

# Lawsuit Claims Merck's Gardasil Papilloma Virus Vaccine Caused Severe Injuries to Teen

By [Robin McCall](#) and [Dr. Gary G. Kohls](#)

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*It is vitally important to acknowledge that the same so-called "experts" in the medical/academic/scientific community, many of whom have serious undisclosed financial conflicts of interest at the NIH, the CDC, the NIAID, the FDA, the WHO, Medical Schools, teaching hospitals and many state Departments of Health (not just Rhode Island) that are currently advising politicians, presidential candidates, presidents, senators, congresspersons, governors, mayors, educators and journalists about the experimental, fast-tracked Covid-19 vaccines are the very "experts" that pushed Merck's Fast-tracked Gardasil (and GlaxoSmithKline's Cervarix HPV Vaccine).*

-Gary G. Kohls, August 24, 2020

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*The national law firm of Baum, Hedlund, Aristei & Goldman filed a Gardasil lawsuit against Merck today on behalf of a 19-year-old woman, alleging **the company misled the FDA, legislators, doctors and moms about the safety and efficacy of its Gardasil vaccine.** The lawsuit asserts Merck purposely downplayed the risk of Gardasil's ingredients, including a proprietary aluminum compound (a potent neurotoxin) and secret and potentially hazardous DNA particles. Plaintiff Julia Balasco alleges she suffered and continues to suffer severe and permanent physical injuries such as an autoimmune disease known as postural orthostatic tachycardia syndrome (POTS) after receiving multiple injections of the human papillomavirus (HPV) Gardasil vaccine.*

Attorneys [Bijan Esfandiari](#), [Nicole K. H. Maldonado](#), [Michael L. Baum](#), co-counsel [Robert F. Kennedy, Jr](#) and local counsel [Christopher E. Hultquist](#) of Hultquist Law in Providence, filed the lawsuit in U.S. District Court for the District of Rhode Island on behalf of Ms. Balasco, who alleges her vaccine injuries were so severe and debilitating, she was physically unable to attend most of high school. The case number is [1:20-cv 00364](#).

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

JULIA BALASCO,

Plaintiff,

v.

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

Defendants.

Case No.

**COMPLAINT FOR**

- (1) Negligence
- (2) Strict Liability (Failure to Warn)
- (3) Strict Liability (Manufacturing Defect)
- (4) Breach of Warranty
- (5) Common Law Fraud
- (6) Violation of Rhode Island's Deceptive Trade Practices Act

**DEMAND FOR JURY TRIAL**

The complaint against defendants Merck & Co. Inc. and subsidiary Merck Sharp & Dohm Corp., both of New Jersey, seeks damages based on the following causes of action:

- Negligence
- Strict Liability (Failure to Warn)
- Strict Liability (Manufacturing Defect)
- Breach of Warranty
- Common Law Fraud
- Violation of Rhode Island's Deceptive Trade Practices Act

The lawsuit also seeks punitive damages against Merck.

According to the complaint, Merck failed to properly test Gardasil before the HPV vaccine was fast-tracked and administered to millions of young girls and boys throughout the United States and the world. Furthermore, Merck knew or had reason to know that its vaccine was defective and ineffective, but instead of warning the medical community and the public, the company wrongfully concealed information and further made false statements concerning the safety and efficacy of Gardasil.

"Merck spent more money marketing and advertising Gardasil than any vaccine manufacturer in history," says Gardasil lawyer Nicole K. H. Maldonado. "The company made billions telling the parents of young girls that Gardasil could eliminate cervical cancer without having any proof to back up the claim. Now, with thousands of severe Gardasil vaccine injuries reported, we intend to hold Merck accountable for concealing known safety risks in the name of massive profits."

"Before there was Gardasil, there was Vioxx," says attorney Robert F. Kennedy Jr. "Merck paid billions to settle civil allegations that it purposely hid Vioxx's cardiovascular risks. They also paid \$950 million in fines as a result of their criminal conduct. When Gardasil came along, the boardroom at Merck joked that its HPV vaccine could 'Help Pay for Vioxx.' Sure enough, some of the same shadowy cast of characters who were involved in the Vioxx scandal worked on

Gardasil, and they employed the very same methods of manipulating science and obscuring risks as they did with Vioxx. And just as with Vioxx, Gardasil has left a calamitous health disaster in its wake.”

