CHAPTER TEN: REGULATING EXPORTS

Blood is a prohibited export. Since 10 September 1991, under the Customs (Prohibited Exports) Regulations, human blood products are included in a schedule[200] of substances regarded as a scarce national resource, along with organs, which need the approval of the Secretary of the Health Department before they may be exported. Sponsors must have a permit to export. CSL has a standing permit, renewed annually. They must declare the volume of each consignment and its destination.

A Health official interviewed after the sale of CSL said the only reason for requiring permits for export is to stop exporters sending out Australian product. CSL's privatisation and plans to move into Asia, the Pacific and North America, could provide other reasons for permits and for more information to be collected on them.

Health Department Official C told the author that exports of human blood in general are regulated but 'not closely watched I wouldn't think. But we are interested in it. Compliance Branch [of the TGA] talks to Customs. Red Cross sends blood products out of the country for relief and gets the nod. If someone wanted to surreptitiously export tissue [includes blood] I can't imagine they'd have much trouble, if you wanted to do something on the sly. [It would] not be difficult [but] people would hear it was happening. You read of people in the press ... one of our officers was asked by a cosmetic manufacturer if there would be any difficulty collecting foreskins for a face cream.'[201]

Directors of the Red Cross Blood Transfusion Services agreed that it would be easy to send or take material out. Large amounts, unless wrongly labelled, would be more difficult, especially if they required refrigeration. Human plasma has passed for orange juice on the international market, according to this author's research. Human plasma described as animal plasma was flown out of South Africa a number of years ago It was destined for Germany but was intercepted in Brussels.

10.1 Role of Fractions Release Committee

Any Red Cross material sent out of Australia must be cleared first by the Fractions Release Committee. This Committee is made up of a senior Red Cross medical adviser, a Director of a Red Cross Blood Transfusion Service (BTS), a CSL representative and a representative of the Health Department from the Therapeutic Goods Administration, who in effect gives customs clearance.

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[200] *Regulation 8, 6th Schedule*

[201] *Health Department official C 12.10.92, telephone interview.*

10.2 Case study - CSL sends Australian blood products overseas without clearance

In the course of this study, CSL was reported to have sent blood products made from Red Cross starting material overseas without Red Cross permission. This was alleged to have happened across a number of years, for a number of products and involving three countries. Only one of these claims is detailed here. The author lacked resources to investigate all of the allegations.

In the instance described here the product was prothrombinex, a concentrated clotting factor used to stop haemorrhage, also known as factor IX. It is derived from plasma collected from Australian donors by the BTS's. Plasmas tested at source for hepatitis and other diseases on individual donations, pooled at CSL in Melbourne and processed. Effective testing cannot be done on the pool because the methods aren't sensitive enough.

10.3 Exported product was contaminated

After Red Cross starting material was processed into prothrombinex, an error in donor level testing for hepatitis C was revealed. The contaminated prothrombinex was recalled in Australia . CSL had sent a certain amount of this product to Hong Kong. A BTS Director said:

> 'We found out a lovely one inadvertently recently. They were sending some of our prothrombinex to Hong Kong without asking us ... This was stuff that had been contaminated by hepatitis C but they didn't think it mattered, because in Hong Kong they didn't screen for hepatitis anyway. That's actually in writing between CSL's administration and the Commonwealth Department [of Health.]
> KB: Who didn't think it mattered?
> Oh, people who didn't know what it was about. I suspect at both ends. I don't think the guy at CSL had any idea what he was doing when he wrote the letter to somebody in that Department. I don't think the Health Department person had any idea of what he was letting himself in for when he responded ...
> KB: How did you find out about it?
> The National Chairman [of the Red Cross National Blood Transfusion Committee] was dealt in on it.
> KB: After the fact?
> Mm ....They said we won't bother to recall [the suspect batch] because Hong Kong doesn't bother to screen for hep C. Turn that round the other way, what they are saying is we fractionate product from Hong Kong which hasn't been screened for hepatitis C, even though we insist the Australian product be so screened ... the message was that it wasn't a dangerous product because hep C gets killed in the processing, so they assume.
> KB: Does it?
> Yes.

KB: If the processing is right.
If.
KB: Have they stopped pooling [foreign with Australian plasma]?
I don't know!

The last reply by this official is not published here to suggest that CSL is still pooling plasma or may be negligent in processing plasma to remove hepatitis C, but to illustrate that questionable practices which have come to Red Cross' attention have caused them to lose trust. Another BTS Director said of the failure to get Fractions Release Committee approval:

> Clearly that didn't happen, and that's where you're talking about an organisation that has to build up trust. That sort of information *has* to be given.

The matter was taken up in face to face interview with two CSL officials in December 1992.

> KB: We understand that there have been some difficulties in pyrogens with prothrombinex, or hepatitis C in prothrombinex recently.
> A: Hepatitis C in prothrombinex?
> KB: Yes, is that correct?
> A: Ah, are you referring to a specific incident?
> KB: My understanding from the Haemophilia Foundation is of difficulties in production of prothrombinex ... some has had hepatitis C in it.
> A: I think what you *may* be referring to here is an incident earlier this year where one blood bank in NSW made a clerical error ... sent us some donations that were not screened ... three or five donations ... we didn't find out about it until those donations had been put together into a pool, its all fractionated ... from that plasma we also made a batch of prothrombinex ... it's a heated product at sixty degrees for seventy two hours but sixty degrees is probably not quite sufficient treatment to inactivate hepatitis C virus ...
> B:They notified us after we had released the product ... we recalled it. I'm not shocked when this happens because there can be an error when testing ... therefore we've tried to develop a technology whereby even [where a mistake is made in testing] we have eradicated it - the eighty degree heating - it is overkill - we presume the virus is there and we act accordingly.

(This refers to a product in development by CSL at the time of the interview, called Prothrombinex HT, meaning high temperature heated.)

> B: With the prothrombinex you speak of in fact that has happened and that is recalled, that material then is destroyed and with

prothrombinex (factor IX) half the time we dispose of it we don't use it.
KB: Our understanding is that some of the prothrombinex was sent to Hong Kong, is that correct?
A: Of this batch we were just talking about?
KB: Yes.
A: Yes. We informed the Hong Kong people about this, I don't precisely know what action they took, I presume they took similar action to what we did here but I'm not certain about that.
KB: Was this Australian source plasma?
A: Yes it was, as B was saying before we have more prothrombinex that we need ... I think this was an occasion where Hong Kong had a fairly urgent requirement and we didn't have, because their input is fairly small, we didn't have a sufficient quantity of HK Plasma on hand to make the product ... so we supplied it from Australian source material.
KB: Was that via the Fractions Release Committee?
A: Um, I think on this occasion probably not.
KB So would that have been done with the Federal Health Department's authority to send it out?
A: It must have had the Commonwealth Department's approval, yes.
B: What's interesting about that particular issue is that Hong Kong at that particular time didn't test for hepatitis C, so I doubt that Hong Kong did destroy it, because it's almost endemic in Hong Kong, so since they don't test for hepatitis C in all likelihood the material that they always use in Hong Kong has hepatitis C in it, if you follow the correlation. Its an interesting thing; there are many countries that don't test to the degree they could or *should* , they use the justification of cost, but in fact in the Hong Kong case I'm inclined to think they didn't destroy it because their approach would be, well, we don't test for hepatitis C anyway, hepatitis C is endemic to our region and therefore they have almost a hundred percent assurance that they have from a thousand donors, that one would have hepatitis C, and until they start screening for hepatitis C they in fact will always have, and I think they'll be hesitant about testing for hepatitis C simply because that would perhaps deny them the level of material they currently have and I don't know that for a fact but there are some countries where hepatitis C is almost endemic, as hepatitis B is in some regions.
KB: How does that action square with the compliance provisions in the [Therapeutic Goods Act] that say it is an offence to export therapeutic goods from Australia if the goods don't conform to the standard application? (sic applicable)
A: Ah, well, until such time as we were notified that there were some unscreened donations in the pool, we had every reason to believe that it did comply.

KB: When it was sent to Hong Kong was it was on the understanding that it was OK? Not after it was found that there was a possibility of-
A: That's right! Sure!

The evidence of Official B, the Head of the Bioplasma Division, that Hong Kong wasn't testing for hepatitis *because hepatitis is ' almost endemic '*is odd. Endemic means consistently present in a population, but this does not mean everyone has it. The incidence could be as low as one in ten thousand, the example Official B gave above. In Australia hepatitis C is now considered endemic on the basis of thirty thousand notifications since 1990.[202] In an endemic situation, those who do not have the disease are therefore very much at risk of infection, which *increases* the need to test blood products, rather than decreasing it.

10.4 Health department knowledge of unapproved export

From CSL's evidence emerges the claim that its export 'must have had' Health Department approval, although not through the Fractions Release Committee, the normal channel. This does not fit with other evidence obtained.

The claim to have taken steps to have the material recalled is also contradicted within the evidence given above. How much of this incident was known to the Health Department is important in assessing its significance as a regulatory failure. If the agency did know, did they take any action in relation to presumptively contaminated Hong Kong product routinely entering Australia, or the possible contamination of people in Hong Kong, or the misconduct of CSL officials? Did they disclose these matters to the Assets Sale Task Force during the due diligence process for the sale of the company? If they did not know, how did their own regulatory system fail them?

After CSL said they had sent the material overseas, the Australian Red Cross Society Medical Adviser, a member of the Fractions Release Committee, when questioned about the matter, volunteered emphatically 'The Federal Government knew nothing about it ... for anything connected with any of our blood or blood products I do not believe in any way that [the Therapeutics Goods Administration] would not consult Red Cross.' Yet the Red Cross interviewee quoted above, claimed that CSL and the Health Department communicated in writing with each other on the subject.

Official C was asked if there were any instances of Red Cross material being exported without Red Cross approval. He replied 'not to my knowledge'. He then volunteered that 'it was the same officer on Fractions Release who is responsible for making the decision to release' and that there was 'very little room for misunderstanding'. However, another Red Cross source claimed

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[202] *Canberra Times 23.8.94 reporting on a meeting of chief medical officers from federal, state and territory governments to plan their attack on hepatitis C.*

that the incident was known to a senior TGA adviser, who had even considered what sort of an offence the action might constitute.

Another Health Department official with regulatory responsibilities in relation to CSL told the author in December 1993 he didn't know anything about any such incident. The interview was to be resumed but when he was recontacted he said he was banned from talking with the author about anything to do with CSL. The author's efforts to investigate this matter took place during the period when CSL was being groomed for sale on the stock exchange. Soon afterwards a BTS Director, one of four who had previously mentioned the prothrombinex incident, was asked for further detail and replied:

> It has been covered up, so well I can't see the outline of it.

10.5 Recall from overseas

To what degree a voluntary recall of the contaminated product was undertaken is unclear. Initially Official B said of the prothrombinex 'we recalled it'. When the author focussed his attention on material having gone to Hong Kong Official A said 'We informed Hong Kong .... I don't know precisely what action they took. I presume they took similar action to what we did here'. Official B, Head of the Bioplasma Division, said 'I doubt that Hong Kong did destroy it, because [hepatitis C is] almost endemic in Hong Kong'. The Red Cross official believed from official sources that product sent to Hong Kong had not been recalled at all.

There are no recall provisions in the Therapeutic Goods Legislation. The sponsor of goods which have been cancelled from the register may be required to recover them[203] and a penalty of thirty thousand pounds.[204] applies, however in this case there was no question of removing the product from the register.

The Trade Practices Act,[205] provides that a supplier who administers a safety-related recall under the legislation must inform the Minister for Consumer Affairs within two days. If the material had gone outside Australia, a report must be given 'as soon as practicable', and the Minister must also be informed within ten days. The penalty for failure to report safety-related recalls to the Minister is ten thousand dollars.

The Federal Bureau of Consumer Affairs was advised direct from CSL on 9th June 1992 of the voluntary recall *within Australia* of three batches of prothrombinex. They say the recall was well publicised by CSL. However, there was no record of any notification of contaminated prothrombinex being sent overseas, nor of its recall.

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203 *S 30 (6) (a) (ii)*

204 *$6,000 penalty in the legislation times five for a corporation per the Crimes Act provisions*

205 *TPA S 65f*

The possible offence[206] referred to in the author's question to CSL Official A, was seen to be not applicable to this incident, on further study of the legislation. While the hopelessly constructed Act and its maze of regulations, orders, schedules and determinations are intended to provide for the safety and purity of therapeutic goods, it is only in an Annex to the Code on Blood and Blood Products that hepatitis C is specifically set down as a required test. The Codes are linked to the Act only by Ministerial determination, thus they are not part of the actual legislation. This makes it possible to send contaminated blood products out of Australia.

Product liability amendments were proposed to the Trade Practices Act in 1991 and cover blood and blood products, despite last minute efforts of the Health Department to have them exempted. These amendments came into force in July 1992 and would therefore not apply here if the prothrombinex was sent overseas before the June recall.

If Hong Kong or Australian patients contracted hepatitis C from the prothrombinex, there could be difficult to prove because of the high incidence of hepatitis C in recipients of concentrated clotting factors. A report of a study at Fairfield Hospital in Melbourne found hepatitis C antibodies in three quarters of the one hundred and seventy six haemophiliacs tested, compared to a 'relatively low' prevalence in the rest of the community, intravenous drug users and homosexuals apart. A haematologist interviewed for this study said 'most haemophiliacs have hepatitis most of the time. Some are getting liver transplants it is so bad. This cures the haemophilia!'

The question arises, however, as to how the product passed through Customs. CSL holds certain general standing export licences. If the product was included under such a licence it could amount to a breach of the terms of the licence. A CAA inspector for air cargo told the author that the agency is reluctant to seize blood and blood products for human use, for fear of interfering with treatment for possibly life-threatening conditions. In any case, seizure would pit them against medical opinion and the CAA official said they couldn't win. CSL official A had claimed in evidence that the prothrombinex was needed in Hong Kong 'fairly' urgently.

If CSL had received a fee for the product, this could amount to unjust enrichment, or an offence under the Victorian legislation banning sale of blood, but they probably only gave the product to Hong Kong. The company is keen to foster its standing in Asia in order to obtain large scale fractionation contracts for its new plant, which was under construction at the time of this incident.

CSL at this time was a statutory authority of the Federal Government, incorporated as a company. Commonwealth Finance Directions say the

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[206] *TGAct 14(3) under Compliance with Standards:*

Federal Government is not liable for culpable negligence by an employee and allow the agency head discretion concerning whether the Commonwealth should pay for the defence of an officer and any damages in a civil action arising in the course of employment.[207] In 1985 the then Attorney-General had already ruled that the Federal Government was vicariously liable for any acts or omissions of the Commission .[208]

The Federal Government indemnity extending to CSL post-privatisation does not cover 'any liability that attaches to CSL because of a deliberate or reckless failure by CSL to satisfy required standards of care in the manufacture of products'[209] but the Sale Prospectus states that 'The Commonwealth has indemnified CSL against losses caused by legal claims arising from the use of certain products manufactured by CSL up to the Settlement Date' and that 'indemnities for claims arising from the use of products sourced from Australian plasma are also included in the Plasma Fractionation Contract.'[210]

10.6 Loss of Red Cross trust

Possible offences aside, the evidence given this study showed that CSL's action compounded and escalated Red Cross' lack of trust in them as a fractionator and supplier, and increased their determination to try to regulate CSL by more formal means, in particular the drawing up of a contract between the two parties governing the conditions under which they are prepared to do business. The contract, discussed later, spells out that Red Cross is the owner of plasma they send to CSL.

