

Court documents reveal clinical trial rigging, regulatory failure and global deception regarding Merck's HPV vaccine

 expose-news.com/2025/05/09/court-documents-reveal

By Rhoda Wilson

May 9, 2025

Merck has rigged Gardasil trials to conceal harms, according to a newly unsealed report by Danish physician Peter C. Gøtzsche submitted to an American court.

Writing about Gøtzsche's expert review, Maryanne Damasi says, "[His] forensic analysis ... lays bare a chilling narrative of clinical trial rigging, regulatory failure and global deception."

In his report, Gøtzsche stated that Merck distorted clinical trial data, making the results scientifically meaningless, and manipulated the recording and reporting of adverse events to minimise the appearance of harm.

He suggested that Merck's actions constitute a profound violation of medical ethics, with millions of adolescents and their families potentially misled into consenting to a vaccine with obscured safety risks.

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Merck Rigged Gardasil Trials to Conceal Harms, Court Documents Reveal

By Maryanne Demasi, 7 May 2025

In what could become one of the most explosive pharmaceutical lawsuits in US history, *Robi v Merck & Co*, centred on the Gardasil HPV vaccine, is set to resume in Los Angeles in September 2025.

At the core of the case are allegations that Merck misrepresented the safety profile of Gardasil – allegations now supported by powerful evidence.

A newly unsealed expert report from Danish physician and world-renowned research methodologist Peter C. Gøtzsche, submitted as part of the pre-trial motion, underpins the claims against Merck.

His 350-page forensic analysis – now part of the official court record – lays bare a chilling narrative of clinical trial rigging, regulatory failure and global deception.

According to Gøtzsche, Merck distorted its clinical trial data so thoroughly that the results were rendered scientifically meaningless.



Peter C Gøtzsche Danish physician and research methodologist

Gøtzsche's assessment is stark and unequivocal.

"The Merck-sponsored trials cannot be used to properly assess the harms of the vaccines," he writes, adding that the company "squandered the opportunity to legitimately study the safety of Gardasil."

After examining 112,000 pages of regulatory documents, Gøtzsche concluded that Merck manipulated its data to such an extent that it would be "difficult if not impossible" for any independent scientist – or even government regulators – to accurately assess the vaccine's harms.

It now raises the fundamental question: Were millions of adolescents misled into consenting to a vaccine whose true safety risks were deliberately obscured?

Trials Designed to Mislead

From the outset, Gøtzsche argues that Merck engineered its clinical trials not to detect harms, but to mask them.

Rather than using an inert placebo – such as saline solution, the gold standard in clinical research – Merck used an aluminium-based adjuvant as the control in all but two small trials.