## What is Gardasil?

In 2006, the U.S. Food and Drug Administration approved the Gardasil HPV vaccine after being “fast-tracked” in just six short months. The FDA’s fast-track process is designed to facilitate the development and expedite the review of drugs or vaccines to treat serious conditions and fill an unmet medical need like providing a treatment for an epidemic which has no existing treatment. Gardasil met neither of these criteria. Cervical cancer was far from epidemic status and the existing PAP smear plus follow up removal of abnormal cervical tissue had substantially controlled most cervical cancers. In fact, according to the National Cancer Institute’s Surveillance, Epidemiology and End Results Program (“SEER”), the incidence of deaths from cervical cancer prior to the introduction of Gardasil in the U.S., was on a steady decline with a rate of 2.4 per 100,000 women.

Notwithstanding, in its bid to fast-track Gardasil and prove that the vaccine treats a serious condition and fills an unmet medical need, Merck allegedly presented misleading data to the FDA suggesting that HPV infections and some abnormal cervical tissue-cervical interepithelial neoplasia (CIN) lesions-inexorably result in cancer, hence the urgent need for the HPV vaccine. The complaint indicates those contentions are untrue.

Merck sought and received FDA approval for Gardasil based on its theory that HPV alone causes cervical cancer, and that Gardasil could eliminate cervical cancer and other HPV-associated cancers. According to Balasco’s attorneys, however, Merck’s theory is unproven – Gardasil has never been shown to prevent cervical cancer, itself. On the contrary, studies have shown that systemic administration of Gardasil leads to increased rates of cervical cancer and other serious health issues.

According to the complaint, [Gardasil contains a host of hazardous ingredients](#), including at least one ingredient that Merck failed to disclose to regulators and consumers. Gardasil contains a secret DNA adjuvant and potentially hazardous ingredient, HPV LI-DNA fragments, to make the vaccine more potent. According to the allegations, Merck used this hidden adjuvant to prolong the immunological effects of the vaccine, but illegally omitted it from its list of substances and ingredients in the vaccine.

Gardasil also contains a particularly toxic aluminum-containing adjuvant – Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS), which is a potent neurotoxin created by Merck, that can result in very serious harm, according to the complaint. Studies show that AAHS can trigger autoimmune disorders and other serious conditions and has never been proven safe. Federal law requires that manufacturers cannot add adjuvants to vaccines that have not been proven safe.

Gardasil also contains borax, polysorbate 80, and genetically-modified yeast, all of which can cause adverse events, the lawsuit alleges. Merck never tested any of these added ingredients for safety in vaccines.

## Gardasil Clinical Trial

In clinical trials, those who receive the active medication are compared with those who

receive a placebo. This is to measure the vaccine's safety against an inactive (inert) placebo, such as an injection of a saline (saltwater) solution.

[Merck's Gardasil clinical trials](#), however, did not use a true placebo, the complaint alleges. Instead, the company "spiked" the placebo with AAHS and the vaccine's other additives, which resulted in approximately equal numbers of subjects in the vaccine group and the placebo group suffering adverse reactions. This gave the impression that the Gardasil HPV vaccine was "as safe as a placebo" when, in fact, significant numbers of subjects in both treatment groups suffered many serious medical conditions, including symptoms of autoimmune disease, the lawsuit maintains.

### Teenage Girl Developed POTS After Two Gardasil Injections

According to Julia Balasco's complaint, she was 13-years-old when she received a Gardasil shot for the first time in August of 2014. A happy, healthy girl with a love for cheerleading, Julia had never experienced serious medical issues before her first Gardasil injection.

