MEDIA MONITORS


A shot in the arm for drug maker
CSL

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A shot in the arm for drug maker

A $140 million contract for a swine flu vaccine may have been a mistake, experts tell **Angus Grigg** and **Khia Mercer**.

The year's shortest day has passed, the weather is warming up, but the predicted "second wave" of swine flu infection is yet to arrive. For Australians of all ages this is good news, but the lack of a pandemic is an awkward subject for the federal government.

It and drug maker CSL put the country on a "war footing" last year in anticipation of a rampant swine flu virus that would continue into this year's flu season.

The dire warnings have not materialised and while 191 deaths have been linked to the virus, according to figures from health departments, this is no greater than the average flu season.

The low death rate raises a question: did federal Health Minister Nicola Roxon approve a lucrative deal with the country's biggest drug company that Australia didn't need?

When asked about CSL's swine flu contract, Ms Roxon has always invoked confidentiality. It was an easy out as pressure mounted over a deal that looked to heavily favour the drug maker.

For nearly a year she ignored calls for greater transparency. But *The Australian Financial Review* has found details of the deal in health department documents and it appears to be a highly profitable one for the company.

The tender documents show CSL was paid $140 million over five months to trial and produce 21 million doses of the swine flu vaccine known as Panvax.

That figure is substantially more than had been rumoured and was the main reason CSL far exceeded its first-half profit expectations earlier this year.

The vaccine has also not been embraced by the public. By June 24, just 9.1 million of the 21 million doses available had been delivered to doctors. It is estimated that about 3.5 million of these doses were wasted after being delivered in packs of 10 that had a shelf life of 24 hours after being opened.

The Panvax experience has raised questions about CSL's ability to continue to win lucrative government contracts. The swine flu problems follow its seasonal flu vaccination being suspended for infants following the death of a child in Queensland.

The Food and Drug Authority in the United States is also asking questions about its manufacturing process after a recent visit to its facilities.

UBS healthcare analyst Andrew Goodsall said the query by US authorities was "not a good look" for CSL, particularly after its problems with the flu vaccine in Australia.

It amounts to unwanted attention at a time when CSL's close relationship with the federal government is under scrutiny. These close links have much to do with the CSL's history.

The company was established in 1916 to service the health needs of a nation isolated by war and remained in government ownership until its listing in 1994.

Since then the government has continued to turn to the company during health crises.

The swine flu vaccine had the potential to save many lives but came at a high price. Not only did CSL get paid up-front, but there was no out clause in the contract, which meant the government was locked into buying all 21 million doses regardless of the severity of the virus.

Peter Collignon, an infectious diseases physician and clinical microbiologist from the Australian National University, said it is unlikely the government would ever sign such a contract again.

"It appears to be a contract in the best interests of CSL, but not taxpayers," he said.

The contract was agreed to despite strong indications when the vaccination became available in September last year that swine flu, which is formally known as H1N1, was not the danger many first believed.

Professor Collignon said pharmaceutical companies exaggerated the threat to boost sales. "The fear generated by these things can lead governments to make decisions that are not in the best interests of their country," he said.

He is not alone in this opinion.

The Council of Europe has launched an investigation into last year's declaration of the swine flu pandemic by the World Health Organisation.

Opposition health spokesman Peter Dutton has also questioned why the government would ever enter into such a contract with

CSL. "I think there is a strong case for an independent inquiry. This could have been better handled," he said. "If the government has nothing to hide then they would welcome an inquiry but we have been stonewalled every time we've asked questions."

A spokesman for the health minister said at the time the vaccine was purchased the swine flu pandemic posed a very real threat to the Australian community.

"The minister approved the decision to purchase the 21 million doses after receiving advice from a number of experts, including the Department of Health's chief medical officer Professor Jim Bishop," the spokesman said.

Like many issues relating to private sector involvement in public health, this one is not black and white. The grey area centres on CSL's position as the only vaccine maker in Australia and its public service obligations to assist health authorities.

A CSL spokesman said it was easy to criticise the response to swine flu "with the benefit of hindsight".

"At the time global influenza experts were very concerned that millions of people could die from the virus," he said.

"There is an expectation that we will step up and perform for Australia when there is a real risk that other countries will close their borders. We are an integral part of Australia's biosecurity."

The doubts raised by the opposition and Professor Collignon centre on value for money and CSL's powerful negotiating position of dominance of the vaccine market.

Health department tender documents show that CSL was paid $9 million to clinically trial Panvax and $131.7 million for 21 million doses.

Analysts estimate CSL made a profit margin of about 50 per cent from the contract. Such a lucrative deal helped the company beat analyst forecasts by 16 per cent at its half-year results in February.

The government has been criticised for allowing CSL to package Panvax in multi-dose vials, which have a shelf life of 24 hours after being opened.

A survey published in *The Medical Journal of Australia* found that 42 per cent of all doses ended up in the bin.

The health department has denied this figure. It says 10 to 14 per cent of all doses were not used, while CSL said multi-dose vials enabled the vaccine to be given to the community far more quickly.

