Court Hears Gardasil Science and Moves Forward

Source: Children's Health Defense

by <u>Lyn Redwood</u>, R.N, M.S.N., President, <u>Children's Health</u> <u>Defense</u> January 29, 2019

On Wednesday January 9th, I attended Science Day Presentations in the Jennifer Robi vs. Merck and Kaiser Permanente case in Los Angeles Superior Court. I want to report to our community on the outcome of this important event and provide some personal commentary.

It is difficult to describe the feelings of elation and frustration that I experienced during the full day of furious arguments that began at 9:30 am before Judge Maren Nelson. Due to the restrictions of the National Childhood Vaccine Injury Act, my son and thousands of children like him, have never been able to have their injuries acknowledged in a court of law. This day gave families around the globe whose children's health was permanently harmed by the HPV vaccine a glimmer of hope that their injuries and suffering would finally be acknowledged. The frustration I felt came from the obvious fact that the science relied on by our federal agencies to approve the HPV vaccine was criminally inadequate and that Jennifer's injuries and those of the thousands of others like her could have been prevented.

Prior to Science Day, plaintiffs' attorneys worried that because Judge Nelson threw out a \$472 million 2017 jury verdict against Johnson & Johnson for causing ovarian cancer in women exposed to its asbestos-containing baby powders, the Court might not be very receptive to their arguments here. However, Judge Nelson gave scrupulous attention to the science presentations by both sides and clearly seemed to be approaching the Robi case with an open mind.

A red-letter day

After 20 years of advocating for vaccine safety, this was the first time that I've watched vaccine science issues adjudicated in a true court of law. It was truly a red-letter day. Jennifer's lawyers brilliantly laid bare Merck's anemic case for Gardasil, dissecting the science in withering presentations challenging both the efficacy and safety of the Gardasil vaccine, and then chronicling the horrifying agency and corporate corruption that lead to its approval.

Jennifer Robi is a 24-year-old former athlete and scholar who has been confined to a wheelchair since receiving her third Gardasil vaccines at age sixteen. She suffers continual uncontrolled neuro/muscular contractions (jerking) and postural orthostatic tachycardia syndrome (POTS) and many other symptoms of systemic autoimmune dysregulation.

Jennifer's attorney, Sol Ajalat, initially brought her case in Vaccine Injury Compensation Program and then, following a judgment in the program, elected to proceed in civil court. Since VICA (the Vaccine Injury Compensation Act) forbids recoveries for product defect or negligence, Ajalat brought Jennifer's civil case under the theories that Merck committed fraud during its clinical trials and then failed to warn Jennifer (and, by implication, other injured girls) about the high risks and meager benefits of the vaccine.

In order to support Sol Ajalat and his sons Greg, Larry, and Steve, who compose the Los Angeles firm Ajalat & Ajalat, a blue ribbon A-Team of the nation's leading plaintiffs' law firms have joined Jennifer's trial team. These include the firms most feared by Pharma: Weitz & Luxenberg (countless major pieces of litigation over 30 years), Morgan & Morgan (Vioxx, Phenphen, Breast Implants, Tobacco), Baum Hedlund, (Monsanto \$289 million verdict 2018 and the \$54 million 2000 verdict against Bayer in Haemophiliac/AIDS case) as well as Children's Health Defense's own Robert F. Kennedy, Jr. and Kim Mack Rosenberg (a co-author of <u>The HPV Vaccine on Trial</u>). The plaintiff's bar has steered clear of vaccine lawsuits since the 2008 Thimerosal fiasco which nearly bankrupted several big firms. Now, Merck, through its reckless overreaching with Gardasil—a public health flimflam currently emerging as the most dangerous vaccine in history—has brought the nation's leading trial lawyers back to the brawl.

The three Merck attorneys who made presentations were Dino Sangiamo, Sally Bryan, and Christina Gaarder. Jo Lyn Valoff represented Kaiser.

Among vaccinologists, it's axiomatic that the duration of immunity correlates directly to the toxicity of the adjuvant; the more toxic the adjuvant, the longer the duration of immunity.

Gardasil's super-powered aluminum adjuvant

Plaintiffs began the day with a 2.5 hour presentation. Sol Ajalat first introduced Paul Pennock of Weitz & Luxenberg. Pennock ran through a riveting 50-minute slide show demonstrating how Gardasil's super-powered Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) adjuvant over-stimulated the immune systems of vaccine recipients tipping them into autoimmune conditions in which their redlining immune defenses begin attacking their bodies' own organs. This "autoimmune process" causes a cascade of illnesses that, in Jennifer Robi's case, resulted in damage and deterioration in diverse organ systems throughout her body.