10.7 Likelihood of repeat activity

It is relevant to consider whether the company might seek to send Australian product overseas again. No evidence was given of any disciplinary action against the officials who sent the prothrombinex to Hong Kong, nor of any direction from the Board to not do such a thing, nor evidence of Government action. Nor did Red Cross take action against CSL for sending product overseas which had been bailed to them in trust it would be returned. One TGA official who clearly knew of the incident said Red Cross should have done this.

Neither CSL Official said that to send Australian product overseas without Red Cross clearance was wrong or should not have happened or attempted to explain it as an aberration. Official B, Head of the CSL Bioplasma Division, talks at length about hepatitis C being 'endemic' to Hong Kong. Some might take his discourse on this subject as an indirect justification for the incident. Others may well read it differently. This executive was not with CSL when the incident occurred. However, there is a claim from a BTS Director, whose

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[207] *Section 21/18-22*

[208] *p 250 of Brogan and his reference 69 for Chap 17: Attorney General's letter, GC/85/10366, 23 Sept 1985*

[209] *p85 of the Prospectus May 1994*

[210] *p 8*

evidence opens this case study, that at least one CSL official did seek to justify the incident after the event on grounds that hepatitis C is endemic in Hong Kong.

Might CSL do such a thing again? One could postulate that, as with the mixing of different sourced plasmas, CSL might be deterred from repeating such an incident because of Red Cross' strong criticism, or perhaps because they may perceive that it isn't worth the risk of being found out, but this is not certain.

At the beginning of this case study, the author mentioned other allegations that CSL had sent Red Cross material overseas, over a considerable time period in one case. These specific allegations would have been put to the chief executive had he not refused to be interviewed.

Clearly, CSL could be *tempted* to send material again. Clearly, the opportunities are there. Fractionators or dealers in blood can find themselves with stock on their hands in a number of ways. CSL has always been obliged to hold various stockpiles of biologicals against emergencies. BTS directors often told the author of CSL's poor performance in accounting to them for how much plasma they received from or returned to Red Cross. A Red Cross blood bank director told the author in 1987 that 'CSL is sitting on a large stockpile of raw, unprocessed immunoglobulin. Developing countries want it but [the Australian government] wants them to pay and they won't'. In the same year the previous managing director of CSL was questioned about these stockpiles. He said that CSL had argued for a number of years that excess immunoglobulins should be made available to countries like Indonesia, the Philippines, Malaysia, Singapore, Burma and Thailand. CSL should be 'an agency for good will'.

> ... Our first position was that the government and Red Cross should see in which way material which was being wasted could be used. We did not get involved in any advocacy on how it should be provided. Perhaps only our costs should be reimbursed, or we could strike a favourable pricing structure.
> KB: What happened to the proposal?
> It is still working its way around..
> KB: How much is being wasted?
> I don't know. Some millions of doses since we first suggested it ... four to five years ago.
> KB: Which products are involved?
> Tetanus and diphtheria - CMV(ed. a common herpes virus) [less so].
> KB: Why is it taking so long?
> [This is] no criticism of the Minister or government, but lots of people have different priorities.

Any profit-oriented entity could find it hard to let such stocks sit around indefinitely and would likely wish to get it processed and onto the market. As to being an agency for good will, CSL could well wish to hand out Australian stock to foreign countries in the hope of securing plasma fractionation contracts.

There are other ways that fractionators may end up with product on their hands. Government may decide that stockpiles are no longer needed in the national interest. A Red Cross official from national headquarters said that the Society had written to the National Health and Medical Research Council asking if they wanted Red Cross to continue making diphtheria immunoglobulin. The Council said that there was no need as the disease in this country is so rare. Thus any stocks with CSL would become excess.

Recalled material may be dumped overseas. A US broker informed the author that plasma sold overseas is often stock that has become unsaleable in the United States because of a new testing standard introduced by the FDA which the plasma can't meet. In Australia, it is up to the company in most cases to certify that recalled stock has been destroyed, according to the TGA and the Federal Bureau of Consumer Affairs. There seems to be no external regulatory control over the disposing of blood products which are not subject to recall but merely expire or have no market.

Whether CSL would make use of any of these opportunities to sell or give away Australian blood again is not known. If the TGA had been more forthcoming, it might have been possible to judge their potential as a deterrent. Certainly, when CSL despatched New Zealand product to an Australian BTS quite recently, TGA officials materialised at CSL in a very short time after being tipped off, although what action followed is not known. TGA's performance in inspecting and investigating the national fractionator is held by TGA to be commercial-in-confidence. The Parliament, Red Cross and the public, including consumers, have no access.

R.66 TGA's Compliance Branch should investigate the sending of Red Cross material to Hong Kong by CSL, and follow up allegations of other instances and practices of doing the same, and TGA's General Manage should provide a report to the Secretary of the Health Department. The Minister should make public the results of this investigations.

R.67 The Board of CSL should also investigate the incident and assist the TGA in establishing whether any other incidents of this nature have occurred. The Board should also publish its findings, and any procedures or disciplinary action instituted to ensure that the behaviour cannot be repeated.

CHAPTER ELEVEN: REGULATING IMPORTS

The former head of the Legal Section of the Health Department told the author that there is no legislative restriction on the importation of blood or blood products.[211]

11.1 Volume of imported blood unknown

The author sought to discover what volume of human blood and blood products are coming into Australia. A customs official said Australian Customs Service wouldn't break down its information on imports 'unless there was a Freedom of Information request. Industry who deal with the information and generate it, know what it means. A lot might be described as blood, a few may say human blood.' (It was a common tactic for un-cooperative officials to withhold information unless it was requested under the Act; an initial application costs thirty dollars.) Another Customs Official during the same interview was more keen to help. He suggested ringing around to barrier officials and asking them for their observations on blood volume coming across the barrier. In any case, data for volume of product coming in are not required by Customs, and an AQIS official said the information is not often entered on the permit. In other words, it is impossible to know how much human blood is moving into the country.

An official from the Australian Bureau of Statistics told the author that the Health Department could request a separate statistical code in their statistics banks to cover human blood for 'ethical' reasons, or in the future if there were substantial trade. She knew of no request from the Health Department.

The movement into Australia of finished blood products, based on empirical research and anecdotal evidence, is currently quite small. Blood fractions in small amounts also enter in laboratory testing kits; samples of blood product are sometimes sent by overseas companies, and blood and plasma comes in for research purposes. Large volume foreign plasma is also entering for fractionation at CSL in Melbourne. CSL expects to process fifty four thousand litres of foreign plasma in the next year.[212]

Increased imports could occur in the near future. First, CSL is intent on foreign contracts, including from the mighty North American plasma industry, and stresses that their new plant capacity could be doubled to half a million litres to deal with foreign processing. Second, if Government continues to commercialise the supply of human blood by, say, introducing a charge to the end user, this will lead to competition and foreign products may take existing markets from CSL by numerous means. The need to monitor volume of imports as well as the quality would increase.

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211 *Personal interview November 1992, referring to Customs Prohibited Imports Schedule 8.*

212 *Prospectus p 21*

R.68 The Therapeutic Goods Administration should require foreign consigners of plasma for fractionation at CSL to provide sponsor certification that the plasma coming in was collected locally and from unremunerated donation, and to specify volume. CSL is currently required to declare the volume of each consignment going out and its destination. These data could be compared periodically to detect disparities.

11.2 TGA involvement

The imported blood products under discussion in this report are classed as therapeutic goods, being either **plasma for fractionation** at CSL or **foreign blood products** approved either for general marketing by TGA or for designated patients under the Special Access Scheme. Some of these products for individual patient use are imported by administering clinicians.

In practice, the agencies responsible for regulating importation have little control over the movement and quality of these products, judging from evidence obtained in this study. The TGA is oriented around regulating at the point of sale, rather than the point of entry into the country. This was considered by the Health Department to be a more effective point for regulatory intervention.

The main impediments to regulating incoming blood at the point of entry into the country appeared from this study to be:

- Difficulty of detecting disease risk;
- Unwillingness to interfere with the transportation of products which may be needed urgently to save lives;
- Weak legislation;
- Lack of use of legislation, due to unwillingness of agencies to risk conflict with parties receiving imported goods, many of whom are medical doctors;
- Weak requirements for information from overseas sources.
- A perception that TGA's activities in regulating at the point of sale are enough.

Some may argue that TGA's provisions are indeed enough. But what if, say CSL, wished to import human placentae to process into albumin for sale? This is not so far fetched as it might seem. Pituitary glands were imported from a number of foreign countries for processing into growth hormones.

Customs, Australian Quarantine and Inspection Service and the **Civil Aviation Authority** can rarely detect contaminated biologicals on sight. In

practice they accept the declaration of the supplier concerning its status. The supplier may have little knowledge of the quality of the blood and little control over the parties for whom the supplier is acting.

11.3 Quarantine of blood products

Blood and fluids derived from it are subject to quarantine control because of the possible risk of infection. This does not include HIV, which is not considered a quarantinable disease. (Such products are separately regulated for their occupational health and safety risk). Yet commonly blood products which pose a risk for AIDS simultaneously pose a risk for hepatitis, which is an infectious disease which should be quarantined.

R.69 Regulators should assume that products which pose an HIV risk also pose a hepatitis risk, which means they should all be classed as potentially infectious for the purposes of regulating them.

11.4Permit information requirements

There is no legal requirement for the agent or manufacturer bringing the product in to declare it as human origin. Once a supplier reveals the goods as human tissue, or containing human tissue, they come under quarantine control and must have a permit which describes the goods. Quarantine refers matters to the Communicable diseases area of the Health Department who get them 'vetted on an ad hoc basis' by Customs.[213]

According to the Principal Veterinary Officer at the Australian Quarantine and Inspection Service,(AQIS) the agency has quite strong powers under the Quarantine Act 1908 but difficulty using them for blood products. The descriptive categories that can cover blood for the purpose of a permit are very broad. Human blood is grouped with animal blood for various purposes, and with anti-sera and 'other blood fractions'. An AQIS official complained that the description of goods required on permits was inadequate, saying human serum could easily pass as animal serum. A separate Human Quarantine Act was being drafted at the time the author interviewed these officials.

11.5 Country of origin data not required for starting material

Permits need not specify the country of origin. Nor is it possible to know in which country incoming blood products have been collected, unless the supplier volunteers the information. The incentive would be in favour of volunteering as little as possible. The AQIS official interviewed for this study considered this was unimportant. Wherever it came from, the blood would still have to comply with TGA, he said. In any event, 'anyone can jump on a 'plane from anywhere and bring in a disease in their body. If the product were for use in humans, then TGA would be very very involved and would look at [its] source'.

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[213]*Health Department official C , telephone interview 12.10.92.*

This official also said that the Health Departments wants to get out of issuing permits for blood products, believing that TGA covers them well enough. The AQIS official envisaged human goods going under a schedule arrangement in place of permits, although the products would still have to comply with usage and product handling requirements.

The author found some government officials with groundless confidence in the ambit, powers and effectiveness of TGA, an attitude of: 'if it's to do with human blood, just give it to TGA'. They didn't necessarily know what TGA would do about it. One AQIS official was dissatisfied with the degree to which AQIS is bound to rely on TGA and said TGA 'had their heads in the sand over blood products'.

AQIS barrier personnel come from State agriculture departments. 'The lines of command get grey and that causes problems, but we have been working to improve that. Attitudes ... towards human blood vary slightly ... but not to the point where importers have traded off the difference,' the official said.

AQIS relies heavily on the company consigning the goods to tell the truth about them, according to the senior official interviewed. The AQIS official who was dissatisfied with TGA's role said he believed the AQIS requirements should be used uniformly without exceptions. Later he said, however, that where the person to whom a blood consignment is shipped may claim they did not know it was coming, to explain not having a permit, then AQIS officials get involved in 'looking at **mens rea** at the barrier', meaning trying to decide if a suspect is knowingly or recklessly trying to evade the law at the time of the offence. 'You look at the demeanour of the person; if he is arrogant you may say 'no' as a gut feeling.' the officer said.

Like AQIS, TGA also has to rely on trust in accepting certifications for foreign blood products. This is inadequate in the event of a deliberate attempt to dump product, or where the company certifying has unknowingly or negligently supplied substandard or unsafe blood products.

It is naive and arguably negligent to build a regulatory system for human blood imports and exports on an assumption that good will and competence will prevail, while making no allowance for error, negligence or malice.

Information concerning country of origin could be of value in regulating blood products. Better still, permits could be required to show which country the blood was harvested in *and* which country processed it. This could be linked electronically to a TGA data base showing overseas product recalls, manufacturing failures and instances of overseas regulators enforcing stricter standards (which can be a prelude to overseas dumping of products rendered unsaleable).

If this had been the case when the UB Plasma company was shut down in Germany in 1993 for omitting HIV testing, the implications would have been clear. The company bringing in Immuno's products could have been immediately obliged to furnish proof they were not made from untested UB Plasma. In other cases, where the risk was an infectious disease such as hepatitis C, the incoming goods could be impounded on grounds of a reasonable suspicion, until the supplier could show they were not infectious.

A Civil Aviation Authority Inspector for Air Cargo, in contrast to the AQIS official interviewed, believed the quarantine permits should be strengthened to direct importers to use correct packaging. He wanted them to in effect comply with international rules regarding infectious substances, so that if an importer breached the conditions their import permit would be rendered invalid by the breach.

This official had also done as much as he could to crack down on poor packaging of blood products transported within Australia. 'We have done all we can to educate through the States - letters to every State and Federal Health authority over the last few years. It was an assumption of mine that the State and Federal agencies had at least technical control over hospitals and laboratories. Responses to the letters were received from two States. The Transport Workers Union assisted the process of raising awareness on the issue of poor packaging of blood products. The airlines were pressured from CAA although 'they didn't need a lot of prodding. It is an offence for an airline to carry blood if it is declared infectious and isn't adequately packaged. They are required to report dangerous goods incidents. There are three to four a year, mostly from small airlines operating remotely where medical people are less likely to want to classify it.'

'When we see goods destined for airlines we always ask: has it been consigned as dangerous goods? If not, we are not about to ring up the consigner. We rely on their good sense. We won't get into a fight with the medical profession over goods of a biological nature because we couldn't win. The onus of proof is on us. We try to have an ongoing process, but we end up fixing problems as they arise, because of resources.' Where people were not complying it was because it was more costly to comply than not to comply. Permits cost between twenty five and thirty dollars.

This official believes the consignee should be required to describe goods as infectious if there is any possibility they may be, as opposed to the consignor having reason to believe they are. This could have interesting ramifications for CSL in respect of foreign plasma brought in for processing, given the experience with product labelled potentially infectious in the past when handlers and unions objected to it. Could foreign companies show, if challenged, that their plasma was not potentially infectious? What of plasma coming from Hong Kong, where hepatitis, according to not just CSL evidence

but the evidence of other experts consulted by the author, hepatitis is endemic.[214]

11.6 Seizures and surveillance

Seizures are provided for under the 1908 Quarantine Act and are quite frequent for blood destined for research use. This is 'for educational reasons as much as anything, to make people more aware of their obligations.' A recipient may claim they didn't solicit the blood and AQIS can't judge the truth of the claim. Companies also send free samples. CAA is reluctant to seize blood and blood products for human use, for fear of interfering with treatment for possibly life-threatening conditions and because it would pit the agency against medical opinion and the CAA official said they couldn't win on this. The Civil Aviation Authority has **surveillance** powers and undertakes **checks** on aircraft ramps. The CAA official had heard of no reports relating to blood.

