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Gardasil's Long Shadow of Autoimmunity Confirmed — Again — by New Study

Girls and young women experiencing complications from Merck's Gardasil HPV vaccine show symptoms and biological markers of autoimmune conditions, according to a new study published in The Journal of Autoimmunity.

By Children's Health Defense Team

Before experimental COVID-19 shots started taking serious vaccine injuries to new and shocking heights, Merck's aggressively marketed human papillomavirus (HPV) vaccine — the quadrivalent Gardasil jab fast-tracked in 2006 for girls and later also for boys — earned a reputation for being one of the most dangerous vaccines ever approved.

Safety signals were already evident during Gardasil's clinical trials, and by 2013, researchers were noting the "unusually high frequency of adverse reactions related to HPV vaccines reported worldwide."

That year, Gardasil's disproportionately harmful impact — even when compared to other shots that are far from benign — was responsible in the U.S. for three-fifths of all serious vaccine reactions reported in young women under age 30, including 64% of deaths and 81% of cases of permanent disability.

Yet in 2014, the U.S. Food and Drug Administration (FDA) went ahead and approved Gardasil's equally treacherous successor, the nine-valent Gardasil 9, and in 2016 — when GlaxoSmithKline (GSK) withdrew its poorly competing bivalent HPV vaccine Cervarix from the U.S. market — Gardasil 9 became "the only game in town."

Currently, Gardasil 9 is FDA-approved for males and females ages 9 through 45 years.

The firm Baum Hedlund Aristei & Goldman and Robert F. Kennedy, Jr., chairman and chief litigation counsel for Children's Health Defense (CHD), have filed more than two dozen lawsuits on behalf of young people injured by Gardasil, alleging a panoply of Merck misdeeds that include fraud and negligence.

In August 2022, a judicial panel consolidated the lawsuits into a single federal courtroom.

Some of the signature impacts observed following HPV vaccination — which afflict a number of the plaintiffs — include permanently disabling autoimmune and/or neurological conditions such as postural

orthostatic tachycardia syndrome (POTS), fibromyalgia and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

Now, a new study out of Denmark, published in the Journal of Autoimmunity, adds to the body of literature linking HPV vaccination and autoimmunity. The study shows that HPV-vaccinated girls and young women experiencing long-term Gardasil complications exhibit not just symptoms but also specific biological markers consistent with autoimmune conditions.

Context for the Danish study

In a type of descriptive study called a case series, clinicians consistently enumerated symptoms of autoimmunity in HPV vaccine recipients.

The Danish study aimed to connect the dots between these reported symptoms and "biologic and/or pathophysiologic changes" measured in hundreds of girls and young women who received quadrivalent Gardasil and who sought care, mostly between 2015 and 2018, for "long-term complications."

The study represents "the to date largest cohort of cases with suspected side-effects to HPV-vaccination in the form of a high proportion of several incapacitating symptoms."

The symptoms arose either after a first (30% of study participants), second (27%) or third (43%) HPV vaccine dose; three out of five participants experienced symptoms within a month of the dose in question.

A third of the study participants (32%) had been suffering from Gardasil's ill effects for more than five years, and another 18% for at least three years.

For comparison purposes, the researchers included a control group of "HPV-vaccinated females free of symptoms," matched by age and sex, and recruited from local schools.

The study's authors (the University of Copenhagen's Dr. Jesper Mehlsen and colleagues from other Danish and German institutions) emphasize two key points that make the HPV vaccines particularly likely to provoke autoimmune responses.

First, both Gardasil formulations (as well as Cervarix) are adjuvanted with aluminum and are, therefore, "highly immunogenic" — the aluminum compounds intentionally "gin up an immune response that otherwise would be unlikely to occur."

Autoimmunity expert Yehuda Schoenfeld, who coined the term "autoimmune (auto-inflammatory) syndrome induced by adjuvants" or ASIA, has emphasized that "the same mechanisms which drive the immune-stimulatory effect of adjuvants have the capacity to provoke a variety of autoimmune adverse reactions."

In the case of Gardasil, the adjuvant is Merck's proprietary (meaning secret), never safety-tested in humans amorphous aluminum hydroxyphosphate sulfate (AAHS); the amount of AAHS in Gardasil 9 is more than double that of the original Gardasil.

In Europe, evidence indicates that the European Medicines Agency allowed AAHS to be introduced without any prelicensure safety evaluation.

A second point reiterated by Mehlsen and co-authors and made previously by others who have studied HPV vaccines is that some of the proteins in the HPV jabs "overlap" with human proteins.

The term that scientists use to describe this overlap is molecular mimicry.

Schoenfeld argues that molecular mimicry — especially when helped along by the powerful adjuvants — can produce immune cross-reactivity, "essentially causing autoimmune disease."