Victims like Jennifer are left exhausted as the body fights off disease on multiple fronts. Pennock explained that vaccine makers add aluminum adjuvants (to weak antigens and a long list of other potentially toxic ingredients) to elicit an immune response, hoping to extend the short-term immunity otherwise provided by most vaccines. Among vaccinologists, it's axiomatic that the duration of immunity correlates directly to the toxicity of the adjuvant; the more toxic the adjuvant, the longer the duration of immunity. Most vaccines provide immunity for only 5-10 years. Gardasil's promoters were promising lifelong protection, and needed a super toxic adjuvant that would provide this unprecedented level of protection. After all, Merck was promising regulators, pediatricians and the public that inoculations given to 9-12year-old girls would provide immunity against a relatively rare cancer that typically doesn't kill until age 58!

Pennock explained that Merck has refused to disclose the contents of AAHS or to provide samples to independent and university scientists for testing. AAHS, astonishingly, has never been safety tested by government regulators or by Merck. Studies on animals conducted by world renowned independent scientists like Dr. Chris Exley, Dr. Yehuda Shoenfeld, Dr. Chris Shaw and others have found that mice and sheep exposed to aluminum adjuvants, at concentrations comparable to those found in vaccines, develop strange behavioral patterns and illnesses resembling autoimmune diseases.

Using a poisonous placebo in the control group allowed Merck to mask the cascade of injuries suffered by girls in the Gardasil group during the clinical trials.

A parade of deceptive canards

Robert F. Kennedy, Jr. next gave the court an explosive 50minute presentation of 112 disturbing slides describing the parade of deceptive canards that composed Merck's clinical trials. Kennedy described a series of fraudulent gimmicks employed by Merck to deceive regulators during the clinical trials including the use of a "spiked" extremely toxic AAHS placebo rather than a true inert placebo that is standard for control groups in blue ribbon safety studies for other pharmaceutical products. Using a poisonous placebo in the control group allowed Merck to mask the cascade of injuries suffered by girls in the Gardasil group during the clinical trials. Half the girls in the Gardasil group and half the girls in the spiked placebo group suffered serious injuries, including several deaths, in the first seven months of the clinical trials, yet Merck was able to claim that reactions in the study group "were similar to the reactions in the placebo group," and that, therefore, the vaccine was safe. Merck reported most of these serious injuries as "new medical conditions" not adverse events, dismissing any connection to the vaccine by fiat. Information about this parade of grave injuries appears nowhere in the Gardasil package insert.

Merck committed its boldest fraud in its key clinical trial, Protocol 18. Merck told FDA that Protocol 18 was the single study in which its researchers gave the control group a true inert placebo. For this reason, FDA declared Protocol 18 "of special interest." However, in reality, Merck appears to have taken the precaution of removing half the aluminum from the vaccines administered to this study group. Plus, The Company laced the "placebo" with a witches' brew of other toxic chemicals. This study, the only "controlled" study that included children in the target cohort of 9-12-year olds, may not have in fact tested the vaccine that Merck went on to inject into millions of young children around the world. Kennedy told the judge that this is not just scientific malpractice, it is outright fraud!

... Merck's control groups did not reflect the target population for its drug.

Another tactic utilized by Merck was to purge the study group of anyone with the slightest vulnerabilities to the vaccine or its ingredients despite the fact that the vaccine would ultimately be marketed to girls with the very vulnerabilities excluded during the clinical trials. This precaution allowed the company to mask effects that occur only in vulnerable

subgroups. Mr. Kennedy drew laughter from the large court room audience when he described how Merck had prescreened the study subjects to exclude people with allergies, immunological or nervous disorders, more than 4 lifetime sexual partners, genetic vulnerabilities to cancer or to any other medical condition, or with any hint of general infection, a history of alcohol or drug abuse, or a serious or chronic illnesses, and so forth. Finally, Merck told its researchers to exclude any individual with "any condition which in the opinion of the researchers might interfere with the study objective." The remaining participants were an elite club of super healthy individuals. "You couldn't get into the clinical trials unless you were a superhero," Kennedy told Judge Nelson. "You had to be eligible for the Avengers." The problem, of course, is that none of the people receiving the vaccine under CDC's mandate are screened for these vulnerabilities. In other words, Merck's control groups did not reflect the target population for its drug.

The mayhem caused by Gardasil

Even these flimflams could not conceal the mayhem caused by Gardasil. Kennedy showed the court data from Merck's own package insert showing that 2.3 % of the girls receiving the vaccine complained of symptoms of autoimmune disease within 7 months. Since cervical cancer kills only 1.5 Americans in every 100,000, he noted, "Merck's own data show that the chances of getting an autoimmune disease from this vaccine are 1000 times the risk of dying from cervical cancer."

Merck's own data showed that administering the Gardasil vaccine to girls who had previous exposure to HPV actually raised their risk of developing precancerous lesions (or worse) by almost 45%.

Not only did a heartbreaking 50% of the subjects in both the study group and the spiked placebo group experience a serious adverse event within the seven months of the trial, death

rates among girls in the study were double background rates. In fact, the rate for girls during the clinical trials (85/100,000) was 37 times the death rate from cervical Birth defects among children conceived during the cancer! study period were 5x those of the control group and miscarriages were doubled over background rates. Reproductive problems among vaccinated girls were 10x background rates. Finally, Merck's own data showed that administering the Gardasil vaccine to girls who had previous exposure to HPV actually raised their risk of developing precancerous lesions (or worse) by almost 45%. This revelation is particularly frightening since sexual behavior is only one of many vectors for acquiring HPV. Many children are exposed in the birth canal. Kennedy cited numerous studies showing many very young children are exposed to HPV, including one in which upwards of 34% of girls had exposure to HPV prior to age 10.