11.7 Injunctions and directives, adverse publicity, education

Injunctions and **directives** are not used for biologically derived products, according to evidence given this study. There are no **fining powers**, and there is no use of **adverse publicity**, but AQIS requirements are published in the agency bulletin. 'Letter drops' are also employed to **educate** industry, and are sent to scientific institutions on an agency register of bodies approved to receive foreign products.

11.8 Prosecutions

He said AQIS used to get bogged down over human sera coming in in small eskies and other badly packaged forms, mostly product for research purposes or analytical or diagnostic testing, and labelled potentially infectious. AQIS referred a lot of these to the Civil Aviation Authority 'because AQIS didn't have the powers to act. We could not prosecute the party responsible because nearly all the people we deal with are only agents for the person bringing it in, and we don't have the power to prosecute, say, someone in a hospital in the US'. On one occasion handlers and unions became towy about human sera labelled 'potentially infectious'. It led to a near walkout, he said. AQIS' 'solution' was to change to 'more appropriate labelling'.

The AQIS official could recall no **prosecutions** for blood products. In a few cases prosecution was considered when serum was improperly packaged - 'chucked into polyurethane eskies with dry ice'. The official said most offenders were individuals and small traders. Asked if any bigger companies were involved, he appeared to have one in mind but would say only that 'there were very few shonkies'.

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214 *interviews with regulatory experts speaking unofficially with the author, 1994 , also Red Cross officials advising the study.*

As mentioned above, the AQIS official said they refer cases to CAA because AQIS hasn't the power to prosecute. Yet the CAA official said that generally CAA 'doesn't grab blood because we don't want to jeopardise someone's health. We need a justification, such as a reason to believe it was infectious when it was consigned.' He knew of none being seized in the last five years. Despite the existence of strict liability offences in the legislation, 'we would have great difficulty prosecuting, even if the product were infectious and not properly packaged. One couldn't prosecute the consignee, because he had no part in it.'

11.9 International liaison

CAA liaises with national aviation authorities in other countries over imported products and relies on United Nations Recommendations on the Transport of Dangerous Goods[215] which define infectious substances in various risk groups and specifies packaging for biomedical substances. 'We communicated with an overseas aviation authority on one biological product, a genetically modified micro-organism, but got no reply. We have not done this for blood. With other dangerous goods - petrol, acids - overseas authorities are very good.'

11.10 Capture and corruption

The AQIS official thought that capture and corruption were not issues for his agency. Since the Royal Commission of 1982 into the meat substitution scandal 'we don't get offered anything by industry; the most is a biro'. Meetings with industry are a big issue, and are very tightly run. There were no bribes known in the biologicals area. No one had been referred to internal investigations in his time. Officials are encouraged to move into industry to work but there were no approaches from industry to officials. The agency doesn't rotate staff (a common way of dealing with capture) because their personnel are skills- based.

The CAA interviewee also said there was no evidence of capture nor of any industry attempts to bribe officials in his agency. 'You are flat out getting a cup of tea out of them', he said.

11.11 External review

Parliamentary scrutiny and external review of AQIS has been extensive. The official referred to 'ongoing Senate Estimates questioning, plenty of publicity (laughter), we are *always* under review! There is a massive re-organisation at present (1993), we have been reviewed regularly over the past three years.' Clearly he thought external review had been overdone. The CAA had also been under external review.

11.12 Imported plasma for fractionation

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[215]*Eighth Edition*

CSL has a number of standing permits for this material which are renewed annually. The CAA Air Inspector knew of no reports of problems with CSL as a consignor or receiver of plasma. Neither AQIS nor CAA picked up the contaminated prothrombinex CSL sent to Hong Kong and neither agency questions the quality of incoming plasma for fractionation at CSL, including the routine importation of Hong Kong plasma which is presumably contaminated with hepatitis C, a highly infectious and serious disease.

Currently, roughly twenty percent of the two hundred thousand litres of plasma processed annually at CSL is said to be of overseas origin.( ) *Business review Weekly, 26.11.. 93* CSL's desire to massively increase their foreign intake of plasma for fractionation was well publicised on the opening of their new fractionation plant and in the run up to the sale of CSL. Therefore it is relevant to focus on the adequacy of regulatory controls for this material.

In defining the term therapeutic good, the legislation includes goods in the form of an ingredient for manufacture. But starting materials are exempted[216] from the listing and registration requirements of the Act and in any even the testing standards defined in the Code on Blood and Blood Products are not legal standards, being only the subject of a Ministerial determination, as mentioned earlier.

CSL official A was asked about the company's specifications for incoming plasma and said they receive it only from foreign blood collection centres who do not pay their donors. Yet not all countries have as healthy donor populations as Australia. In March 1994 the Philippines blood supply was reported to be contaminated:

> The Philippines' blood supply is contaminated with AIDS or other diseases, the Health Secretary, Juan Flavier, said yesterday, calling for a phase-out of all commercial blood banks.
> He said that a least 4 per cent of the country's blood supply was contaminated with either AIDS, hepatitis B, malaria or syphilis, according to a study of 426 'blood bags' conducted this year.
> Mr Flavier said he believed recipients has received contaminated blood.
> **He said 64 per cent of the country's blood supply came from commercial blood banks ... He acknowledged that some contaminated blood had been found in government hospitals and the Red Cross.**[217]

According to the CSL Sale prospectus, CSL has a license to make factor VIII for the Philippines, as well as Hong Kong, Malaysia, New Zealand and the South-West Pacific .[218]

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216 *Schedule 5 TGA*
217 *Canberra Times, 2.3.94 p 7*
218 *p 86*

11.13 Donor questioning

Asked about the standard of donor questioning in overseas blood collection centres, the CSL official said 'we don't impose rules on that'. Donor interviews are a key means of trying to ensure blood safety, and are very closely regulated under the TGA Blood Code. Some blood collection centres were even failed in their first TGA inspections mainly on fine points relating to donor interviews.

CSL's official A said 'the material before it is shipped has to undergo the same sort of tests as in Australia.' Yet foreign countries do not all test to the same standard as in Australia, as we saw with hepatitis testing in Hong Kong and New Zealand. The Government has even had to grant CSL an indemnity for damages claims over HIV-infected blood from New Zealand and Papua New Guinea.

Further, in explaining CSL's response to the discovery that a blood product they had sent without approval to Hong Kong was contaminated with hepatitis C, the Head of the Bioplasma Division at CSL said in December 1992 that Hong Kong doesn't test for hepatitis C. At that time, and still,[219] CSL has been fractionating Hong Kong plasma on a commercial basis. Yet Red Cross sources say they began testing for hepatitis C in February 1990.[220] The official's statement therefore implies that CSL has been importing considerable amounts of untested and presumably contaminated material into Australia over a long period. Yet the practice is not unlawful under the Therapeutic Goods Act.

> KB: Since the material goes back to Hong Kong, why do you have to care at all if it's contaminated?
> A: Because of the safety of the operators and the risk of accidental contamination of equipment ... There are always people involved ... there is a possibility of splashing.
> KB: Have you formulated a written policy on what, in practice, the standards mean for your imported plasma?
> A: Good question. We've taken the attitude that we will manufacture to the Australian code **unless there's an exception** (words missed here) - both the Code for Blood and Blood Products and the good manufacturing code.

That the legislation does not address this matter is even more startling in view of the fact that safety breaches have already occurred: for over two decades, according to Red Cross evidence, CSL mixed foreign plasma with Australian material. The author noted during this study how haematologists and associates of haemophiliacs more or less accepted the extraordinarily high rate of hepatitis amongst haemophiliac users of blood products. It wasn't

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[219] *p 18 of the Sale Prospectus 1994.*
[220] *ACT Red Cross Blood Bank, 5.5.94*

even mentioned even mentioned until late in this study and no information was proffered to explain how they contracted the disease. The mixing of Australian with foreign material contaminated with hepatitis seems an obvious possible answer.

According to the CSL Sale prospectus, the only indemnity the government granted CSL in respect of hepatitis is for harm 'as a result of the therapeutic use by that person or that person's natural parent or spouse ... of a CSL plasma product **derived from Australian plasma and produced pursuant to this contract.**'[221] The contract referred to is the one signed in February of this year. For hepatitis damages caused by CSL products before the February 1994 contract, the sale prospectus mentions another indemnity, which covers 'products **derived from plasma collected from blood donated by people in Australia**'[222]

Did Government not know that CSL mixed plasma over more than two decades? Are these indemnities worded so as to avoid responsibility for possible future damages claims? It is doubtful whether the regulatory responsibility for this area should be so thickly spread upon one agency, the TGA, as there is no backstop if they err for any reason.

R.70 For human blood and blood products imported into Australia, permits should be required by law to declare (a) where the goods are of human origin, (b) whether they are for human use or otherwise (c) the country of origin of the blood or blood fraction in the product, (d) the country of manufacture and manufacturer's name in that country (e) whether there is any reasonable possibility that the goods could be infectious.

R.71 Quarantine permits should be strengthened to direct importers to use correct packaging. Consideration should be given to whether a requirement that permits meet international rules regarding infectious substances, would have the effect of rendering the permit invalid if an imported breached these conditions. The option for strengthening permits should be considered if it would have that affect.

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[221] *CSL Sale prospectus p 84, additional information 8.5.1*
[222] *p 92, Additional information, 8.6.2*

PART THREE: CONSUMER PROTECTION AND REDRESS

CHAPTER TWELVE: PRODUCT LIABILITY

The Therapeutic Goods Act and State legislation prohibiting sale of blood are the principal legislative means of protecting consumers from unsafe or defective products. There are numerous other means to achieve this. Unions, parliaments, the media, and consumer groups can all play a part in the process, but there was little evidence of activity by these stakeholders. This chapter briefly looks at the role of the courts, although the resources for the Australian Blood Regulators Study did not extend to a thorough examination of this avenue. Much of the study that was undertaken related to the effect of legal suits on the activities of Red Cross and the Federal Government, and is not reported on in detail here.

Litigation lawyers, the courts and the Trade Practices Commission seemd to function as a kind of regulatory force or presence, an invisible fist, waiting to strike at the first sign of the son or daughter of AIDS; this is by contrast with TGA's 'benign big gun' presence. Product liability claims, and the threat of them, was found to be potent influence upon parties responsible for manufacturing, supplying or regulating human blood products. Regulators and manufacturers get 'pushed around' by their fear of litigation suits, and by the difficuly in obtaining indemnities and insurance for biological products. This is not to say that all regulators and manufacturers necessarily understood the legislative and common law avenues for redress particularly well.

Legal product liability claims concerning processed blood products can be brought by civil actions through the courts or by civil actions under the Trade Practices Act consumer protection provisions.

12.1 Consumer protection under the Trade Practices Act

The TPA avenue was introduced in July 1992 to allow individuals to bring action for defective goods. The aggrieved person does not have to show a contract between themselves and the party they are suing; they may sue simply as an aggrieved consumer. Negligence need not be shown. The legislation applies to government when it engages in business, to corporations, and to other entities when they engage in trade or commerce across State or territorial boundaries and in certain other circumstances. It applies to CSL pre and post-privatisation and could potentially apply to Red Cross which sends plasma to CSL for manufacture into blood products. The Commission has no record of any cases brought against blood products to date and certainly there are no decided cases.[223] A TPC official interviewed for this study commented that if CSL were anything less than completely

[223] *personal interview 19.5.94*

rigid in their safety procedures and blood manufacturing processes they would be committing commercial suicide.

How effective may the legislation be, as a mechanism for regulating the safety and quality of fractionated blood products through consumer claims? The answer is complicated. What follows is not a complete analysis of the Act and is not a substitute for legal advice or interpretation of the Trade Practices Act 1974.

Starting with the simple part, the consumer protection provisions of the Act apply only to goods supplied after May 7th 1992. Therefore they are of no use for past CJD cases, whether transmitted by hormone or blood products. Nor are they useful for HIV cases from the eighties, (nor for harm from CSL whooping cough vaccine supplied before that time, nor measles/mumps/rubella children's vaccine, nor HIB, nor for blood products made from placental material). A common law action would be the only recourse in these cases and for these, negligence must be shown and the claim brought within six years of the harm occurring. Under the Trade Practices Act, the rights of the consumer expire three years after the cause of action arises and, in any event, ten years after the goods were sold to the consumer. By and large, the more time that passes between the supply of goods and the claim, the more difficult it is to demonstrate either the defect or negligence.

Under the legislation, goods are considered 'defective' if they do not have the degree of safety which people generally are entitled to expect in all of the circumstances. This may involve the court weighing community benefit from the marketing of the goods against risks of harm, such as infection. It is a defence for the manufacturer to show that the defect could not have been discovered in the light of scientific and technical knowledge at the time.

The most difficult aspect of this provision for fractionated blood products could be deciding what people generally are entitled to expect by way of safety, of distinguishing between what is defective and what is simply dangerous or inherently risky.

This study found that Red Cross, CSL and Government have never routinely informed the public, all of whom may need blood or blood products at some time in their lives, of the innate risks in using blood and blood products. Australians have long held quite unfounded expectations of blood and blood product safety. Yet these expectations are at least partly a result of chronic false claims as to safety. CSL generally was found to disclose as little as possible about its manufacturing errors for blood products. The Trade Practices Act also prohibits misleading and deceptive conduct, which could apply to false claims as to the safety of blood products.

How will the courts decide between harm caused by an innate risk and harm from faulty processing or supply, especially when biologicals manufacture is

fraught with difficulties in any case? How will judges pick their way through these issues - or will cases be decided on which side can afford the most convincing expert witness, until no one can afford to use the mechanism at all?

Claims brought jointly against CSL and Red Cross could also involve the Federal Government, as a funder and possible indemnifier of Red Cross, and arguably as a regulator of both Red Cross and CSL if it failed in its duty to regulate. Its stance on compensation is therefore relevant in deciding on the possible effectiveness of the provisions.

Late in the process of approving the product liability amendments under the Trade Practices Act, the Health Department tried to have blood and blood products exempted from these provisions. This could be viewed as a variation on regulatory legalism, discussed earlier. Legalism says don't do anything unless you have a law, and if you have one then enforce it irrespective of the regulatory outcome. The Health Department approach says: avoid having a law at all - if that would cast a responsibility upon the Federal Government.

As the then head of the agency's legal section said to this author in 1992 'why should the Commonwealth put itself at risk when a manufacturer could be done?' This was in response to questioning about attempts in 1984 to have a no-fault compensation scheme introduced for medically-acquired HIV. The same official described group actions, together with the TPA product liability provisions introduced by the Federal Bureau of Consumer Affairs, and cross vesting (the ability of a claimant to transfer a claim to another jurisdiction) as 'the three card trick that Attorney-General's deliberately played on us'.

His view was that because blood products 'are in the public interest and of biological origin and therefore by nature impure it is not appropriate that they be included' under product liability. The attitude of the Federal Bureau of Consumer Affairs was that because blood products are all of the above, and especially because they are in the public interest, they definitely *should* be included.

One official summed up the Federal Government position on blood this way: 'All we do is fund the Red Cross and only indemnify on a case by case basis. ... Attorney General's and Health didn't want a class action for HIV, because it is not the way we do it in this country; ... not five hundred cases with varying degrees of risk. It's unjust on the defendants.' Earlier, though, he had said 'We agreed we should fight [claims], because the best cases would be the first and they would be lost - this would stem the tide.' (The official wasn't indicating his sympathy with that stance).

Various interviewees, including a Federal Government official, said the Government 'leant' on the States to stop them settling HIV cases. Others said

they made various threats, such as refusing Medicare payments to people with medically-acquired HIV. 'All the States bar Western Australia were leant on by the Commonwealth not to settle; it was done through AHMAC,' said one interviewee. Finally, after massive court costs, the Federal Government saw that it's strategy had been wrong - it was cheaper to settle than to fight one case at a time in court and, if it came to that, have to pay only one lot of damages at a time. They had planned to run all their cases in Victoria, where CSL was based, before a jury. The first case cost well over twelve million dollars to defend.