Julia's mother, Michaela, allowed her daughter to receive the Gardasil shot after years of exposure to relentless online, print, and television marketing by Merck representing that Gardasil is very safe, that Gardasil prevents cancer, and that "good mothers" must vaccinate their pre-teen daughters with the Gardasil vaccine. Little did she know that Merck had engaged in "Disease Mongering" and used false advertising and scare tactics to enhance Gardasil sales. A year later, Rhode Island mandated the Gardasil vaccine for all school children before 7<sup>th</sup> grade entry.

Within hours of receiving the first dose, Julia experienced flu-like symptoms, including achiness, headache, nausea, and low-grade fever. The symptoms lasted for approximately 24-48 hours. In the weeks that followed, Julia experienced ear pressure, tinnitus, and headaches. Her symptoms were atypical and over-the-counter medication did not bring her any relief.

A few months later, Julia experienced more frequent and severe ear pain and tinnitus. Her mother took her to her doctor who prescribed Julia steroids. She received her second dose of Gardasil during this visit and proceeded to experience the same flu-like symptoms as before.

As months passed, Julia began to experience headaches of varying seriousness and continued to deal with ear pain and tinnitus. She also complained of fatigue and body aches. Her symptoms were severe enough to increasingly keep her from attending school.

Julia and her mother visited multiple specialists to understand why she was experiencing these "spells" that caused severe dizziness, headaches, ear pressure, and tinnitus. No one could give them a satisfactory answer or relief, and her symptoms continued unabated.

When Julia was due for her third Gardasil injection, her mother started to believe that Gardasil may have been the cause of her daughter's symptoms. The family doctor agreed that the timeline following each of the shots and the symptoms Julia experienced was suspicious but could not say for certain that Gardasil was the cause.

Julia was put on several different medications over the next several months but nothing alleviated her symptoms. She continued to miss school regularly and saw her quality of life

diminish. Her mother helped her change her diet and altered her school schedule to include online learning in the hopes of reducing her stress and improving her symptoms. Nothing worked.

After being diagnosed with fibromyalgia and years of struggle, Julia's life continues to be altered in very dramatic ways. Now 19, she struggles to keep up with friends and cannot participate in many of the things she used to enjoy. She was forced to stop cheerleading because she could no longer participate, and has switched to online learning exclusively instead of attending in-person classes.

"This is no life for anyone," her mother says.

According to the complaint, Gardasil caused Julia Balasco to develop serious and debilitating autoimmune disease, including POTS, and a constellation of adverse symptoms, complications, injuries, and adverse events.

POTS is an autoimmune disorder that can be incapacitating; it affects a branch of the nervous system that regulates functions we do not consciously control, including blood pressure, heart rate, perspiration, and body temperature. People with POTS often experience fainting, migraine headaches, anxiety, and other life-altering health issues.

If Mrs. Balasco had been informed about the known safety risks associated with Gardasil, she never would have allowed her daughter to receive the HPV vaccine.

Gardasil, the Most Expensive Vaccine on the Market, Also Causes the Most Injuries

Julia's symptoms after receiving Gardasil, are far from unique. According to data from the Vaccine Adverse Event Reporting System (VAERS), more than 64,000 case reports of adverse events have been reported after individuals received the Gardasil vaccine. Experts estimate that only one percent of vaccine adverse events are actually reported.

According to the complaint, Gardasil now has more reported injuries than any other vaccine, and the Vaccine Injury Compensation Program has paid out [millions of dollars in damages for Gardasil-induced injuries and deaths](#).

Gardasil is also the most expensive vaccine on the market; two doses of Gardasil 9 presently cost about \$450, plus the cost of two office visits. In 2018, Merck made \$2.2 billion from Gardasil sales in the U.S. alone. In 2019, Merck made \$3.7 billion in worldwide Gardasil revenue.

Ms. Balasco seeks to hold Merck accountable for its alleged negligent, reckless, and fraudulent conduct, and for causing her physical and emotional injuries and harms as a result of Gardasil. Today's lawsuit alleges the company willingly placed Gardasil's profits ahead of patient safety. Ms. Balasco is requesting that exemplary (punitive) damages be assessed against Merck to deter the company and other would-be defendants from engaging in similar alleged reprehensible conduct.