LOBBYING LEGEND

CSL's lobbying to have cervical cancer vaccine Gardasil publicly funded is legendary in Canberra. It began after the Pharmaceutical Benefits Advisory Committee rejected CSL's application in November 2006, saying there were too many uncertainties about the vaccine's effectiveness, including the company's claim that it would provide lifetime protection.

The committee decides which drugs get government funding.

CSL then began one of the most effective and lucrative lobbying campaigns in Australian history.

The company raised concerns about the decision-making process.

Then the drug's inventor, Australian of the Year Ian Frazer, gave a series of media interviews to push the vaccine.

Lobbyists also began pressuring MPs and distributing flyers that showed how the government had exploited the vaccine to promote Australia's biotechnology industry overseas.

When then opposition leader Kim Beazley pledged his support to fund Gardasil publicly, the fight was effectively over.

Then prime minister John Howard folded and said Gardasil would be publicly funded – it was just a matter of price.

The Pharmaceutical Benefits Advisory Committee had initially said CSL's asking price of $625 million over four years was too high.

Figures from CSL's annual reports show the drug maker has received $504 million in payments from the federal government over the past three and a half financial years. That would suggest CSL knocked about $100 million off the price from its initial offer.

The initial four-year government program, begun in 2007, provided catch-up provisions for females aged between 13 and 26 years.

The program has seen nearly 70 per cent of Australian women in the target age group receive the vaccination. It is now winding down but CSL has begun quietly lobbying to have the drug given to adolescent boys.

"Boys are entitled to be protected like girls," Professor Frazer said last year.

He said the human papilloma virus that causes cervical cancer in woman also caused a range of cancers in men.

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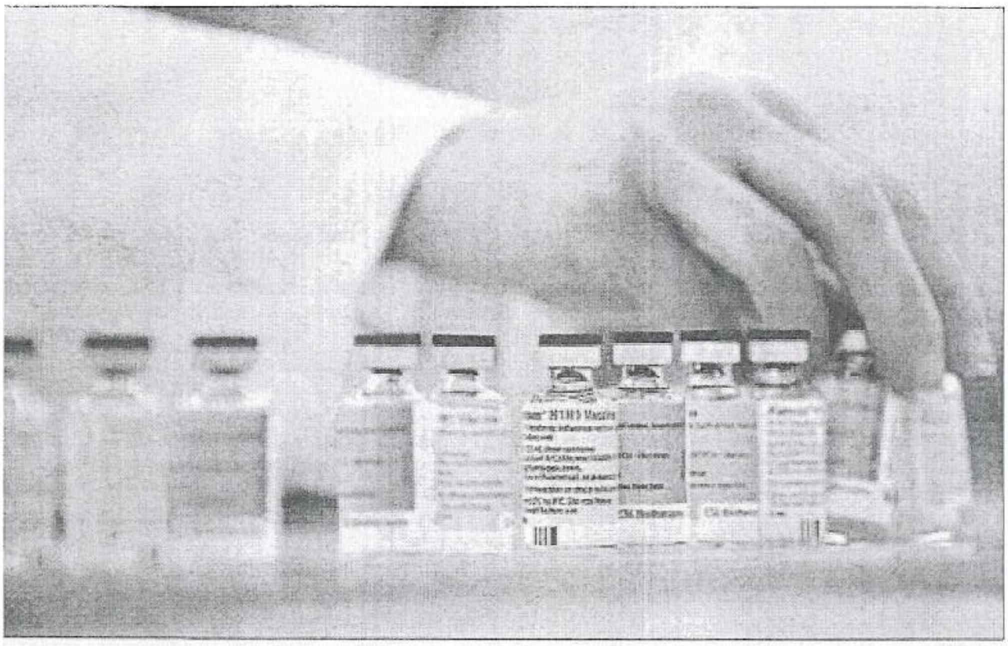

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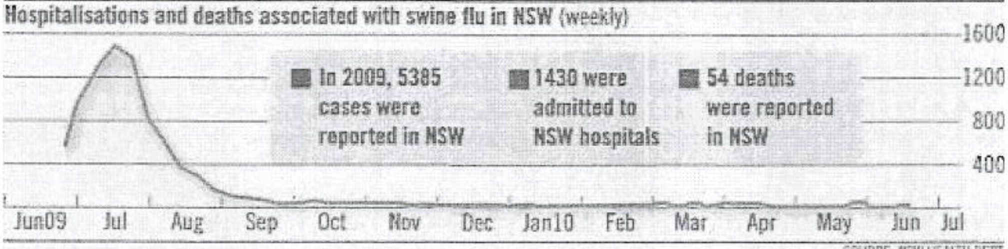
Hospitalisations and deaths associated with swine flu in NSW (weekly)



SOURCE: NSW HEALTH DEPT

Australia's chief medical officer Jim Bishop with Health Minister Nicola Roxan; and (below) swine flu vaccinations ready for shipping.
Photos: CRAIG ABRAHAM