In 1994, the Health Department applied to have roughly one hundred CJD writs from women who used CSL hormones on a Health Department program struck out, on the basis that there was no precedent for compensation for stress and anxiety over something that had not happened.(Something *had* happened! The women's lives had been placed at risk!) At the same time the Federal Government took this path, the agency was offering counselling to women who had discovered their vulnerability to the disease after taking growth hormones. There is a slight irony in this, in that by the time the event now provoking stress did come about, the women would be unable to sue, since they would be dead.

Based on the Department's performance with HIV claims,(not addressed in detail in this report), on its attitude towards the product liability amendments, and on evidence of its general disposition towards like claims against the Federal Government, it can be inferred that the agency would strenuously resist paying out rather than encourage citizens to press their legal right to bring action for faulty products. State and Territorial health departments were, in general, not found by this study to be as dedicated as the Federal Government to avoiding compensation. Whether the TPC would bring a case itself, without the support of the Health portfolio, is unknown.

Despite the challenges in using the trade practices legislation, it may still function as an 'invisible fist' to discourage CSL and foreign blood product suppliers from providing defective goods, particularly as the Trade Practices Commission is known to use its powers, (as has the Federal Bureau of Consumer Affairs). Braithwaite and Grabosky found that 'no business regulatory agency in Australia has been able to impose as firm an enforcement orientation as the Trade Practices Commission.'[224] The Commission can also secure sanctions from the courts far in excess of those obtained by any other agency. For the consumer protection offences the maximum fine is two hundred thousand dollars for a corporation.

12.2 Common law litigation

Negligence was alleged in one HIV case brought against CSL in the period before AIDS testing and was unsuccessful. In common law litigation the first

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[224] *Of Manners Gentle 1986, p 91*

target is usually the doctor, then the hospital and then the supplier. The difficulty in suing the supplier is lack of a contract. A patient can't sue the supplier on the basis of the contract between it and the hospital. Common law litigation as a regulatory mechanism for blood and blood products is addressed in more detail in later reporting on the Australian Blood Regulators Study.

12.3 HIV

Product liability suits in respect of HIV acquired from CSL fractionated blood products have been limited to civil actions, since all commenced before CSL was corporatised or because the cause of action preceded the enactment of the consumer protection provisions.

Federal, State and Territorial Governments had been involved in settlement of some four hundred claims at the time of writing this. The Federal Government has paid all of CSL's and a percentage of Red Cross' contributions and costs. Claims made in the ACT and NSW have been the last to reach settlement. Legal proceedings have also been commenced against CSL and the Red Cross in Australia by haemophiliacs in New Zealand.

12.4 Creutzfeldt-Jakob Disease

There is debate at this time about whether the disease can be carried in blood, but the presumption is that it can. There is no test for CJD. Blood Banks have been told to exclude donors who have used growth hormones.

Then there is the issue of what CSL and the Health Department did to inform blood banks and other stakeholders about the possible risk of transmission in a timely way. If it has been carried or is being carried, product liability claims could arise under the Trade Practices Act or through civil suits for negligence. The issue of blood products from placental material is taken up in chapter five.

12.5 Hepatitis

A new wave of litigation began in 1994, over blood contaminated with hepatitis C. This report deals with the issue of who decides what tests should be run on blood donations at 6..4.7. The Australian Blood Regulators Study discovered the successful use of a surrogate hepatitis C test on some donations collected by Red Cross, whereas other blood banks had elected not to use it. Before the recent wave of hepatitis C cases came into view, a Red Cross blood banker using the test said he was aware that he might be called as a witness for the prosecution some day. The issue of whether to use this test had been discussed at the level of the National Blood Transfusion Committee.

12.6 No-fault compensation

Australia does not have a no-fault compensation scheme as New Zealand has. The idea was suggested for medically-acquired AIDS in the early eighties but

came to nothing. Legislation was introduced in States and Territories limiting the liability of the blood supply and blood products (though it is not uniform). Individuals bringing claims must prove negligence, for which the test differs depending on the jurisdiction. In 1992 the Legal Working Party of the Intergovernmental Committee on AIDS recommended a no-fault compensation scheme for health care workers who contract the disease in the course of their work,[225] but there is no sign of such schemes being adopted for disease acquired by consumers of blood or blood products. The Australian Drug Evaluation Committee and Australian Health Ethics Committee both favour a no fault scheme for subjects injured during trials of therapeutic goods.

There is no experience with the Trade Practices Act consumer protection provisions in blood or blood products, but it could prove useful.

R.72 In order to reduce product failures leading to product liability suits, the Federal Health Department should (a) assume its responsibilities for regulating testing procedures, especially the need for a uniform national policy on what tests should be run; (b) assume its responsibilities for informing Australians of the innate risks in blood and blood products; (c) enforce informed patient consent and (d) recognise that its responsibility for establishing a national blood service includes compensating those who are harmed through use of these products.

R.73 The Federal Government should, in conjunction with the States, examine the costs and benefits of a no-fault compensation scheme for biological products provided on behalf of Government in the public interest. Carriage of this review should not lie with the Federal Health Department, because of its past unsatisfactory record in taking proper account of the public interest and the rights of consumers.

[225] *Civil Liability for Transmission of Aids, April 92, p 44*

CHAPTER THIRTEEN: A KENNEL FULL OF WATCHDOGS - RED CROSS BLOOD BANKERS

In this chapter we deal with the role of consumer protection groups, particularly Red Cross and less so the advocacy group which represents haemophiliacs. The chapter shows how Red Cross, sole supplier of Australian plasma to CSL and its major client, has fallen to trying to regulate CSL where government and CSL are failing. The practicality of this informal function is discussed and suggestions are made for a more effective role for Red Cross. The need to empower consumer groups representing users of products other than clotting factors needed by haemophiliacs is also emphasised.

13.1 Red Cross as a default regulator

> KB: Do you have a watchdog role in relation to CSL?
> BTS Director: I think all of the Directors see themselves as a kennel full of watchdogs.

The study found that the Blood Transfusion Services function to some degree as a surrogate or 'default regulator' of CSL in respect of its national blood fractionation role.

A 'default regulator', as defined by this author, is one who, when an entity with whom it must deal is improperly regulated, becomes sucked into the regulatory vacuum and takes on the role of the official regulator by default. The default regulator will always be a party who is dependent on the other entity's performance, and as a 'regulator' is vulnerable for a number of reasons. It lacks official authority and the protection, access and information that comes with it, and thus will always have limited success. It risks the chagrin of the official regulator if its role comes to their notice, since its default regulator efforts underscore the fact that the official regulator has been lax or failing. It risks resentment from the body it tries to 'regulate' as it may hold vital information from that body and can be seen as a standing reproach. That body may try to punish the default regulator, either openly or subtly, and is in a good position to do so. There appear to be innate risks in taking on regulatory responsibilities without acquiring commensurate authority.

Red Cross was found to be a 'default regulator' of CSL (and other parties) firstly in place of the Federal Minister for Health, through whom CSL reported to Parliament and who had powers to regulate CSL, secondly in respect of CSL itself, whose Board of Directors and executives have self-regulatory powers or roles, and finally in respect of the Health Department, to varying degrees.

Red Cross' role has come about because of factors such as:

- its proximity to and dependence upon CSL as the sole processor and supplier of products made from Red Cross plasma;

- disinterest by most Federal Health Ministers in using their power under the CSL Acts 1961 - 1991 to regulate CSL blood processing activities;

- disinterest or inability of the Health Department to perform its role;

- CSL's failure to adequately self-regulate for this area of its activities;

- a natural tendency of quite a number Red Cross Blood Transfusion Service Directors personnel to use their influence to improve the quality and availability of blood products issuing from their donor material.

Red Cross is committed to goals such as ensuring optimum supply, optimal clinical use and timely service. This produces a constant interest in such issues as CSL'S manufacturing yield, product quality and availability, and also in the timeliness of CSL's response to Red Cross and others' requests for new products.

Red Cross blood banking officials have always assumed they own the starting material given them by donors. Human blood is a scarce national resource needed for life-saving and serious medical treatment. While CSL has had to buy or pay inducements for animal offal to grow Salk vaccine, hen eggs to grow influenza vaccine, mice and rabbits for research, mice and other animals for testing purposes, pituitary glands for hormone preparations and sometimes its red backs and funnel webs, it doesn't have to pay collection costs for the human blood it processes, and certainly would have never paid women for their placentae either. Blood is bailed by Red Cross to CSL in trust they will process it appropriately and efficiently. As the head of the CSL Bioplasma Division said in interview in 1992:

> As far as I am concerned there is a team working together to deliver a product to the health care community of Australia and that is Red Cross, CSL, TGA, and the Department of Health services and the clinicians (I use this to be the same as the hospitals). So we are all a team to address the health care needs of Australia.

In the context of contractual relationships between Red Cross and CSL, the Federal Government declared in 1994 that 'Ownership of plasma and the derived products resides with the Red Cross'.[226] Red Cross had considered it necessary to spell out Red Cross ownership of the plasma, as a further effort to impress on CSL that the corporation was not free to treat Australian plasma according to their own desires.

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[226] *CSL Prospectus p 85.*

Red Cross willingness to extend its sphere of influence, in effect acting as a default regulator, can also be seen in its efforts to deter overseas imports and internal trading in blood and to effect appropriate usage of blood and blood products, as seen in chapter eight.

As seen earlier, Red Cross also has the prevailing word on when its donor material may be sent outside Australia via the Fractions Release Committee. Official C recalled no instance of Red Cross' opinion on releasing material for overseas being overridden. (Later evidence suggested that a change in policy may have occurred after this conversation, at least in the case of one application).

The Society seeks to follow principles of impartiality, neutrality and independence.[227] In practice they tend to avoid involvement in anything smelling of politics or public controversy, although some Directors speak out strongly against the commercialisation of human blood supplies, and against donor remuneration because it diminishes the quality of starting material and can exploit donors.

A BTS Director, recently seconded to Geneva to work as head of the blood donor arm of the International Federation of Red Cross and Red Crescent Societies, was responsible for formulating the highly influential 1990 Hanover Statement on the Ethics of Voluntary, Non-remunerated Blood Donation. The principles of voluntary donation were embraced by the European Community who announced their determination to phase out imported commercial plasma. This sent the massive US commercial blood lobby spinning all the way to the White House, where they prompted US President Clinton to respond in 1993 that his administration would 'intervene in Brussels' to protect their billion dollar export business.[228] If an issue close to Red Cross' heart is involved, it will get involved in politics, though unobtrusively if possible.

Over years of study, a picture emerges of Red Cross Directors as considerably autonomous. Many are 'Red Cross people' as well. Most are keen to assume rather than evade responsibility, feel their mistakes keenly, are eager to regulate themselves, and object to sloppiness, wastage and inefficiency. They tend to prefer persuasion rather than confrontation in dealing with others but can be very persistent if they feel the need. CSL official A commented that they have not always been the easiest people to get on with. The Directors tend to avoid media and publicity, unless in the cause of attracting donors.

Despite this background of public reticence, this author found a high degree of willingness to co-operate in the Australian Blood Regulators Study, although Directors did not relish speaking about certain matters, including CSL. After one interview a Director volunteered: 'The reason I am talking to

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[227] *see the Seven Principles of Red Cross, annual reports*
[228] *Financial Times, Washington, 10.8.93 p 6.*

you is that I believe in the importance of what we are doing and I believe we should be open with people such as yourself and with the Australian public and that we should be seen to be open.

Red Cross and other interviewees who deal with CSL evidently feel very frustrated with the National fractionator, and nervous about what it will be found doing next with human plasma. The Health Department, which funds and regulates Red Cross blood banking activities, and is CSL's principal regulator, never came up in interview as an authority to whom these parties felt they might turn for help with their CSL problems.

> KB: When complaining to CSL didn't work, did you contemplate other action?
> BTS Director: I always found [CSL official A] to be a scholar and a gentleman. [That] wasn't enough to get results - I didn't know what else to do.
> KB: What about the Federal Department?
> It didn't occur to us to go to the Federal Government. [CSL] has a position on the National Blood Transfusion Committee. The Commonwealth might have controlled CSL but it wasn't visible. You wouldn't have known it was happening.

The Health Department never indicated knowledge that CSL's clients have difficulties with CSL. Some Directors have spoken with the agency informally; formal complaints have been few. Before the sale a BTS Director said 'CSL acts as if it were not part of Government. In any case, we don't need to run to the stepfather when the siblings are at war.' Few saw the Department as a useful regulator of matters outside TGA. 'I'd like to think they'd help us out of a mess but I wouldn't trust that they would. It depends on the person you're talking to on the day. ... We went to them for help with HTLV testing and look what we got: bugger all. It's proving the same with factor VIII supply [problems].'

For some of CSL's questionable practices, such as the mixing of plasmas from different sources, Directors used the National Blood Transfusion Committee to flush out information from CSL and regulate its behaviour. Whether it was Red Cross or Health Department presence which motivated CSL to stop mixing is not clear. Official A says they were 'forced' to stop 'by the Government'. The NBTC was also used to inform Red Cross of the prothrombinex incident. Red Cross certainly protested, including to this author. What the Health Department did is unknown.

13.1.1 Red Cross/CSL Contract as a regulatory tool

Red Cross Directors frequently pointed out their lack of real power to influence CSL. Progressively they placed emphasis on the need for a formal contract. It was slow coming. The annual report for the Society in 1990-

1991[229] says 'During the year work was undertaken on a contract to be made between the Society and CSL'. The advent of TGA raised possibilities for urging the idea along. A Director told the author in 1992 'The trouble is that you have a Federal system which is a national service but funded through the States. Nobody makes the decisions. Who makes the decisions isn't clear .... CSL is not linked to the Blood Transfusion Service. There is no line involvement. Yet they are each others' biggest customers. [But] under TGA we will need an agreement.' Another seasoned Director believed Red Cross needed agreements with all parties:

> I am totally convinced that gentlemen's agreements are not enough when people are in there for different reasons.

While trying to lead CSL to the contractual table, some Directors also formed a working party with CSL to address the relationship. Most said that CSL was 'really trying' but claimed the mechanism produced few results. In 1992 a Director said that if the working party mechanism didn't work 'we won't have a blood program to speak of ... It is imperative to develop better communications, even more important if CSL goes to private enterprise, that we not have to read in the newspapers about stuff we should have been told well before'.