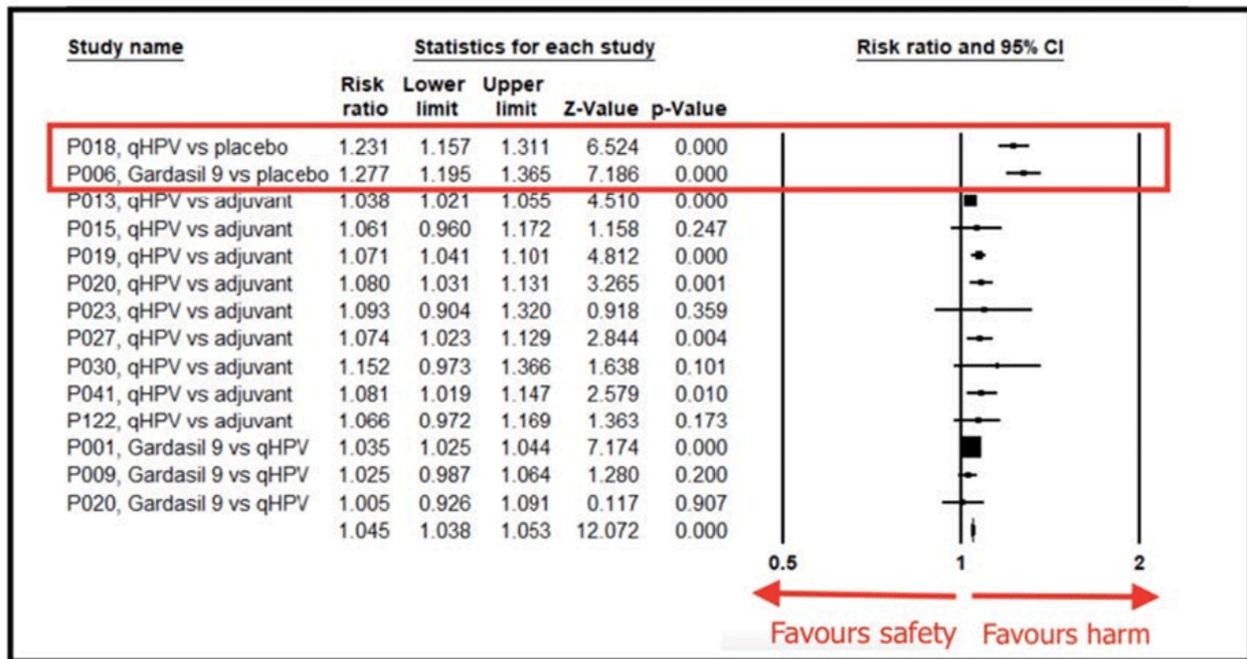
Aluminium adjuvants are known neurotoxins that trigger immune responses and can cause local and systemic side effects on their own.

“It is indefensible that Merck avoided comparing its vaccine with placebo,” Gøtzsche writes.

This tactic had a clear purpose: to minimise the appearance of adverse effects by ensuring that the “control” group would experience side effects similar to the vaccinated group, making the vaccine seem safer by comparison.

Even the World Health Organisation (“WHO”) has warned that using an active comparator like an adjuvant instead of a true placebo “makes it difficult to assess the harms of a vaccine.”

Only under pressure from regulators did Merck conduct two small trials using a saline placebo. And those two trials – marked with a red box below – showed a significantly greater incidence of harm compared to trials that used an aluminium adjuvant or a comparator vaccine as the “placebo.”



Adapted from Expert review of Mercks HPV vaccine studies Peter C Gøtzsche 9 September 2024 pg 5

In short, Gøtzsche’s assessment was that these trials were designed to deceive.

Concealing Harms by Slicing the Data

Beyond trial design, Gøtzsche details how Merck systematically manipulated the recording and reporting of adverse events.

Participants were monitored for harms for just 14 days following each vaccine dose – a relatively short window. Autoimmune reactions and other vaccine-related harms can take weeks or months to emerge, and sometimes years to diagnose, as in the case of

conditions like postural orthostatic tachycardia syndrome (“POTS”).

If an adverse event occurred outside this 14-day window, it was not counted as a vaccine-related effect but reclassified as a “new medical history,” obscuring any connection to the vaccine.

“By calling adverse events ‘new medical history’, Merck not only concealed important adverse events but also their severity,” Gøtzsche explains.

Reactions that occurred outside the short observation window were excluded unless they were classified as serious – such as being life-threatening or resulting in disability, hospitalisation or permanent damage – but even some of these reactions were omitted by Merck from its reports.

As a result, thousands of adverse events that could have revealed patterns of harm were systematically excluded from the final analysis.

This was not a matter of simply taking their eye off the ball – it was a calculated strategy by Merck.

The Disappearing Harms

One of the most striking sections of Gøtzsche’s report concerns Merck’s handling of results from Study P001, one of the largest clinical trials for Gardasil.

In this trial, over 14,000 participants were enrolled to compare the original Gardasil vaccine with its newer version, Gardasil 9, which contains twice the amount of adjuvant and five more disease antigens than Gardasil.

The trial data showed that 3.3% of participants receiving Gardasil 9 experienced a serious adverse event compared to 2.6% of those who received the original Gardasil. Merck dismissed the difference as “low and comparable.”

But Gøtzsche’s analysis revealed that this increase was statistically significant. He calculated that for every 141 people vaccinated with Gardasil 9, one would suffer a serious adverse event – a rate he described as “alarming.”