Kennedy closed his powerful presentation by chronicling the parade of corrupt conflicts that caused HHS officials to turn a blind eve to the rife fraud that characterized the clinical trials. Merck loaded the two FDA and CDC panels that approved Gardasil, with paid toadies. He showed that the pharmaceutical industry actually pays 45% of FDA's annual budget and that NIH and its officials own part of the patents to the Gardasil vaccine and collect royalties on every vaccine sold. NIH collects tens of millions of dollars annually from Gardasil sales. Finally, 45% of CDC's budget goes to promoting and purchasing vaccines. Merck exerts control over the CDC with millions of dollars in contributions to the CDC foundation, which allows funding for pet projects. This level of support gives Merck the power to also punish the CDC by withholding funding if displeased by the agency.

Jennifer's illness due to Gardasil

Nicole Maldonado of Baum Hedlund next described the onset of Jennifer's illness which worsened with each stage of the three vaccine series and how her symptoms were identical to the symptoms seen among hundreds of injured women during the clinical trials around the world, in places as diverse as Japan, Australia, Colombia, and Denmark (where special clinics have been set up to treat Gardasil's victims), as well as among many girls here in the United States. These symptoms included menstrual irregularities, gastrointestinal dysfunction, musculoskeletal pain, neurological conditions and even death.

One courtroom observer, a concerned mother identifying herself as Rachel Harris said she felt sick to her stomach at the revelations. Jennifer Robi's mom told me that she felt elated that Mr. Kennedy had mastered the facts so completely and that their family's story was finally being told.

...Merck's AAHS adjuvant was safe because of the small quantities of this known neurotoxin in each vaccine. She told the judge that 'the dose makes the poison,' and that even water in large enough doses can be toxic.

The rebuttal

The Defendants' three-hour rebuttal was mainly toothless. Sangiamo doggedly described six studies, that he claimed were relied upon by the plaintiff, that had been retracted. However, only one of those studies was even mentioned on the plaintiff's lengthy exhibit list (Plaintiff's attorneys never referred to it in their briefs) and that study was republished elsewhere after the original journal retracted it under pressure from its pharmaceutical advertisers.

Sangiamo argued that the plaintiff had relied on case studies rather than large scale epidemiological studies of the kind largely funded by industry or the NIH which owns the Gardasil patent and profits on every injection sold. He cited five of those NIH and industry-authored epidemiological studies that found no causal relationship between Gardasil and autoimmune diseases. All are plagued by fatal defects such as only looking for a very limited number of potential injuries for a short period of time following exposure to the vaccine, despite the fact that autoimmune diseases can take months or years to manifest. The authors of these studies had financial ties to Merck.

Finally, Merck's Sally Bryan rose to the podium to explain to Judge Nelson that Merck's AAHS adjuvant was safe because of the small quantities of this known neurotoxin in each She told the judge that "the dose makes the poison," vaccine. and that even water in large enough doses can be toxic. She pointed out that there are only 225 micrograms of aluminum in each vaccine. To illustrate how small this is, she asked Judge Nelson to imagine a dollar bill - which weighs one gram - cut into 1 million tiny pieces. She pointed out that only 225 of these pieces would be in any Gardasil vaccine, far too little to cause any adverse outcome. So in one breath, Merck was telling Judge Nelson that the amount of aluminum in Gardasil was substantial enough to permanently alter a person's immune system to prevent cancer for the next half century and, at the same time, small enough to cause no harm.

The path forward

At the end of a long day, Judge Nelson ordered both sides to work out a discovery schedule and to reappear in court on February 7 to resolve any differences.

In Merck's zealous promotion of the Gardasil vaccine, the company and its allies have shamed parents into vaccinating their children, through a series of misleading ad campaigns which play on parental instincts to protect their children from harm, especially from a disease as frightening as cancer. One commercial depicts young girl and boy actors recounting how they developed cancer from HPV and asking their parents if they knew this could have been prevented. "Did you know – Mom and Dad?" Jennifer Robi has had the courage to tell a reallife story that the public rarely hears – about the risks of the Gardasil vaccine itself.

Watch RFK, Jr. describe his plan to take this issue to the courts

https://youtu.be/w9y-0TaJP0Q

RFK, Jr. (from the video):

"We're going to fight this battle for you. We're going to take it to the streets. We're going to take it to Congress. We're going to take it to the regulatory agencies. We're going to force the press to start covering this issue honestly for the first time, and allowing this debate to take place. And above all, we're going to take it to the court room, and we're going to win these cases. We're going to find justice for you, for your families and for our country at last. If we're going to do this effectively, we need your support."

www.childrenshealthdefense.org/donate