Official B, CSL's newly appointed Bioplasma Division manager, said in late 1992:

> We're working very hard to improve our relationship ...[Official A] has become very much involved. Our goal is to become more involved with Red Cross. We want to ensure that we fully understand what the Red Cross perceives are the needs of the health care community of Australia and to better serve those needs ... to work with Red Cross to see if we can come up with some efficiencies throughout the system ... our relationship with Red Cross will get better.
> RS: Will you formalise it?
> B: [That's been] looked at for some time; that's possible.
> KB: What benefits could you see in it?
> B: I don't see any benefits in it. We're not encouraging it, but it seems there are people who are speaking about the importance of formal agreements where in the past it's always been informal.
> KB: Red Cross?
> B: Yes.
> KB: Can you see benefits, [A]?
> A: Theoretically yes, practically no. I think the interrelations between the people involved are very good and have been very good. You can imagine there will be fallings out but if you have to rely on the written word to make something work then it's not going to work anyway. People have to rely on good will, which is there fortunately, to make

[229] *Australian Red Cross Society annual report, p 4*

the system work; and as [B] said, we are working to get closer together.
KB: Why do you think the Red Cross wants it?
A: Don't know.
KB: Can you see any disadvantages in it for you?
A I think if someone wants to get [a contract] out regularly and read the fine print and point to something that hasn't been done maybe that could make things a little more difficult but I hope that's not how it will work ... there are potential safeguards there for all the parties but that's about all.
B: [If] we're looking at the litigious nature of the matter, and from a litigation point of view I'm sure ... our attorney would be very adamant that in fact such documents ... should exist. He's a lawyer, and lawyers by nature love agreements.
KB: Sometimes they're right.
B ... I'm only a simple businessman. I don't understand these things. I guess over my lifetime I've seen so many agreements that have gone wrong and so many handshakes that have gone right , but I think you're right. We're moving into an era when the litigious nature of society is changing the ways we do business, so I guess I'd have to say yes, we really should have agreements and agreements on agreements, because we are moving from the handshake mentality that I grew up with to the litigious nature ... in the United States you could sue just for walking out your front door. ... This is the society that we're doomed to live in.

The Bioplasma Division manager's comments on the role of legal agreements echo views put by businessmen in Macauley's classic 1963 text on noncontractual relations in business:[230]

> If something comes up, you get the other man on the telephone and deal with the problem. You don't read legalistic contract clauses at each other if you ever want to do business again. One doesn't run to lawyers if he wants to stay in business because one must behave decently.

Perhaps the most striking thing in CSL's evidence is the apparent perception that trust and good will still exist between Red Cross and CSL. From the perspective of Red Cross BTS Directors, the contract was needed precisely because trust was said to be exhausted.

Not all the reticence towards a contract lay with CSL but it was signed in late April. It is understood to provide for an annual meeting of an advisory committee made up of both parties. The meeting will consider projected production for the coming year. Red Cross will be able to 'inquire' about

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[230] *quoted by Braithwaite and Ayres in Responsive Regulation - Transcending the Deregulation Debate, OUP 1992, p 61:*

production processes and specifications and progress with developing new products, but will not be able to inspect. A Red Cross source said 'we still have to rely on what they tell us'. He conceded that if it were not for TGA the contract would do nothing more than put in writing the conditions blood banks have tried to achieve for many years in dealing with CSL.

'There will be no more standing jokes about six monthly projected returns which CSL doesn't fulfil', said one Director. Another said that CSL had described itself as a subcontractor of Red Cross in a TGA licence document.

> Well, then, it is time the Red Cross brought their sub-contractors into line. And if they can't perform, we should ... put it out to tender.
> KB: But they're the only player!
> The only one in Australia. We could go overseas - with the attendant problems that could bring of course - but what can you do? They chronically under perform, in yield, content, volume and preparedness to communicate openly with us.

Even an official Health Department spokesman in interview late in 1993 acknowledged the need for CSL and Red Cross to 'spell out the business they are to do with each other' in the form of a contract, whereas previously Federal officials had never indicated a view on this matter.

The contract between Red Cross and CSL is unlikely to give Red Cross the control it wants, for two principal reasons. First, the inefficiencies probably need more radical address than would be spurred by a contract. Contracts can't deliver attitude. Codifying or highlighting faults - whether positively or negatively expressed - may even bring out more resistance. Second, Red Cross and CSL are unequal partners. Without independent access to CSL or to TGA information, Red Cross cannot evaluate what CSL tells it.

When the contract between CSL and Red Cross was signed, the Head of the Bioplasma Division, Official B, said both parties had produced an 'excellent document'. He also said demand was increasing but plasma supplies from Red Cross had remained static, but he was convinced the two parties could work together to deal with the increasing demands being made upon them. 'The mutual trust so clearly in evidence throughout all the discussions which culminated in our new agreement makes me confident of continuing success in our vital relationship' the executive said.[231]

Red Cross also expressed confidence in the mechanism as an answer to their problems, at least publicly. There was hardly any point saying otherwise. Yet the contract cannot be much more than a written formulation of the conditions both parties seek with each other. It is not a mechanism for forcing CSL to disclose anything that Red Cross might find significant. When Red Cross forced the plasma pooling incident onto the NBTC table, CSL

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[231] *Inside CSL, June 1994, front page*

representatives didn't understand why Red Cross was so upset. 'They probably thought we were just finicky and parochial' said one official. 'They distribute vaccines around Asia, so why not our blood?' The contract is a symbol to wave around. More is needed than symbolism at this point.

13.1.2 Means for changing CSL

The real stuff of change, this author predicts, will come about between the two parties in three other ways, assuming it does change.

First it may come about if Red Cross uses the TGA or other parts of the Health Department such as Health Care Access Division, as a complaint channel, and pushes Health to fix Red Cross and other client problems with supply. As long as it remains in a position of unequal power, Red Cross won't be able to rely on settling its differences with CSL alone. The lack of success so far makes that plain. The formula will have to change.

Second, it will come about if CSL's lack of responsiveness to client needs is modified by management will, or by Government or public pressure, or possibly even market forces if non performance is high.

Third, improvement will come about by demand if Red Cross and other stakeholders such as hospitals and product user groups organise themselves to press for change, much as a public interest movement. In fact, while Red Cross cannot hope with its current operational mindset and lack of authority to function as a de facto regulator, it already contains many of the elements of a public interest force, though some of its officials may not feel comfortable with this reality.

The need for Red Cross and other CSL clients to draw an informed and empowered third player into the game is manifest. Besides, limiting the regulatory game to two players - TGA and CSL - even in an ideal setting, massively undermines the democratic will, as Braithwaite and Ayres observe:

> If we assume the regulatory agency is an uncaptured fiduciary of the democratic will embodied in the law, then it will bargain for the level of intervention required by the law. The firm that acts in the profitability interests of shareholders will bargain for a level of intervention lower than required by the law. It will play games with the political masters of regulators to mobilise pressure for such lower intervention. The result ... will be a level of intervention higher than the company wants and lower than the law requires'.[232]

However, if a conglomerate of public interest groups - Red Cross and its natural allies - becomes a player in the bargaining game, using empowered regulators as leverage, it can advocate for a level of intervention higher than

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[232]*Responsive Regulation, Braithwaite and Ayres, 1992 p 82*

the law requires, or at least equal with the law. This would at least partly balance the lower demands made by the corporation.

Red Cross is in a peculiarly powerful position to function as a public interest player in respect of CSL, for the following reasons. First, it is the sole Australian supplier of plasma to CSL. Second, within its ranks is considerable expertise and experience in the business of haematology and blood supply. The want of expertise on these matters is possibly the greatest barrier to other potential public interest groups entering the game. Third, Red Cross distributes CSL's products to users via hospitals and clinicians and has a natural interest in the regulatory goals of sound usage. Fourth, Red Cross is subject to the TGA Code on Blood and Blood Products and therefore must submit to inspection by the same authority that inspects CSL. This means that if it were to function as a watchdog on CSL by vesting its concerns in the TGA or the Health Department's Health Care Access Division, either regulator is in a good position to appraise the substance of the concerns raised because of their access to CSL and Red Cross. Fifth, it already has standing with Government and many other sectors relevant to the game. Admittedly, there are some potential conflicts of interest in Red Cross embracing the role of third player in the regulation of CSL, but these would not be difficult to offset.

What *is* needed is greater empowerment for Red Cross in its dealings with CSL. An obvious start could be made by permitting Red Cross to attend TGA inspections of CSL. (CSL could be given the same power in respect of Red Cross if it was able to show the need, or in any case when relations between the two parties became marked by more successful two-way communication and by trust.)

Red Cross should also use the self-regulatory opportunities within CSL in a formal and systematic manner to address its concerns. This could be done by recording in writing the sorts of problems mentioned to this author and routinely sending them to the most appropriate official at CSL. This might be a director specially designated by the Board to oversight supplier and customer relations, or the marketing manager and quality assurance manager.

Depending on the company's responsiveness, the complaint records might also be sent to the TGA, other Health Department regulators or even the Minister - whoever it is should be called upon beforehand to pledge their interest in the success of the process and should be educated by Red Cross so that they understand the importances of the process succeeding. This should be explained in the terms of the goals of regulation set out in chapter one of this report, all of which are incontestable from the viewpoint of regulatory players. Even if the Health Department doesn't care to involve itself in certain of these goals at present, it would not be difficult to secure their commitment. It will be even easier once the TGA has sorted out its role and responsibilities

in respect of the States. These external regulators need not be drawn into the detail of the negotiating process between Red Cross and CSL, but CSL should understand that if they do not improve their performance, Red Cross will call on the corporation's formal regulators to intervene.

By agreement between the parties, regular written reviews of progress should be made, through extra meetings of the National Blood Transfusion Committee or other channels. These reports should be agreed between the parties and signed by both, at least in the early stages. The Health Care Access Division of the Health Department and TGA as applicable should be informed of progress, as should other stakeholders such as hospital blood transfusion committees and user groups like the Haemophilia Foundation. As performance improves, CSL should be subjected to less disclosure to these parties. Of major importance is the need for Red Cross and other players to fully acknowledge CSL's progress.

Should it transpire that CSL has unstated grievances with Red Cross as supplier of product to them, they ought themselves to understand that they can initiate the same mechanism with Red Cross. In this way, the two players, who are so very dependent on each other and on whose successful relations consumers are in turn so dependent, will know they are playing on equal terms and should come to see in time that both can win. Red Cross will come to understand that 'dobbing CSL in', or 'running to the Feds' (or whatever computations make them timid and impractical in the regulatory domain now) are simply added significances that can have no place in the business of protecting the blood supply. CSL will no doubt find that taking it on the chin from Red Cross in a controlled context is preferable by far to reading about Red Cross exasperation in reports like this.

There are more opportunities for involving Red Cross constructively in a tripartite system of regulating CSL. But the principles are uniform. Red Cross has important cards and it should play them as needed. More communication, and better placed communication, with CSL is the entry point. Running on hope, waving around a set of symbols in the form of a written contract, or communicating without the threat of regulatory escalation in the event of non compliance, will likely go in the same direction as earlier efforts, that is, next to nowhere.

Red Cross is a vital and powerful public interest player in the game of regulating CSL. In 'personal' terms they have more to lose than almost anybody except CSL, if CSL continues to fail. But more than that, just as they receive donor blood in trust from citizens wanting it to reach fellow Australians in need, they are stewards of a great deal of vital information concerning the blood supply and are in a unique position of potential power and because of that. Information constitutes power - and so does trust. There is an implied trust on the part of Australians (whether they are aware of it or

No other player sits at the crossroads of supply and demand as does Red Cross. They should recognise the gains to be made for themselves and the public, and play accordingly through other players and directly, to make CSL responsive and efficient. This may require demanding some authority of Government and insisting also that regulatory agencies define and use their own powers. It may involve using TGA, Health agencies, the media and consumer groups to communicate for their cause as needed. But CSL can be brought to see and must be brought to see that it has no other option for its own survival than to be responsive and dependable and to demonstrate these qualities to all its stakeholders, including the general public, any of whom may need CSL blood products at some time in their lives.

Red Cross, because of its unique relationship with CSL , and the fact that it is way ahead of any other player in commitment and willingness to accept responsibility, is the obvious point of entry into the non-optimum situations described in previous chapters. In the view of some at Red Cross it may not be cricket for its officials to take on such a mantle. It may seem like a 'hill ten' at times, it may seem an offence against dearly held views of what constitutes seemly conduct for the Red Cross. But it is vital, for everyone concerned, that Red Cross proceed.

R.74 A complaints mechanism should be established within the Health Department for matters referred by Red Cross, clinicians, and other clients of CSL in respect of blood product development, manufacture and supply. Responsibility for receiving and co-ordinating complaints should not lie with the Therapeutic Goods Administration, but should lie with an official responsible for blood policy, senior to those officials with responsibilities for regulating the agency's business with CSL, or funding Red Cross via the States.

R.75 Designated Red Cross blood banking officials should be permitted to accompany TGA inspectors on inspections of CSL for manufacture of product derived from Red Cross owned starting material. Alternatively, such Red Cross officials should be given access to TGA inspection reports.

13.2 Other consumer protection groups

While Red Cross is well placed to play a major role in consumer protection, it has other roles as a harvester and supplier of blood and in caring for the interests of donors. The burden of these responsibilities may limit its potential for consumer protection, or at times may conceivably conflict with it. The solution is to give users a direct voice by Government empowering consumer groups to represent them. These groups should work co-operatively with Red Cross, benefiting from Red Cross expertise and experience and benefiting Red Cross with feedback about user needs and concerns.

13.2.1 Haemophilia groups

CSL claims their products are used by half a million people annually. Yet currently, the Haemophilia Foundation of Australia, with its State and Territory counterparts, is the sole user-representative group active in influencing supply, demand and quality of blood products in Australia. In the absence of other groups. this has the effect of casting the organisation into the role of a special interest group. Blood and plasma goes to make many more products than the clotting factors, and consumer demand for one product over another can distort overall supply and demand. While the national and global haemophilia population is numerically negligible compared to those who need other blood products and whole blood, their usage of clotting factors is high and their demand for the purest and best available products is understandable, particularly following the tragic effects of HIV on this group. If recombinant factor VIII takes over from plasma-derived clotting factors, there will be no effective consumer voice for users of blood and blood products in Australia at all, apart from Red Cross.

The Haemophilia Foundation organisation lobbies on behalf of fifteen hundred affected individuals. The Foundation's national Executive Director told the author 'we are quite neutral here at the Foundation'.[233] It has received considerable Federal Government funding since sixty percent of its members with severe haemophilia were contaminated in the eighties by Australian blood products containing HIV. It has also received funding and assistance from community organisations such as Rotary, from CSL in very small amounts pre-privatisation, and from commercial sources, such as the pharmaceutical company Bayer Australia Limited.[234] In 1992, the year CSL sought a licence for recombinant factor VIII from the Baxter company, the company gave the HFA its first substantial CSL funding, an untied research grant annually for the next three years. The Executive Director said this grant resulted from approaches they made to numerous corporations and was motivated by the threat of cuts in Federal funding, although this did not eventuate.

The organisation also lobbies for government to bring in more and different foreign blood products in preference to Australian-sourced materials, and is strongly advocating for recombinant factor VIII. The Executive Director believed the product should be available in Australia at the same time as its release overseas, but Australian product evaluators in the TGA disagreed. This executive said in December 1992:

> [Parents] have no choices here ... I [used to be] one of the group that thought: isn't it great I live in Australia where we have our own blood products, where we don't ... pay donors, we use our own blood, we don't bring in imported blood with all the inherent risks etc etc etc. I've now turned right around ... I've gone through HIV and found that

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[233] *preliminary telephone interview 1992*

[234] *for publication of Haemophilia Care - A Way of Thinking , HFA 1991*

> our blood transfusion service was one of the worst affected in the world ... really bad... So despite the fact that we have unpaid donors etc. it's not any safer than any other system. And I now, because of my work internationally, have been to many, many meetings with presentations with all sorts of companies who produce blood products, and I believe that they do just as good a job, if not better in some instances, than what happens here in Australia. ...We have dropped behind ... in the last five to ten years ... We just haven't got on with it here. ... CSL has always said to us 'we can't do a monoclonal product because its not cost effective to produce it for a small number of people'. ... It does take a lot of yield, it's difficult and it's expensive but it's a purer product. What we are looking at here is the purity of the product. ... if you've got HIV and you've got a compromised immune system ... because of the blood products.