The Danish authors mention that some epidemiological studies have found associations between quadrivalent Gardasil and a laundry list of autoimmune conditions — Addison's disease, Behcet's syndrome, celiac disease, Guillain-Barre syndrome, Hashimoto's thyroiditis, lupus, pemphigus vulgaris, Raynaud's disease, type 1 diabetes and more — before resorting to statistical shenanigans to erase the significance of their findings.

The Danish findings

Through clinical observations, interviews and questionnaires, the Danish researchers found that the top four symptoms — reported by 86% to 92% of study participants — were fatigue, dizziness, cognitive dysfunction and headache.

More than 8 in 10 (83.3%) participants — but none of the controls — reported fatigue that was "moderate" or "severe."

At least 70% described trouble sleeping, nausea, abdominal pain, heart palpitations and muscle weakness.

The researchers assessed two different laboratory measures of autoimmunity:

- In testing for antinuclear antibodies — "often used as key biomarkers in rheumatic diseases" and found frequently in those with POTS and other autoimmune conditions — significantly more study participants (59%) tested positive versus 25% of the background population.
- When the researchers measured the "functional activity" of antibodies directed against autonomic nervous system receptors called "G-protein coupled receptors" (GPCRs), they found the autoantibodies in 92% of study participants but only 19% of controls.

Regarding the latter finding, the Danish researchers note the superiority of their functional antibody test versus the ELISA test used in other studies, which is not equipped to detect associations between autonomic nervous system dysfunction and autoantibody levels.

Other studies have detected elevated GPCR autoantibodies in 89% of POTS patients, mostly young females.

Russian roulette and regulatory negligence

To explain the pronounced differences between their study population and "healthy" HPV-vaccinated controls, the Danish authors hypothesize that some HPV vaccine recipients may be more "biologically vulnerable" to adverse reactions than others, suggesting that "physical as well as mental chronic stress" could "precondition" them to "autoimmune manifestations when exposed to the HPV-vaccine."

For example, they observe that antibodies toward GPCRs are also found in healthy people, but the antibodies "may become dysregulated and increased in susceptible individuals and cause autoimmune disease."

Schoenfeld and colleagues identified several groups of people who might be susceptible to developing ASIA — individuals with a medical history of allergic reactions or autoimmunity, individuals "prone to develop autoimmunity" and individuals who suffered "post-vaccination autoimmune phenomena" in the past.

However, the only contraindications listed in the Gardasil 9 package insert are "Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL 9 or GARDASIL" — vague advice that would not have helped the three in ten Danish vaccine recipients who developed debilitating symptoms after their very first HPV dose.

Given that over 8% of the study participants took at least six months to develop symptoms, one also wonders whether some of the "healthy" controls could have shifted into the "patient" category at a later date.

The authors do not comment on why they chose to limit their analysis to the HPV-vaccinated rather than select a control group that had received no HPV shots.

They also leave unmentioned the fact that serious adverse reactions to HPV vaccines are also occurring in boys and young men.

A broader point not addressed by the Danish researchers has to do with the disturbing fact — also true for the COVID-19 shots that are leaving a terrible swath of destruction in their wake — that regulatory agencies in the U.S. and abroad are seemingly comfortable ignoring safety signals in the short- and long-term.

After all, it was already apparent in 2009 that Gardasil was associated with "at least twice as many Emergency Room visit reports; 4 times more Death reports; 5 times more 'Did Not Recover' reports; and 7 times more 'Disabled' reports" as a meningitis vaccine given to the same age group.

Those findings from the National Vaccine Information Center were so startling that journalist Sharyl Attkisson even managed to report them on the mainstream CBS Evening News, where she emphasized that for some categories of side effects, adverse event reports were up to 30 times higher for Gardasil than for the comparison vaccine.

Fortunately, the American public is ahead of regulators — a study published last year in the Journal of the American Medical Association (JAMA) reported an 80% increase "in the proportion of parents who refused the HPV vaccine for their adolescents due to safety concerns" over the 2015-2018 period, with the increase evident across 30 U.S. states.

Unfortunately, this heightened awareness does not help the tens of thousands of young Americans already injured by Gardasil — with 43,330 cases reported to the Vaccine Adverse Event Reporting System (VAERS) as of mid-November in those under age 30, and tens of thousands more injuries likely going unreported.

Some of the principal allegations of the lawsuits brought by Baum Hedlund are that Merck "risked the lives of patients with full knowledge of Gardasil's questionable efficacy and its serious and sometimes fatal side effects" and "made conscious decisions to not warn or inform the unsuspecting public and medical providers," creating "a substantial risk of significant harm."

Though the plaintiffs may not be able to recover their health, one can hope that they may, at least, see justice served.

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Children's Health Defense Team