Navigating the data for this study was no small feat. Gøtzsche describes the trial documents – running over 8,734 pages – as dense, disorganised and deliberately structured to obscure critical findings. “Important results might easily pass unnoticed,” he warns.

In his view, Merck didn’t simply fail to investigate vaccine harms – it actively constructed barriers to hide them from public scrutiny.

Post-Market Red Flags Ignored

After Gardasil's release onto the global market, reports of serious side effects began to surface – particularly cases involving neurological syndromes such as POTS and complex regional pain syndrome (“CRPS”).

Rather than conducting independent reviews, regulatory agencies like the European Medicines Agency (“EMA”) relied on Merck's internal analyses to assess whether these conditions might be linked to the vaccine.

However, Gøtzsche highlights that Merck's database searches were narrowly defined and poorly constructed – effectively ensuring that many relevant cases would not even be captured in the search for key terms.

“The EMA's official report did not mention that the search strategies the manufacturers used to search their databases were inadequate and must have overlooked many cases,” Gøtzsche writes.

Rather than challenging these deficient analyses, regulators accepted them at face value. Gøtzsche calls this what it is – regulatory failure.

“It is remarkable that drug regulators accepted Merck's contradictory, biased and misleading reports based on trials that were already flawed by design,” he says.

The Erosion of Informed Consent

For Gøtzsche, these issues go beyond mere scientific misconduct – they represent a profound violation of medical ethics.

Participants in the trials were lied to; they were told they were receiving a placebo when in fact they were injected with an aluminium adjuvant. Nor were they adequately informed of the true scope of potential harms associated with the vaccine.

Without honest disclosure, Gøtzsche argues, informed consent – the bedrock of ethical clinical research – was denied.

Millions of adolescents and their families made decisions based on safety data that were incomplete, selectively reported or actively concealed.

This isn't just a scientific scandal. It is a betrayal of public trust.

Regulators Weren't Just Passive; They Were Complicit

Gøtzsche's report also shines a harsh light on the regulatory agencies tasked with protecting public health, including the US Food and Drug Administration (“FDA”) and the EMA.

“It is well known that regulatory agencies are understaffed, which means it is unlikely they would be able to undertake a thorough review of Merck’s data as presented,” Gøtzsche notes.

When concerns about Gardasil’s safety prompted a formal review in Denmark in 2015, the EMA largely relied on Merck’s self-submitted data to reassure the public.

But buried deep within those submissions were warnings that regulators either missed – or chose to overlook.

According to Gøtzsche, this was not simply a failure of vigilance, it reflected a systemic breakdown in regulatory oversight.

A Reckoning For Public Health

The *Robi v Merck* lawsuit could mark a historic turning point in pharmaceutical accountability. The case is not just about one vaccine or one company – it is about the broader mechanisms by which drugs are tested, approved and marketed around the world.

If proven, Merck’s conduct would not merely represent corporate misconduct but a collapse in the systems designed to protect public health.

The Merck-sponsored trials “cannot be trusted,” Gøtzsche concludes.

That simple but devastating conclusion may reverberate far beyond this lawsuit.

If this case succeeds, it could force a long-overdue reckoning – one that reinstates transparency, scientific integrity and the right of every patient to make a fully informed choice.

For now, one urgent question remains: How many were harmed because the truth was hidden?

Additional information:

- Internal emails reveal Merck’s negligence in Gardasil safety testing
- Court Documents Reveal “Undisclosed” Adjuvant in Gardasil vaccine
- Gardasil on Trial: Did Merck Mislead the Public on Cervical Cancer Prevention?

About the Author

Maryanne Demasi is an Australian investigative journalist and formerly a television presenter with the Australian Broadcasting Corporation (“ABC”) Catalyst television programme. She holds a PhD in rheumatology from the University of Adelaide and has

worked in various capacities, including as a speechwriter and political advisor for the South Australian Science Minister. She is also an author and writes for online media and top-tier medical journals. In 2023, she was named a Brownstone fellow.

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