The executive claimed that the HFA was also 'now a great resource to doctors, ... they see us now as a resource'. When asked how clinicians set treatment levels for their patients she replied that it was up to each clinician, and said clinicians are influenced by their readings of the literature that she gives them, 'medical stuff that comes across my desk on HIV and blood products', distributed to doctors in monthly mailings and at yearly meetings organised by the Foundation, 'but not in an advertising way'. The organisation provided statistics to a group at Monash University appointed by the government to review haemophilia treatment. The same executive said 'A lot of the [company] stuff is very impressive, to see all the stages that their manufacturers go through. I don't understand all the science but I understand enough of what they do to get the very clear message, how they harvest their blood ... regulations they operate under, ... I'm not the only one who's been turned around ... it's fairly obvious that our products are just a long way behind ... One of our members actually went up to one of the people, they have a lot of pharmaceutical companies displaying at these conferences, and said 'If your process were used on our material' - and they said [Australian material] would not be acceptable. Now that's only anecdotal.
RS: What company?
Can't remember. It was a German one ... I think.
The executive then referred to an article she had written about Australian product being a long way behind, and the problems in this country. She claimed that a CSL blood product executive had agreed with her.
KB: Is it [because of] bad equipment?
I think we've just got behind. [A speaker at an overseas World Haemophilia Association conference] said that nowhere in the world had it been proved that an *unpaid donor* system had worked. (emphasis added).

This executive's analysis of the merits of Australian-sourced product compared with other countries and with foreign commercial products is important, given the influential relationship the Haemophilia Foundation is

building with the commercial sector, clinicians, CSL, and in last year, with politicians and lay media. It is the same line of associative thinking as that of the commercial sector, who constantly claim that when non commercial blood products based on unpaid blood cause harm, this 'proves' that the non commercial sector is no better than the commercial sector, or that it is worse. Differential thinking, on the other hand, would lead one to ask *why* the harm came about and to differentiate amongst the many possible causes of product failure in either sector, whether it be failure by donors, screeners, collectors, testers, manufacturers, distributors, clinicians or regulators.

The promotion of the viewpoint expressed by the Haemophilia Foundation executive has two important possible effects with bearing on the regulation of blood products. In the first place it may create uncritical acceptance of or demand for foreign commercial products. Secondly, it may produce misplaced distrust of unpaid blood donation, the basis of the Australian system. Such views can take form in the minds of public, parliamentarians, media and others without any specific intention to form them on the part of the players involved in the debate. Most stakeholders have been starved of information with which to assess the import of what they hear.

The Haemophilia Foundation feels its highest duty is to obtain the best available products from whatever source and persuade governments to pay for them where the cost is beyond the means of individual users,. It does this by working through whatever channels will achieve this result, and this includes educating medical practitioners to their viewpoint.

There is a fine line between this approach and drug promotion. Pharmaceutical companies are prohibited under their own code from promoting prescription products direct to lay public in Australia. The Media Council of Australia's therapeutic goods code regulates the advertising of pharmaceuticals. A counter to the possible harmful effects of media dissemination of information about the merits of selected blood products by non-medical user groups, is to educate the media so they can understand the public health import of these representations and be aware of the need to draw on the views of a wider spectrum of players with interest in the supply of blood products and whole blood. Community-based consumer protection groups would be well suited to educating media to this end.

R.76 Consumer groups should be empowered by government with resources and information so they may represent the views of all users of blood and blood products.

PART FOUR: THE TROUBLE WITH THE NATIONAL FRACTIONATOR

CHAPTER FOURTEEN: HOW BROAD IS THE PROBLEM?

The questionable practices discussed thus far relate to CSL's Bioplasma Division, formerly named the Blood Products Division. One reason for wanting to interview senior management at CSL was to gauge the degree of corporate awareness of these practices. Another was to elicit a response to questions concerning general regulatory matters as these would have bearing on the Bioplasma Division of the Commission's activities.

When requests for interview were ignored the author pursued an alternate line of inquiry, of trying to determine if such practices were limited to blood product activities only, to see if recommendations for company-wide reforms would be needed to ensure changes in the blood processing division. No general attempt was made to access other official records because of official resistance already encountered. Then followed about eighty hours of interview with scientists and officials who have window onto CSL from the sixties onwards. The author asked whether CSL was adequately regulated in the view of the respondents. Follow up questions were designed to discover the source of perceived success or failure.

No respondents to this study ever indicated any problems with either the manufacture or regulation of veterinary products or anti venoms. (Brogan's history refers to difficulties in maintaining virus-free animals for testing purposes, which prevented CSL's manufacture of avian vaccines, for poultry and other birds. Brogan also blames increased competition and 'excessively stringent testing requirements of the New South Wales Department of Agriculture'.[235] (These requirements had been developed by NBSL in collaboration with the NSW Department.)

However, across a wide range of CSL's production activities. evidence was given of significant questionable practices, dangerously unyielding resistance to external regulators, and serious failures in self-regulation. The official CSL history is reliably silent on most of these, but refers to three instances of self-regulatory failure from the sixties.[236] The more recent questionable practices addressed in this report are not mentioned by Brogan's text, though he was given 'free and full access to CSL's records' by the then managing director. Brogan's accounts were found to be incomplete when followed up by the author, the data given rarely permitting the correct cause of the failure to be known. The instances mentioned are as follows.

14.1 Manufacture of cosmetic ingredients

CSL began development work on a bovine albumin for a cosmetic manufacturer to use in face cream. This was beyond CSL's statutory powers, not being for therapeutic use. Of why it occurred, the author says merely

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[235] *Brogan 54-56*
[236] *Brogan p 174-7*

'inexperience and naivete prevailed at CSL at the time.' Of how it was picked up, he says that 'realisation dawned' but not what prompted the realisation.

14.2 Products for infusion

The second self-regulatory failure involved production of large volume infusions under license from a foreign company, a project which was 'in trouble from the outset'. The product was not a biological product and therefore CSL did not have legal power to make it. The custom-made plant 'did not work to specifications'. Plastic ampoules from three different suppliers kept splitting. When CSL finally got into sporadic sales, the product was 'plagued by mould and discolouration'. The author's informants said that NBSL's inspectors finally gained access to CSL because of complaints of nonsterility including mould growing inside the bottles.

'All those involved at CSL gave of their best' in the manufacture of these infusion products, according to Brogan. Others, scientists trying to regulate CSL, maintained that CSL had simply failed to acquire fundamental knowledge in quality control procedures necessary to produce such a product and had 'bad programming, bad procedures and bad evaluations'. One informant described the production as an 'utter fiasco - someone at CSL went overseas looking for products they could make under licence. They didn't get [the production] right, but they marketed it anyway. There were complaints, and samples of the contaminated bottles came to NBSL. The plastics that they used were not completely suitable for the purpose. This meant CSL had problems sealing the bottles; stuff leaked out of the plastic containers into the outer plastic envelope and provided an ideal medium for mould growth. 'There was the most prolific and spectacular yellow and green mould growth' another informant said.

These products had to be sterilised. This was done by autoclaving them, which involves heating under pressure for a specified time. This treatment was needed to render them safe from micro-organisms which can cause hepatitis, gangrene, tetanus and other infections. CSL had problems in autoclaving the plastic, said an informant, 'and so they played ducks and drakes with the sterilisation procedures, altering the temperature and pressure conditions'. CSL was meant to check the progress of this procedure by recording temperatures with probes in the autoclave, and observing the index on a time/temperature recorder. The recorder didn't work however, so CSL had no knowledge of how effective the procedure had been.

This failure was checked by the National Biological Standards Laboratory acting on behalf of the public, not by CSL's 'self-regulation'. NBSL ordered the immediate withdrawal of all stock, according to this author's sources. CSL sought to cease production. No contract had been struck with the overseas client for the manufacture. CSL had to pay its way out, says Brogan, but he doesn't say why. CSL had not strictly adhered to the terms of their licensing agreement. Brogan refers to losses of 355,800 pounds from the

venture, apart from costs of lost staff time over two years and the cost of materials.

14.3 Antibiotics

In the third episode, CSL signed a contract to bring in foreign raw materials for antibiotic production before a market had been established via product registration. Then there were 'difficulties in satisfying the National Biological Standards Laboratory concerning the moisture level in the product', an artful way of saying CSL failed on quality control. If CSL had had quality control procedures in place they would have tested the material themselves and found the moisture content was deficient; alternatively, if they had not resented the efforts of NBSL to assist them through inspections, the defect might have been picked up that way', an NBSL source told the author.

14.4 Home testing kits for sexually transmitted disease

CSL announced in the lay media their intention to develop manufacturing home testing kits for sexually transmitted diseases. There is various State legislation against these kits [237] - which, along with over the counter HIV testing kits are criticised by the Inter Governmental Committee on Aids Legal Working Party for their lack of specificity. They are considered to be highly problematic as first line tests for AIDS. The use of these tests at home also affect the ability of agencies to monitor disease spread. Users may not present for counselling although it may be vital for their welfare, for the prevention of disease spread and for tracing contacts already infected. TGA and Health Department policy stances together could effectively prohibit marketing approval for such kits. A company official told the author in 1994 that the proposal had been abandoned, for reasons of this type.[238]

14.5 Diagnostics, penicillin, vaccines, water supply

Staff of TGA's predecessor, the National Biological Standards Laboratory, told the author their scientists were continually suspicious of CSL and 'itching to get in'. They would infer or hear of slipshod procedures occurring and were frustrated at having to wait on an opportunity to get into CSL in order to find proof. Their concerns included ineffective viral inactivation, manufacturing failures, inadequate sterility procedures and substandard plant construction, applying to a large range of products including infusions, penicillin, influenza vaccine, an arthritis diagnostic product called adrenocorticotrophic hormone or ACTH, derived from sheep pituitary glands; polio vaccine, whooping cough vaccine and blood products.

CSL was reported by a number of sources to have chronic difficulties in keeping their water supply free of bacteria and pyrogens. Water is used to clean containers and production machinery between batches of plasma fractionation and other manufacturing processes, and also goes into some biological products. Saline solution for example, is used to dilute various

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[237] *ref to the Inter governmental Committee on Aids, Legal Working party*

[238] *Personal interview with CSL official 1994.*

preparations for intravenous infusion. NBSL officials found water in clear tubing was growing algae because the tubing was placed in front of windows; they say CSL technicians did not know that this prompted the growth.

Of ACTH, the preparation used to diagnose arthritis, inspectors found the product was quick acting when it should have had a delayed action, because of a mistake in the formulation by CSL. This could lead to an overdose, depending on how much the doctor prescribed, which was 'not necessarily' a hazard, but could be. When the regulators wanted to fail the product because of the problems associated with it, CSL claimed they were 'part of the Department and couldn't be regulated. They felt they were out of out reach. They felt the rules didn't apply to them'.

14.6 Polio vaccine

This case study involves manufacturing and testing failures on a wide scale for Salk polio vaccine, forced regulatory intervention by TGA's predecessor NBSL, and CSL's response to that intervention. This account has never been published before. The 1990 official CSL history contains a version of it which contrasts markedly with the version here. The official historian had, as mentioned already, 'free and full access' to CSL records. Why major sections are omitted is of course unclear. This author's account relies for the most part on evidence from individuals, and upon some documentation.

CSL began manufacturing poliomyelitis vaccine in the 1955, using the Salk method. This type of vaccine production involved hard, tedious work. Monkeys were caught in Asian countries (not Africa) and brought to Australia by chartered aircraft. Tissue cultures of minced monkey kidneys were seeded with live virus and left to grow, then harvested, put into a solution which was filtered for the liquid vaccine, and by stages inactivated. This was done until all the virus was gone, so that infectivity was eliminated but the vaccine would still elicit the desired antibody response when mixed with other material before issue for use. The slightest trace per gram of polio contamination in the final product is enough to transfer the disease to the recipient on vaccination.

Polio had for long been present in the community, occasionally turning epidemic. It has a high mortality rate and leaves many survivors deformed. 'The community today has no appreciation of the tragedy wreaked by poliomyelitis', says Brogan.[239] In Australia there was a steady rise in the age of people contracting it, although young children are particularly at risk.

14.6.1 Foreign polio vaccine contaminated with live virus

In 1955, there was public jubilation around the world over the US release of Salk vaccine. Then the Cutter tragedy happened. Two hundred and four cases of poliomyelitis were contracted, seventy nine by children vaccinated

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[239] *p113*

with the Cutter company product and a hundred and twenty five by the people that they infected. Eleven died. A report by the US Surgeon-General in June 1955[240] found there were very small amounts of live virus in the vaccine, but sufficient to cause polio. Scientists investigating the tragedy also looked at other biologicals companies. They declared that the virus inactivation process was inadequate 'in the hands of some members of the industry'. They also said that live virus was frequently found in a vaccine pool of combined virus types, known as the trivalent vaccine, even when that pool was made up of monovalent pools which had tested negative. (There were three vaccine types to combat the three types of polio occurring at the time and these were combined into the final 'trivalent' version.)

At this time, the US regulator of the companies making polio vaccine, the precursor to the Bureau of Biologics, required manufacturers to submit protocols of manufacturing and testing of batches of vaccine to the authority before approval would be given for their release, but it did not require manufacturers to notify it of failures of batches to pass safety tests. Had it had such a requirement it would probably have been alerted to the existence of a problem in time to avert the Cutter episode, for the investigators found Cutter was submitting reports of protocols of successful batches to its regulator, the Bureau of Biologics, but withholding data on failed batches. Such failures were found with several manufacturers.

Was CSL aware of the findings of these investigators concerning manufacturing failures for Salk polio vaccine? The CSL official history refers to the official Report of the Cutter tragedy in a chapter entitled Poliomyelitis Vaccine: The Last Major Triumph? The then Director of CSL, the late Percival Bazeley referred to the report when writing in the Medical Journal of Australia in 1956.[241]

One would expect Dr. Bazeley to be conversant with the contents of the Cutter report because poliomyelitis was his area of expertise at the time. He had long been passionately keen to combat poliomyelitis with a CSL vaccine. Tissue culture work had begun at CSL in 1951. Bazeley had been responsible for the pilot developmental work for the Jonas Salk polio vaccine project in the US, where he worked directly under Dr. Salk. According to the CSL History, Sir Macfarlane Burnet, himself keen to see a poliomyelitis cure, had dealt directly with Prime Minister Menzies and Salk to create a path to the US for Bazeley to work on polio vaccine development.[242] When Salk made history and Dr. Bazeley returned to Australia, he was considered a celebrity because of his US contributions to the development of the vaccine. The Government readily provided resources for the Australian production of the Salk vaccine at CSL. Bazeley established and ran the unit. Brogan says 'the

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[240] *Public Health Service Technical Report on Salk Poliomyelitis Vaccine, June 1955, US Department of Health Education and Welfare*

[241] *P L Bazeley, 'Immunisation against Poliomyelitis', Medical Journal of Australia, 19 May 1956, pp 821-2, at p 275, footnote 19 of Chapter 12 referred from footnote 38 on p 276.*

[242] *Brogan 114*

expertise and experience of Val Bazeley seemed to overcome difficulties almost as soon as they were recognised, and his leadership, demanding thought it was, led to a sense of pride and team spirit'.[243]

14.6.2 CSL's polio vaccine contaminated with live virus

But in 1961 and 1962 CSL confronted two major problems with its polio vaccine. One was the detection of live virus in two of the three vaccine types, as in the Cutter incident. These types were derived from highly virulent strains of polio. Therefore the manufacturing failure represented a serious potential threat to vaccine safety in this country. The second problem was that cell cultures, used to test vaccine samples for the presence of live virus, were failing sensitivity testing. These test results indicated that the cultures were not sensitive enough to polio viruses and the cell culture. In short, they could not be relied on to detect live virus.

