

[Fluvax Inadequate safety studies](#)

<http://www.theaustralian.com.au/national-affairs/health/flu-vaccine-production-methods-triggered-fits-csl/story-fn59nokw-1226403509900>

[CSL produces its own vaccines, tests its own vaccines, sells its own vaccines and 'investigates' its own vaccines...]

They say that what happened could not have been predicted, but if the vaccine had been properly tested using acknowledged gold-standard scientific methods such as RCTs, predicting would not have been a problem. It would have been known about before Saba Button became brain damaged; before Ashley Jade Epapara was killed and before the hundreds of other children were injured. Where is the government's duty of care?]

Flu vaccine production methods triggered fits: CSL

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AUSTRALIAN drug giant CSL has admitted its vaccine production methods probably triggered seizures in children, in the first results from its two-year investigation into the Fluvax fits.

But CSL refused to say yesterday if it would pay compensation to the families of children hospitalised after being immunised with Fluvax, which has been banned for pediatric use after sending one in 100 children into febrile fits in 2010.

The preliminary results of CSL's two-year investigation conclude that its manufacturing methods may have failed to fully split the viruses used to make flu vaccines.

As a result, gene fragments and lipids from "inactivated virus" -- as well as "residual whole virus or clusters of both" -- may have created higher levels of immune-stimulating hormones, known as cytokines.

"CSL's method of manufacture preserves more short gene fragments and lipids from the virus than other manufacturers," the company stated.

The process, combined with the three new strains of seasonal and swine flu virus selected to make the 2010 version of Fluvax, "elicited an excessive immune response in some young children, triggering increased fever and fever-related convulsions".

"While influenza vaccines must contain virus components to stimulate sufficient protection against influenza, it appears that components of the inactivated virus retained in Fluvax in 2010 overstimulated the developing immune systems of some young children," CSL said.

The company's vice-president of medical and research, Darryl Maher, said CSL would not change its manufacturing methods until the scientific investigation was complete. "I'm sure we will be," he said. "There is just a bit more work to do."

Dr Maher said CSL had been using the same vaccine production processes for 25 years and "it stood us in good stead up until 2010".

Asked if CSL would compensate children who suffered severe side effects from Fluvax, Dr Maher said he could not comment on individual cases. "I know some of them were very unfortunate and quite tragic," he said.

"I think we accept that Fluvax has been a contributory cause of these reactions; I don't think there is any doubt about that.

"But what happened in 2010 couldn't have been predicted; it was quite unexpected. There was nothing we could have done to avoid it."

The Australian revealed last October that in 2005, a three-year-old child suffered a fit and became "non-responsive" for up to seven minutes after being injected with CSL's flu vaccine during a clinical trial supervised by the federal government's top immunisation adviser, Terry Nolan.

A second child involved in the trial of 298 children had to be admitted to hospital for rehydration after high fever and vomiting.

The federal Health Department yesterday said it was "applying close oversight" to CSL's manufacturing operations. "These findings justify the government's policy to keep the current ban on the use of this vaccine in young children in place," Chief Medical Officer Chris Baggoley said.

The Australian revealed a year ago that the US regulator, the Food and Drug Administration, had threatened to revoke CSL's licence, citing manufacturing deficiencies and an inadequate investigation into the Fluvax fits.

The FDA chided CSL over "high-risk deviations" in its vaccine production, including "failure of the viral inactivation cycle".

FDA audits accused CSL of "deficient" tests to check whether viruses were properly split to prevent side-effects. Dr Maher said "the majority if not all of the findings of last year's inspection have been closed out by the FDA".

The federal government recently renewed CSL's contract to supply flu vaccines under the National Immunisation Program, which gives free flu shots to the elderly, indigenous people, pregnant women and Australians with underlying health problems.

Fluvax remains banned for the under-fives, yet dozens of children were mistakenly given the vaccine again this year -- including a toddler admitted to intensive care after a febrile convulsion.