500 companies accountable, influencing public policy, raising public awareness, and improving product safety.[1] For example, Wisner Baum is the firm that tried the Monsanto Roundup cases in San Francisco and Oakland, resulting in groundbreaking verdicts in favor of their clients. Wisner Baum lawyers not only advocate for their clients in the courtroom, but they also advocate for the health and safety of all citizens. For instance, Wisner Baum shared internal Monsanto documents (known as "The Monsanto Papers") with regulators around the world, including in California, which resulted in important policy changes that protect citizens of California and elsewhere from being exposed to dangerous chemicals.

Gardasil Litigation and Why it Matters to AB 659

In August 2022, the federal court system granted consolidation of all Gardasil injury cases pending in federal courts across the country in front of one judge in a multi-district litigation (MDL) proceeding. See *In re Gardasil Prod. Liab. Litig.*, No. MDL 3036, __ F.Supp.3d. __, 2022 WL 3138681 (U.S. Jud. Pan. Mult. Lit. Aug. 4, 2022). There are currently 77 cases pending in the MDL, seven cases pending in various California state courts, and 207 cases pending in the United States Court of Federal Claims, Vaccine Injury Compensation Program.

[1] https://bestlawfirms.usnews.com/profile/wisner-baum-pc/overview/37616

In addition to the cases in active litigation, Wisner Baum has been contacted by thousands of young women and men, and their parents, claiming they have been injured by Gardasil. Hundreds more cases are in the pipeline to be filed in the MDL in the coming months.

Alongside Wisner Baum, Gardasil injury cases are being litigated by some of the most prominent law firms in the United States, including The Lanier Firm (which achieved a $253 million verdict against Merck in a Vioxx trial), Morgan & Morgan (the largest plaintiffs' law firm in the United States), the former Attorney General for the State of Hawaii, Margery Bronster of Bronster Fujichaku Robbins, and former federal prosecutors Justin Gelfand and Gregory Bailey of Margulis Gelfand.

We provide this information, not to toot our own horns, but to illustrate the caliber of the lawyers conducting this litigation and so that the Assembly will appreciate that such lawyers will have done their due diligence concerning Gardasil's risks and benefits, whether the company failed to warn about the known risks, and whether the company committed fraud in its conduct and reporting of its Gardasil studies. We have extensively studied the literature, engaged scientists from some of the top universities in the nation, including Stanford, Columbia, and Johns Hopkins, and have amassed millions of pages of internal Merck documents that not even the FDA gets to see. In the coming months, we will be taking depositions of Merck's executives, employees, and scientists. Jury trials are scheduled to begin in California in May of 2024.

Based on all the evidence we have gathered so far, and in consultation with top-notch experts in the fields of immunology, epidemiology, oncology, cardiology, neurology, etc., we can confidently state that Merck has overstated Gardasil's efficacy in preventing cancer and ignored and kept quiet about the risks. We would also note that, in our litigation, Merck has resisted producing internal documents, studies, and analyses every step of the way and is still holding out on producing all internal adverse event reports related to Gardasil. As you will see in the "Facts about HPV and Gardasil" in the following pages, the science regarding Gardasil is far from settled. There is more we could state about the evidence we have accumulated; however, we are bound by confidentiality agreements that prohibit us from stating more at this time.

What we can state is that there have been more adverse event reports regarding Gardasil than almost any other vaccine in history, and the United States Vaccine Injury Compensation Program has paid more than $70 million in damages awards to children who have been injured by Gardasil.

Furthermore, whether Gardasil prevents cancer (not to mention lifetime immunity) is unproven because Gardasil studies were not designed to test whether Gardasil prevents cancer, instead, the studies were conducted on surrogate endpoints (lesions), not cancer itself, and indeed, the vaccine does not even target all carcinogenic HPV

strains. Thus, AB 659's "Cancer Prevention" meme is perversely misleading to legislators and parents.

The most effective and side-effect free means of preventing cervical cancer is the Pap test. Studies show that young women who have received Gardasil have a false sense of security and are foregoing routine Pap tests. Data has also shown that, in countries where uptake of Gardasil is high, cancer rates are increasing in younger women, for a cancer that usually appears when women get into their 50s and 60s, while the cervical cancer rates among older women continue to decline in regions where routine Pap screenings are conducted. Our children should not be subjected to a state mandate that turns them into guinea pigs and places them at a heightened risk for the very disease they are being told this vaccine prevents.

Conclusion

We strongly oppose Assembly Bill 659 and urge the committee to, at a minimum, wait until the evidence has been fully aired and the jury has spoken. Our research into Gardasil's mechanism of action shows that some individuals are at risk for debilitating autoimmune conditions who should not be mandated to be vaccinated to go to school.

Medical decisions involving cancer are very personal and often involve a complex trade-off between risks and rewards. The balance of risk and reward is equally important, perhaps even more so when it is not a disease that is being treated, but the potential of acquiring a disease, usually decades later, as is the case with the HPV vaccine Gardasil. As the risk of adverse health effects increases, the question of reward becomes more important. The decision of whether to receive the Gardasil vaccine should be a personal one, guided by informed consent—which requires an honest disclosure of the risks and rewards of vaccination, alternative treatments (or prevention), or no treatment at all. This is not a vaccine that should be mandated. **We urge the Assembly to review the "Facts about HPV and Gardasil" in the following pages.** We are happy to provide more information upon request.

With Warm Regards,

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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 vaccination does not target all high-risk HPV strains. Riva, Espinosa, "Has the HPV vaccine approval ushered in an era of over-prevention?" Journal of Scientific Practice and Integrity, Vol. 2, Issue 1 (2020).

- 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 have 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.

- 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.

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

- 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).

- 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); Tatang et al. Human Papillomavirus Vaccination and Premature Ovarian Failure: A Disproportionality Analysis Using the Vaccine Adverse Event Reporting System, DRUGS REAL WORLD OUTCOME, (March 2022).

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.").