14.6.3 Government secretly imports foreign vaccine

These problems led to delays in issue of vaccine by CSL as batches failed. Government secretly imported vaccine from overseas countries to cover for the product failures of CSL, up to half a million doses at a time.[244] Where foreign supplies were unobtainable, vaccination programs were interrupted. The delays and interruptions received press coverage and attracted parliamentary questions, as polio epidemics were occurring at the time, with 2,300 to 2,400 cases annually in Australia.[245] Data presented to the Poliomyelitis Committee of National Health and Medical Research Council in 1961 show that the pattern of incidence of polio had changed over the previous thirty years from isolated epidemics in the earlier period to an endemic (always present) disease with a high rate of epidemics.

Brogan claims[246] that there were already problems with polio vaccine before 1960 but maintains they had been conquered 'without detriment to the flow of finished product'. This seems improbable. Consecutive batches, as he points out, had been failed by the Director-General before 1960, despite clearance by CSL's Director. Two batches represent at least three month's production. As epidemics were occurring, demand for the vaccine was urgent.

14.6.4 CSL fails to correct its vaccine failures

To identify the causes of these problems which CSL confronted in 1960, they had been studying their own production, testing methods and data from vaccine batches for many months, but had failed to find answers. In April 1961 the Director-General of Health requested information from the CSL Director on the history of issues of polio batches. Bazeley admitted that two

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[243] *Brogan p 119.*

[244] *eg minutes of NHMRC Committee on Epidemiology and Infectious Diseases meeting at CSL 7.2.1962.*

[245] *Poliomyelitis Vaccination Reviewed,, in Modern Medicine, 21.12.1970*

[246] *p 122*

recent batches had failed inactivation and safety testing and according to Brogan he detailed three difficulties.[247] He said that 'experience' had convinced him the testing was inadequate and this had been tightened but it had greatly increased the workload. He said the monkeys had been poor quality, some containing simian viruses (see later). He said there were staff shortages because of Public Service Board cuts and his repeated requests for more people had been ignored. He could hardly have omitted mentioning the testing problem. The rest of the defence fits the CSL characteristic of blaming external factors, what Braithwaite calls the 'culture of excuses'.

14.6.5 Expert Committee of NHMRC asked to investigate

In May 1961 an expert committee of some of Australia's top virologists, meeting as a sub-committee of the National Health and Medical Research Council, was set up by the Minister at the instigation of the head of the Health Department (the official history says Bazeley requested it)[248] to inquire into 'fundamental problems in virology thought to be involved in the technical difficulties newly encountered in the production and testing' of CSL polio vaccine. They were to report to the Minister on their findings and suggested remedies. The Committee was chaired by Sir Macfarlane Burnet and included other eminent scientists in the field of virology in Australia, as well as CSL representation.

14.6.6 Expert Committee fails to finds causes

The Committee was given CSL records relating to manufacture and testing. It met in May 1961 and was unable to identify the actual causes of the problems. It found there was 'no immediate occasion for a special investigation into virological recombination or reactivation'. The consideration at all of such exotic explanations as recombination or reactivation meant the Committee had already ruled out the possibility of anything being wrong with the production process for Salk vaccine at CSL. (Recombination in this context means the co-operation of two or more poliovirus particles whose RNA has been damaged to restore infectivity of a host cell to which they have been absorbed; reactivation means restoration of infectivity of virus particles which have been made non-infectious by physical or chemical damage.) Brogan tells us that the Committee recommended setting aside extra samples for repeat testing. Referring to a CSL file[249] he says the Committee told the Minister for Health 'that the allocation of staff responsibilities be changed to eliminate possible human factors as a cause of divergent results between CSL and Fairfield,'[in sensitivity testing].

Here the official history takes over the story, telling us that in August 1961, only three months after the Committee commenced its investigation, the Committee suggested it disband since it 'appears that the advice given at its

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[247] *Brogan 123*
[248] *p123*
[249] *61/1213 at footnote 59 of p 124*

first meeting and changes initiated by [the Director] have been effective in dealing with the immediate problem'.

This opinion seems based on optimism rather than fact. Given the capacity of CSL's limited production line and the interval between batches, (averaging ten a year) the pronouncement of an all-clear could only have come after one or at the most two batches. Yet the production failures which had caused the Committee to be brought in had been intermittent, like the testing failures. That suggests a run of clear batches should have been required before the problem could be pronounced fixed. Indeed, if the Committee had followed overseas procedures for consistency requirements they should have required each batch to be the last of an uninterrupted sequence of five batches, each of which had passed safety testing before it could be released. To have imposed this requirement would have required CSL to have ceased supplying Salk vaccine in Australia altogether, at a time when availability of vaccine from overseas manufacturers was limited. The fact that CSL was operating under a dispensation regarding consistency requirements should have meant that other available regulatory mechanisms were tightened to account for this slack, rather than loosened as would be the case if the Committee's opinion had prevailed.

14.6.7 CSL'S official history omits relevant data

At this point the official story of polio vaccine ends abruptly with the following statement: 'This brief account of the supply problems of 1961 does not do justice to the intricacies of the science, nor to the breadth and dedication of the work undertaken to restore the situation. It is to be hoped, however, that it provides a sufficient statement for a general history such as this.'[250] That depends on whether the purpose of the text is to promote a favourable image for CSL or recount basic facts.

Here are some relevant omitted data. The majority of these data were known to considerable numbers of people at the time. Indeed, in December 1960 and March 1961 the Director-General of Health issued press statements about vaccine shortages. (CSL's then Director Percival Bazeley wrote to the Director-General about his press statements saying 'I must ask you not to repeat this form of public announcement unless you have my agreement personally beforehand'.)[251] But although numerous people know what really lay behind the polio problems, the actual reasons have not been aired. That they have stayed secret until now is a function of CSL's desire. It is also a function of the Health Department's warped interpretation of official secrecy versus disclosure over many decades, which has served to gag officials wishing to disclose in the public interest.

It will be interesting to see whether that suppressive ethos is still in evidence, that is, whether any attempt is made to identify, intimidate or punish any of

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[250] *p 125*
[251] *Brogan p 150*

the individuals who have spoken with the author about the following events of more than thirty years ago.

14.6.8 Intervention by NBSL scientist

The 'supply' problems, as the official history euphemistically calls them, did not end with the recommendations of the expert Committee at all, nor even in 1961. After the NHMRC Committee failed to find the cause of polio vaccine manufacturing and testing failures, a watchful and very concerned virologist in the Health Department's NBSL inspectorate asked for permission to investigate. This official, V, was well versed in the Cutter tragedy and could have unravelled CSL's problems years before, without the need for an 'expert committee' and major delays. Neither CSL - nor the Federal Government- sought the assistance of NBSL, which had recently been established as the national control authority with responsibility for ensuring the safety of pharmaceutical and biological products, including vaccines.

V knew that CSL's problems had not ceased when the Committee issued its findings. (What the Committee meant in its recommendations by 'eliminating possible human factors' is unknown. However a CSL official subsequently reported that sabotage had been put forward as a possible reason for live virus in the final product. CSL had tried to solve their problem by putting locks on the cold rooms where the monovalent and trivalent pools were stored, pending results of tests.)

V thought it very likely that CSL'S problems with live virus in monovalent pools and trivalent batches of polio vaccine were continuing because the virus inactivation process was failing and that therefore the expert NHMRC committee had been wrong. This would mean Australia was at risk of its own equivalent of the Cutter tragedy: that while most children would be protected after three doses of the vaccine, some might contract poliomyelitis as a result of vaccination. Furthermore, since vaccine production had begun in 1956 but the residual live virus problem only became apparent in the late fifties, it was probable that the problem would intensify over time.

This virologist wished to reopen the matter. Anticipating resistance from CSL, he sought and obtained the permission of the Director-General of the Health Department to discuss his contrary views with the chairman of the expert committee, Sir Macfarlane Burnet. This was given and V carried a letter from the Director-General to his meeting with Burnet in Melbourne at the Walter and Eliza Hall Institute for Medical Research. V reports that the chairman said he did not think that live virus, in the small amounts seen in CSL's vaccine, was capable of causing disease in children. Yet top scientists in the field of poliomyelitis at Yale University had considered that the Cutter tragedy proved the opposite. V was astonished.

Having failed to obtain the chairman's support, V then asked the Director-General of the Health Department for permission to study CSL's testing and manufacture at first hand. He went to CSL with the backing of the Director

General and the head of NBSL. There he received every assistance from the two senior members of the Salk vaccine production unit with whom he liaised, Leo Davis and Bill Collins.

14.6.9 Tracing the testing failure

But V needed information about the status of the American live virus standard, the material against which CSL calibrated its own standard. (The standard is the material used to test cell cultures used in safety testing for sensitivity to polio virus. Samples of vaccine are put into cell cultures which are left to grow). As these two officials had no information about the history of the US standard V had to pursue this matter with Bazeley, recently demoted by the Public Service Board as Director of CSL, as seen above had worked and studied with Jonas Salk and was CSL's expert on Salk vaccine. When V approached him in the company of a CSL Salk production scientist, Bazeley called V an 'inquisitor sent by the Department of Health'. Finally V was able to pacify Bazeley and extract the information he needed.

V soon demonstrated that the American standard had been partially inactivated when it was supplied to CSL. This sub-potency was passed on to the CSL standard when it was calibrated against the US standard. It had lost roughly eighty percent of its activity when CSL got it in 1956 and more since. All that was needed to solve the sensitivity test problem was an adjustment to the standard, by changing the dilution.

He obtained copies of the data provided to the Committee by CSL. Studying it, he concluded the data on contamination had been misinterpreted and that the CSL data on its own vaccine batches closely resembled in general terms the data of US manufacturers given in the US report of the Cutter tragedy.

V's considerations also led him to conclude that the problem with the vaccine was greater than had been thought by CSL. Not only was there more live polio virus present than CSL's tests had revealed, but there had probably been other inactivation failures which had not been detected. Coupled with the data in the Technical Report of the Cutter Episode, CSL's inactivation procedures had to be considered highly suspect at least.

The fact that CSL had to repeat safety tests, necessitated by the chronic failure of the sensitivity tests, had caused a good deal of delay yet the repeat tests had reduced the likelihood of these batches being issued with live virus in them. Had V pressed for the standard to be corrected at this point, CSL would have done fewer safety tests. This would have raised the risk of contaminated vaccine being released, since there was still a fault in production. Therefore V expediently refrained from forcing CSL's hand to correct the standard at that point. To him the only sensible course was to make that correction only after the live virus production problem had been solved.

14.6.10 Likely release of contaminated polio vaccine

However, CSL had not been completely saved from themselves by the fortuitous need to repeat their safety testing, because in some cases retesting had not always been necessary. Because of this, there was a substantial risk that a few batches of polio vaccine containing small amounts of virus, sufficient to cause the disease in recipients, had already been issued for use in the vaccination campaign. V moved quickly onwards to discover the production fault causing live virus in a substantial number of batches. (A batch was roughly three to four hundred thousand doses)[252]

14.6.11 Tracing the production failure

Based on overseas manufacturers' experience and Salk's polio theories as well as the CSL data which had been given to the Expert Committee, V narrowed down the most likely causes of fault to the filtration stage of manufacture, before inactivation processing. This is when the brew is filtered to let through the liquid vaccine and strain back the particulate matter, including bits and pieces of live virus. He could find no other fault in production methods capable of explaining the problems. It appeared that the Committee may have misinterpreted some of the data they were given by CSL.

CSL was using filters of minute ground glass fragments bound together. These scintered filters could develop cracks and over time their porosity could also increase. They had been discarded by some manufacturers in the US and Canada, including Connaught who claimed this solved their problems with residual virus in the polio vaccine. (Connaught was supplying large amounts of vaccine to Australia to cover CSL's failures.)

14.6.12 CSL refuses to correct production fault

V recommended replacing the scintered glass filters with compressed fibre (Seitz) filters being used successfully by some, if not all, vaccine manufacturers in the US and Canada. CSL refused and continued using glass ones, even though the residual live virus problem continued to interrupt supplies.

Polio epidemics were continuing in Australia. As one source said 'the Department of Health had had a bellyful of throwing out vaccine ... public servants were wetting their pants'. Overseas suppliers in a number of countries could scarcely meet Australia's demands. After another failure and another shortage of vaccine, the Director General of Health was brought in again. A meeting was convened in his office with the Director of CSL and V. The Director spoke yet again of CSL's efforts to overcome their problem and his confidence that they would be successful. V replied that unless CSL changed its filtration technique there would soon be no CSL polio vaccine at all.

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[252] *extrapolating from data in CSL's official history and based on NHMRC Committee minutes.*

The Director-General asked CSL's Director to meet with CSL scientists and V to hear CSL argue their case. (At one of these meetings between NBSL scientists and executives and the Director-General, the Deputy Director-General was present. He had been responsible for CSL when employed further down the departmental hierarchy. His response to the refusal of the scientists to approve the release of contaminated batches was to attempt to 'stand over' them and have the vaccine issued.)

14.6.13 CSL's capitulation forced by NBSL scientist
At a meeting at CSL in Melbourne, CSL put their case and V explained once again why new filters were needed. After some discussion, the new CSL Director asked the clutch of CSL scientists present and V to resolve the matter by a vote! All those who were against the proposed change were to raise their hands - and in the presence of their boss who was highly antagonistic towards V and all he stood for. V watched aghast as the hands went up. V responded that scientific matters were not to be decided by a show of hands and he regarded the vote as invalid. He informed the Director and scientists that he would report the proceedings to the Director-General. The CSL Director then said that CSL would change its filters.

14.6.14 CSL Director censors contact with national regulator
Before V left the meeting the Director told him an 'iron curtain' would have to be drawn between NBSL and CSL. NBSL's Viral Products Section was due to take up residence in a laboratory on CSL grounds shortly. This was to allow NBSL to continue in its role of assisting CSL to solve its problems, (and to take over the repeat safety testing role previously being carried out by Fairfield Infectious Diseases hospital).

After the Director made his remark to V about drawing an iron curtain, CSL officers confirmed receiving instructions not to communicate with NBSL's virologists. Nevertheless, where relatively junior scientists considered the exchange of information was essential, they continued to participate in covert exchanges across the curtain.

14.6.15 Production failures cease
The filters were changed and CSL experienced no further difficulty with virus inactivation for the monovalent and trivalent types. The inescapable conclusion was that the scintered glass filters, after performing satisfactorily during the first few years of Salk vaccine production, had become faulty in some way. (There is some suggestion that they were cleaned with an acid that eroded the glass, letting virus particles through).

14.6.16 Later batch failure due to another cause
Later, CSL had trouble with another failure of testing procedure which had to be investigated. The fault this time was that the test cultures weren't lasting the distance and therefore couldn't detect the presence of any polio virus that may have been in the preparation. One scientist informed the

author that the cultures were of such poor condition it was doubtful if they could have supported polio growth at all, yet CSL kept on using them.

14.6.17 Should CSL have detected its problems?

Dr. Bazeley had the Cutter report. Had he referred to it he should have seen remarkable similarities between his own production records and those of US manufacturers prior to the Cutter episode. Informants laughed at this idea, saying the faintest suggestion that there could be any similarity between his Salk unit and Cutter's would have made Bazeley 'apoplectic'.

That malfunction of filters was not considered the most likely cause of the manufacturing failure is difficult to understand, unless, again, CSL was completely ignorant of the notorious Cutter incident and the report on it. Yet Bazeley, as seen above, wrote about it in the Medical Journal of Australia in 1956. Whether the NHMRC expert Committee headed by Sir Macfarlane Burnet had the Cutter report from CSL or any other source is not known. A former Health Department official told the author that at this time such committees did not have the services of a research Secretariat in the Health Department as they do now. They 'discussed issues with other people, friends in high places I suppose'.

