Big Pharma: Profit first, Safety second

by Cathy O'Leary via stele - The West Australian *Friday, Jun 24 2011, 10:39am*
international / health related / other press

> The parents of WA girl Saba Button, who is severely disabled from a flu vaccine reaction, have made a scathing attack on Australia's medicines regulator, saying US authorities have been tougher on the Australian company that made the vaccine.

Their comments came after the US Food and Drug Administration sent a highly critical letter to CSL, which makes the seasonal flu vaccine Fluvax, raising concerns about its manufacturing practices in Melbourne.

The FDA claimed the pharmaceutical company did not do enough to find out why dozens of Australian children, including two-year-old Saba, suffered fever and convulsions last year after getting the vaccine.

Fluvax was used in last year's State Government free childhood vaccination program but is no longer given to young children.

Saba, who has organ and brain damage, had a seizure after her vaccination in April last year, just days before the WA and Federal governments stopped the jabs because of bad reactions in hundreds of children.

Through their lawyer Julian Johnson, Mick and Kirsten Button confirmed yesterday they would name CSL as the first defendant in their statement of claim for an ex gratia payment to go before the courts.

Their claim, which was still being finalised, would be made under the Trade Practices Act on the grounds the vaccine was defective.

"Although (the FDA findings) have nothing directly to do with Saba's claim, the family are extremely upset and concerned at reports contained in the FDA correspondence, in particular that CSL's investigation into the April 2010 events was inadequate and inexplicably was not in any way documented," the couple said.

"It also appears that a far more robust and firm position seems to have been taken in relation to these issues by the US FDA rather than our own TGA (Therapeutic Goods Administration)."

CSL Biotherapies spokesman Jeff Davies said the company was committed to high standards and was taking the FDA letter "very seriously".

A TGA spokeswoman defended the agency's monitoring.

http://tinyurl.com/6aw6722
