

Regulating Blood

A recent report by the Institution of Engineers — reviewed later in this newsletter — illustrates the sometimes tragic consequences of the failure of regulation. Here, Clive Hamilton exposes a serious regulatory failure that has so far gone unnoticed, despite the fact that it could pose a severe threat to public health.

A Federal government department spent \$400 million of tax payers money without checking that it received what it paid for. The same department paid out on a contract in which certain costs had been counted twice and then claimed that it does not have expert staff to negotiate contracts.

This department regulates a private company whose work could expose the public to severe health risks. The company was caught out last year in breach of strict rules to protect the public, but, not only did it escape punishment, its actions were retrospectively approved by the Federal Government.

The Commonwealth Auditor-General has revealed all of these in the Federal Health Department's regulation of blood processing by the private company CSL.

CSL (formerly the Commonwealth Serum Laboratories) is Australia's sole producer of blood products. The Commonwealth pays CSL to process or fractionate blood collected by the Red Cross and to send blood products to hospitals for use in transfusions and other medical procedures.

The Labor Government privatised CSL in 1994. Shares fetched \$2.30, but are now trading at around \$23. A financial analysis by the Australia Institute concluded that the sale of CSL would result in a net loss to taxpayers of over \$600 million.

The executives of CSL received generous share options with the sale, and the Managing Director Brian McNamee has been described by the *Australian Financial Review* as the only manager of a privatised public company to make serious money out of a float.

There have been several scandals overseas involving contamination of blood products by HIV, hepatitis and other infectious diseases. In Australia, CSL has been blamed for several cases of the deadly brain disease known as CJD from use of its human-growth hormone. In the past, CSL has also been accused of supplying blood infected with hepatitis-C to haemophiliacs. In 1995, the major parties blocked a move by the Australian Democrats to refer the issue of CSL and blood contamination to a Senate Committee. Senator John Coulter told the Senate in August 1995 that one reason given by an Opposition senator was that such an inquiry might affect the share price of CSL.

In 1996 CSL admitted that up to 1984 it had mixed Australian blood with blood from several foreign countries for distribution in Australia, and had only ceased the practice after the Red Cross threatened to stop using CSL products. The regulation of blood products by the Commonwealth is therefore a public health issue of the utmost importance.

The Auditor-General's report

In December last year the Australian National Audit Office released a report entitled *Commonwealth Management and Regulation of Plasma Fractionation* (see www.anao.gov.au).

Despite its importance to public health, the report has received almost no attention.

Among his observations, the Auditor-General found that between 1994 and 1999 the Commonwealth paid out over \$400 million to CSL to process blood without any procedure to check that the blood products had actually been received by the designated recipients.

In addition, when negotiating price adjustments under the Plasma Fractionation Agreement with CSL (involving millions of dollars), the Health Department did not obtain any legal, accounting or industry expert advice to help it deal with the extremely complex issues involved.

In renegotiating the price paid for blood processing by the Commonwealth, the Department accepted CSL's accounting advice on how to treat depreciation and ended up compensating CSL *twice*. It appears that the Department is not making any attempt to reclaim the money. Reading the Auditor-General's report gives the impression that the Health Department was snowed by CSL's clever accounting.

The Department told the Auditor-General that in the crucial period when the contract was being renegotiated it did not have any 'corporate memory' as no-one involved in the development of the original contract still worked in the area.

Indemnities

When selling CSL the Commonwealth provided indemnities to the new private owners against any claim arising from contaminated blood. These indemnities cover blood products produced before privatisation and, in the case of HIV/AIDS and hepatitis, any liability arising from contaminated blood now that CSL is privately owned. In other words, if CSL makes a mistake and people fall ill due to contaminated blood, the tax-payer will pay for CSL's mistake. The liability could be enormous if a batch of blood were contaminated with HIV.

As a result of this arrangement the Commonwealth pays the cost of CSL's insurance against the effects of any blood contamination. The Auditor-General reported that the Health Department did not hold any copies of insurance policies obtained by CSL even though the Commonwealth pays the premiums in the case of HIV/AIDS.

The principal asset owned by CSL when it was privatised was a brand new state-of-the-art blood fractionation facility at Broadmeadows in Melbourne. It has more processing capacity than needed for the Australian market and CSL has a lucrative business processing blood from other countries.

It is not clear whether any foreign-sourced blood is from people who are paid to give blood. Unlike Australia, where all blood is donated through the Red Cross, in some countries blood is obtained from providers who sell their blood. In some cases, selling their blood is an important source of income for street people.

Clearly, mixing foreign-sourced blood with Australian blood poses a severe health risk, and strict protocols governing segregation and cleaning procedures are in force to ensure that mixing does not occur. These rules are developed and enforced by Health Department. A central component of the procedures is the requirement that CSL provide the Department with plasma master files for foreign-sourced blood. These master files allow all blood to be tracked to source.

The Auditor-General reported that in October 1998 a Health Department officer on a visit to the

USA accidentally discovered that CSL had breached the agreement by importing and processing plasma from at least one US source without the Department's knowledge and without submitting the plasma master file.

As a result of this discovery, Health officials raided CSL's Broadmeadow facility on 24 November 1998. They confirmed that breaches of the agreement had occurred. Unaccountably, no action was taken against CSL. However, legislation was amended so that from 7 December 1998 CSL would be legally required to submit plasma master files and could not process foreign-sourced blood without the express approval of the Secretary of the Health Department.

Despite this, between December 1998 and June 1999, CSL continued to process foreign-sourced blood without the approval of the Secretary. When this breach became known to the Health Department, instead of taking action against CSL, in June 1999 the Secretary wrote to CSL giving retrospective approval for CSL's activities. It is hard to avoid the conclusion that the regulator has been captured by CSL, and the objective of both is to avoid any obstacles getting in the way of CSL's commercial interests.