

Vaccine family to sue CSL over botched flu shots

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AFTERMATH: Mick and Kirsten Button, with Saba. Picture by Karin Calvert.

A PERTH family whose 11-month-old daughter was severely disabled after being vaccinated with CSL's influenza vaccine is about to launch legal action against the Australian pharmaceutical giant.

PerthNow understands that Kirsten and Mick Button will shortly launch a lawsuit against CSL. The suit will allege the vaccine supplied by Australian pharmaceutical giant CSL, and distributed for free to parents by the WA government, was defective.

In April last year health authorities told doctors to stop giving young children CSL's seasonal flu vaccine after 23 WA kids were admitted to hospital with convulsions and

high fevers following their injections. CSL stopped distributing the Fluvax vaccine and later voluntarily recalled the product.

Mick and Kirsten Button's daughter, Saba, suffered brain injury and liver, kidney and bone marrow failure after she went into convulsive seizures following her flu shot. Saba may never walk or talk, according to Mr and Mrs Button.

Lawyers for the family confirmed today that CSL will shortly be named as the first defendant in a lawsuit that will also target the state government.

The Button's will be represented by medical litigation specialist Julian Johnson, who told PerthNow today the legal action will be taken under the Trade Practices Act.

The news comes after PerthNow revealed yesterday CSL's manufacturing standards have been called into question for the second year in a row by investigators for the powerful US regulatory agency, the Food and Drug Administration.

FDA inspectors visited the Australian company's Melbourne manufacturing plant in March, and told the company this month they found "significant objectionable conditions relating to your facility's compliance with [current good manufacturing practices]" in relation to a number of its influenza vaccines.

The FDA also slammed CSL's internal investigation into last year's vaccination scandal as "inadequate".

"You failed to thoroughly investigate any unexplained discrepancy, or the failure of a batch or any of its components to meet any of its specifications, and failed to extend the investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy," said a letter sent to the company this month.

While the FDA did not reach any conclusions about whether manufacturing problems were responsible for the adverse reactions in WA kids, the regulator said CSL did not work hard enough to identify the cause of the serious reactions the vaccinations caused in about 1 per cent of children who received the shots..

Mr Johnson said the FDA's letter, while not directly related to the Button family's lawsuit, had caused the family great distress.

He said the family is particularly concerned that "the US FDA considers CSL's investigation of the April 10 events was inadequate in a whole range of respects and inexplicably, apparently not in any way documented".

“The fact is it appears a far more robust and firm position is being taken in relation to CSL and the flu-vax is being taken by the US FDA than our own TGA,” said Mr Johnson.