"It's too late for my daughter. The damage is already done, but it's not too late to warn other parents about the truth about Gardasil," said Michaela Balasco, Julia's mother. "Thousands of families are going through what we are going through. I have made friends around the world whose children are suffering like my Julia. She is not alone. I want Gardasil

off the market so my grandkids and other children don't have to needlessly suffer these injuries."

#### Additional General Allegations Against Merck

- Merck provided financial incentives to legislators to attempt to make the Gardasil vaccine mandatory in all school children;
  - Merck pushed Gardasil using trusted doctors and third party front groups;
  - Merck deceived regulators and the public by classifying many serious adverse events, which afflicted nearly half of all study participants, as coincidences;
  - Merck manipulated the study protocols to block participants and researchers from reporting injuries and designed the studies to mask any long-term adverse events
  - Merck deceived regulators and the public about its pivotal Gardasil Clinical Trial (Protocol 018);
  - Contrary to Merck's representations, Gardasil may actually cause and increase the risk of cervical and other cancers;
  - Merck has concealed the fact that Gardasil (including its adjuvants and ingredients) induce and increase the risk of autoimmune diseases;
  - The Gardasil vaccines' harms are not limited to the United States, rather the vaccines have injured patients all over the world:
1. In light of Gardasil's serious and debilitating adverse events, the Japanese government rescinded its recommendation that girls receive Gardasil;
  2. Denmark has opened specialized clinics specifically focused on treating Gardasil-induced injuries, including Gardasil-induced autoimmune diseases;
  3. Gardasil-induced adverse events caused the government in Colombia to conclude that Gardasil would no longer be mandatory;
  4. India halted Gardasil trials and accused Merck of corruption after the death of several young girls who were participants in the trial.

#### About Baum Hedlund Aristei & Goldman

[Baum Hedlund Aristei & Goldman](#) is one of the nation's leading law firms representing victims [harmed by the Gardasil HPV vaccine](#). In practice since 1973, our firm has won more than \$4 billion in verdicts and settlements on behalf of more than 20,000 clients in personal injury and wrongful death claims across the nation, including cases against major pharmaceutical companies.

The firm has repeatedly been honored and awarded for its \$2.24 billion groundbreaking and landmark jury verdicts against Monsanto (now Bayer) for its Roundup weed killer causing cancer.

Robert F. Kennedy, Jr. is co-counsel on this case. Mr. Kennedy has been fighting for safer vaccines for years. He is not "anti-vax" as some would label him, but is a staunch advocate for safe and effective vaccines. His reputation as a resolute defender of the environment led him to be named by Time magazine as one of the "Heroes for the Planet." As a protector of waterways around the world, Mr. Kennedy has sought to alleviate mercury pollution and prevent mercury contaminated fisheries. As he says, this does not make him anti-fish, he is anti-mercury in fish. Likewise, he is not against safe and effective vaccines, he is opposed to



toxin contaminated vaccines.

Mr. Kennedy was also co-counsel with Baum Hedlund on the Monsanto Roundup cancer cases. He is Founder and President of Waterkeeper Alliance and Founder of Children's Health Defense, an organization devoted to promoting childhood health by exposing and reducing toxic exposures that harm children's health.

Baum Hedlund is at the forefront of the Gardasil vaccine lawsuits and is in the beginning stages of litigation. So far, we represent two dozen clients but expect to see these numbers grow rapidly as we are receiving hundreds of calls now that the word is out that plaintiffs can sue Merck in civil court if cases do not resolve in vaccine court.

It is important to note that, while there is currently a great deal of controversy surrounding vaccines, our firm wishes to stress that we and our clients are not against vaccines. They have the potential to eradicate disease and save millions of lives.

We are, however, against intentional efforts to mislead consumers about the safety and effectiveness of a drug or vaccine. Our firm has always fought—and will continue to fight—for the rights of consumers to be fully and honestly informed about risks associated with any drug, vaccine, chemical or medical device. We will work tirelessly to ensure those rights are defended and victims of injustice are compensated for their injuries.

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*Featured image: Julia Balasco, Gardasil Plaintiff (Source: ExpertClick)*

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