CSL could have obtained help in detecting their problems from NBSL from 1960 if they had wanted it. The Health Department regarded CSL as part of the family. CSL saw it differently, when it came to matters such as reporting home with failed test results. CSL's management had a habit of resisting regulation or external help, seeing it, revealingly, as 'surveillance' and a threat.

NBSL's virologist, looking at the data given to the Committee by CSL, had seen the problem. For CSL not to have seen it would have necessitated them ignoring the data, for some reason, or seeing it but not recognising its significance. On this point, one informant said 'It comes back to the quality of the scientists who end up in industry - academics had fashioned the idea that science graduates who go into industry are second class citizens. That makes anyone with any ability reluctant to join such organisations. They end up getting people without much real scientific perspective, people who are not taught scientific thinking, only cookbook science and scientific facts.' This informant also believed that a lack of adequate scientific leadership was a major problem at CSL.

It is of interest that the scientists involved 'on the ground' in the polio vaccine production and testing were found by NBSL to be adhering well to the processes they had been taught, and had done their best to comb their data for clues to the cause of the failures. It was when a larger viewpoint, an analytical perspective was required, that they were out of depth. But there is no point criticising these scientists for not doing what they were not trained to do, for trying to assign responsibility where neither knowledge nor the duty to have knowledge lay. That larger viewpoint necessary to unravel the

production and testing failures could only really have been provided at the highest executive level of the project, and required either the scientific ability and will to evaluate the situation and locate the source of the problem, or alternatively a *timely* resort to external review. The evidence suggests that when neither happened the responsibility for both failures lay at the most senior level of the organisation.

14.6.18 Was live virus in polio vaccine released?

Given that the tandem problems in manufacture and testing were chronic and the reference standard had been progressively losing potency since 1956 when it hadn't been up to scratch anyway, how do we know that polio vaccine containing live virus particles was not being issued by CSL to Australian children before NBSL forced its way in and cleaned the problem up? 'The odds are that vaccine containing small amounts of live virus *did* go out' an expert informant told the author.

14.6.19 Did contaminated vaccine harm recipients?

Did it cause polio in the recipients? In addressing this issue the author was dependent upon expert advice from among the group of scientists who assisted this study.

Performance of vaccine in the field was subject to surveillance by State Departments of Health. Their data shows some cases of poliomyelitis occurred in the three weeks following the first dose of Salk vaccine. However, as polio had been epidemic in some States in summer and early autumn for several years, the statistical problems prevent this possibility being tested.

The NHMRC obtained statistics showing polio cases in a substantial proportion of people who had received one to three shots of CSL vaccine. Commonwealth Year Book statistics report the numbers of cases of polio occurring in individuals who had been vaccinated between 1956 and 1967, the year after Salk vaccine was replaced by a more effective vaccine called Sabin. They show fifty four cases in 1959, rising to one hundred and five for 1960, four hundred and fifty for 1961 and two hundred and sixty for 1962, then dropping to thirty six in the following year, after CSL's production failures were finally stopped. The 1961 statistics could derive from two periods of epidemicity (as the disease characteristically increased during summer) but most would be likely to arise from the end of 1961 to the beginning of 1962. It was mentioned at the beginning of this case study that CSL's problem with live virus in their vaccine occurred in these two years. They were the two highest totals of any years in which Salk was issued, apart from 1956 when vaccination campaigns were just getting under way.[253]

Do these statistics prove anything? The statistics prove nothing conclusively either way, other than that vaccination campaigns, to that time, had been

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[253] *that year shows 1,192 cases.*

unable to prevent epidemics. the vaccine didn't work in those cases. If a vaccine is being used in the face of an epidemic, as was the case in Australia at this time, cases of polio induced by the vaccine itself would be very difficult to detect against the natural occurrence. The statistics show the highest incidence in NSW and Queensland, where epidemics were occurring. In the Cutter episode it was only possible to demonstrate the connection between the disease and use of the vaccine because the vaccine had been used in areas of America where there was little or no naturally-occurring polio to mask the observations of what the contaminated vaccine was causing in recipients. Also, after an epidemic, there is a trough in incidence as the density of the 'susceptibles' builds up to a point where another epidemic can be sustained. An expert adviser told the author that the Year Book statistics were 'not inconsistent with seeding going on', but that is all one can say.

Could other proof be furnished? The same expert advised the author that, conceivably, if viruses had been isolated from these cases and kept deep frozen over the years in the virology department of a hospital or somesuch, their RNA could be analysed and compared with that of virus strains used in manufacture at the time. (In this way, in the early seventies it was established that nineteen of twenty one outbreaks of foot and mouth disease in Europe had been caused by the presence of live foot and mouth virus in the vaccine used to prevent the disease.)

14.6.20 Discussion

The polio case study reveals a number of practices and attitudes. Many are like those found more recently in the blood product division of CSL. Poor scientific method, resistance to external regulators, refusal to admit error, management hostility towards internal efforts at correction, undue separation from relevant research communities, failure to read relevant scientific literature, refusal to reassess operating methods in the light of new findings, lack of accountability within the company by production and development executives, too many tasks concentrated in one person, lack of recognition of harm caused by faulty products, lack of concern for safety, failure to inform the public of risk, and defaming of regulators within their professional and expert communities, are some of these elements.

14.6.21 Defaming of regulators

About the time the fight over Salk production was over, it was alleged to V that CSL's Director had told a Health Department official and members of the poliomyelitis committee of the NHMRC that V was 'antagonistic to CSL and had used his position to torpedo CSL'S vaccine production program'. This is a most darkening and untrue construction to put upon the action of a regulator in the national control authority who in order to avert disaster for Australian children had tried to help CSL solve their own problems despite extreme hostility from senior management. At the same time of course it is a construction which is most revealing of the mentality at CSL.

Defaming regulators may seem to some a petty or side issue, but is less so than it seems. For a start, a wise regulator would hear it as a signal to look more thoroughly at the production area of the company or of the individual originating the defamation. But there are other reasons why defamation should not necessarily be ignored. In the same way that employees in a manufacturing company will perform better in a just and safe environment, so will government employees. If inspectorates and product evaluators such as the Therapeutic Goods Administration and NBSL were permitted to disclose more of their surveillance results, inspection findings and test results to the public, defamation of regulators would likely have little place. The morale of regulators would rise as a result of receiving publicity for their good works. The regulatory failures disclosed could also serve as vital cautionary messages or as education for other manufacturers who may not be aware of similar failings in their own manufacturing practice.

Those they regulate would also know their failures could become known to a wide audience, including consumers, shareholders, politicians and media, which would serve as a further impetus to perform well at the same time as increasing the involvement of these external groups in the regulatory process.

Governments who expect their regulators and other officials to do their best at protecting the public from dangerous goods and practices but to lie down and be trampled on in public by critics, are short on understanding of how to use their most valuable asset. The morale, commitment and performance of officials in agencies which were not censored from public comment was found in this study to be markedly higher than in agencies where communication was suppressed by spoken or unspoken order of senior officers. For example, AQIS, the Trade Practices Commission, and the Federal Bureau of Consumer Affairs (prior to censorship by the current Minister from late 1993) contrasted markedly with the TGA, some other sections of Health, the Department of Finance and much of CSL.

It is hard to appreciate and hard to convey the depth of feeling and concern amongst these scientists who have for so long been silent while CSL gave the world their version of vital events impinging on public health and safety. When the author contacted one NBSL official and opened with the standard question 'Can you comment on how CSL responded to external regulation?' he could not stop laughing for some minutes - not that he thought the subject was funny. Laughter was a common response, the laughter of rejection or incredulity or anxiety, often changing to bitterness, anger or contempt. Some said the subject sickened them. Even officials who chose not to talk, gave similar indications. As one put it: 'They claimed to be "The Nation's Laboratory". Pah! The one area at CSL that was highly efficient was PR'.

14.7 Simian virus DNA in Salk vaccine

Just as the official history omits vast tracts of applicable fact from the account of polio production, so does it leave out relevant facts about the presence of

monkey virus in the vaccine. Again, it is not known if all the facts are on files and were at that author's disposal.

SV40, or vacuolating virus is a simian (monkey) virus which caused major problems in Salk vaccine manufacture. It is a common infection in monkeys, taken then as now to be a possible human pathogen which therefore had to be excluded, yet known to be more resistant than polio virus to inactivation with the formaldehyde used on the Salk vaccine preparation.

CSL's biographer tells us that the problem was eventually solved by the excellent work of a CSL biochemist, John Withell.[254] Sources agree that John Withhell's work was excellent, but say he was at NBSL by this time. What wasn't mentioned in the official history is that NBSL's scientists were in dispute with CSL because CSL continued to carry out an ineffective test on the material for SV40 virus presence. NBSL finally had to insist that CSL adopt a proper test instead of the easy but ineffective one.

CSL was warned about the low but not insignificant risk of SV40 DNA in polio vaccine, according to the author's sources. Unlike the virus, the DNA couldn't be detected. This DNA could become incorporated into the genome or chromosome set of the host and there become active, causing disease. It appears that despite warnings, CSL issued the Salk vaccine anyway.

It is now thought by some experts, because of animal test results, that SV40 may act as a co-carcinogen with asbestos,[255] potentiating its action for producing mesothelioma, the mostly inoperable tumours which can be found in the lungs of individuals exposed to asbestos dust. The heavily litigated asbestos industry would no doubt welcome a chance to leven their burden of liability if they were able to demonstrate that litigants exposed to asbestos and CSL Salk polio vaccine as well were more vulnerable to SV40.

14.8 CSL resists introduction of safer polio vaccine

By the time CSL's Salk production had been straightened out by an NBSL scientist there was an alternative superior vaccine in use. Sabin not only protected the recipient but also prevented most recipients from spreading the disease. Unlike Salk vaccine, Sabin conferred immunity in the intestinal tract, preventing excretion of live virus in faeces to infect contacts. Overseas field trials in children were impressive. Taken by mouth, it could be given by nursing staff, saving time and money. The vaccine itself was also much cheaper. In Australia epidemics were still occurring despite Salk campaigns. But some opposed the introduction of Sabin, particularly the State Poliomyelitis Officers responsible for Salk vaccination campaigns, and CSL. Director Bazeley was asked at a seminar when CSL would begin using Sabin and he replied 'Never'.[256] CSL had not obtained a Sabin manufacturing

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[254] *p 124*

[255] *New Scientist 25.5.94 Mystery Virus linked to Asbestos Cancer*

[256] *author interview with scientist involved, 1994*

licence and Salk was its major money spinner at the time that Sabin became the preferred form of vaccination in many other countries.

CSL strongly resisted the replacement of Salk with Sabin, according to informants interviewed by the author. The Director of Public Health in the Health Department had followed the US debate on Sabin versus Salk and favoured Sabin being introduced as soon as possible. At a meeting of the Poliomyelitis Committee at CSL to review and discuss the evidence for and against Sabin, which the Chief Virologist of the National Biological Standards Laboratories had been invited to attend, there was long and sometimes heated debate when CSL refused to accept the evidence in favour of Sabin. A Health Department official who recalls CSL's opposition to Sabin was asked what the grounds were. He said it was because they lacked the know-how to make it themselves and couldn't get a licence to manufacture it.

CSL, throughout its time as part of the Health Department and then as a statutory authority has involved itself with the national advisory body, the National Health and Medical Research Council. A number of informants pointed out the conflict of interests in CSL having a role on the NHMRC. This body often makes public statements encouraging the public for and against various health options, including the use of vaccines which CSL makes. An official of the Health Department told the author that CSL would no longer have representation on the Council after it was sold.

In June 1962 the NHMRC said Sabin should be imported and stored at CSL, but only for emergencies or pilot studies, not for widespread vaccination campaigns. Yet Council minutes show that the Council accepted the superiority of Sabin over Salk. They record 'recent experience in Queensland, and to a lesser extent in New South Wales, has revealed that wholly protective levels of antibody against poliovirus Type 3, have not uniformly been achieved in persons receiving a complete course of three injections of Salk vaccine'. The Council had recommended a fourth dose a year later as the solution. In 1962, they say that in making that recommendation they had been mindful that 'C.S.L. Salk vaccine has been a most effective agent in the control of poliomyelitis in Australia over the past six years'. Then they say the epidemics were moving south and could result in another more serious outbreak in the coming spring or summer. They say at length that Sabin is vastly superior; that Sabin is already in use in many countries including USA, UK, Canada, New Zealand, South Africa, Russia, Hungary, West Germany etc'. They say it is the only immunising agent which will terminate epidemics and its safety has been proven. What they don't say is let people have it now, in place of CSL's Salk.

This situation remained stalled for some years, with Australians being deprived of the safer, more effective Sabin and given CSL's product instead, until finally the Director of Public Health in Tasmania contrived to implement a major trial of Sabin in his state, which was a great success. But the NHMRC, as the author of CSL's official historian puts it 'died hard' and

didn't agree until July 1966 to use Sabin in polio vaccination campaigns. CSL had ceased production by the end of the same year. Australian Year Book statistics show that by 1967 the incidence of polio in vaccine recipients had dropped to one, in contrast with the hundreds quotes above in the case study on Salk vaccine.

14.8.1 Public never informed

The 1994 Sale Prospectus , prepared jointly by CSL and the Federal Government says:

> [In] 1955 CSL commenced manufacture of polio vaccine and provided 25 million doses which, over the following decade, virtually eliminated the disease in Australia.[257]

The 1990 official history of CSL ends its own brief treatise on CSL's polio vaccine and the delayed introduction of Sabin with these words:

> Another significant chapter in CSL's history, in which it had again saved Australians from pain, suffering, death and heartache, had closed.

It tells us that Bazeley, Father of the Year, OBE'd for polio work having been CBE'd after penicillin, summed up the importance of the polio teamwork in a letter to the Prime Minister. He said in an enterprise that had resulted in the 'wide distribution in Australia of a vaccine against Poliomyelitis which for quality is not equalled anywhere, 'Single individuals cannot easily be mentioned' So the Director acknowledged no one. Brogan at least puts lots of CSL names into the 1990 history.

Just occasionally the chapter on polio does tell us how the Health Department helped - with getting the monkeys out of the jungles for instance.[258] Otherwise the regulators are presented as an irritating check upon CSL's greatness, as when Bazeley objected to the Director-General refusing the release of batch number 27-28 in 1958 after Bazeley had certified it fit, or objected when the Director-General acknowledged to the public that vaccine shortages existed. Bazeley thought this was unfair as it would harm CSL's reputation, as if reputation should be founded on something other than what one does. Regulators and the Department are spoken of with an attitude of long-suffering antagonism, petty sarcasm[259] or not at all. Neither Bazeley nor Brogan mention V, the individual in the National Biological Standards Laboratory, nor any other Health Department regulators or executives, who responded to V's persistence by combining to save CSL from itself and probably stopped Australia going on the world map as the country where a

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[257] *p 12*
[258] *Brogan p 120 .*
[259] *eg p 117*

world-class tragedy occurred even after the rest of the world had evidently learned from the Cutter tragedy and put itself beyond such a possibility.

CSL's silence on matters like this, usually covers times when they needed an external regulator like their next breath. The silences tended to remind this author more and more of the words of a senior Red Cross official in 1992, which for a long time she had taken as overstatement, although the informant had never been given to exaggerating. This official said 'CSL never admits to anything and never credits anyone else'.

Research bore out the claim amply. In the early decades of CSL one may fairly readily find acknowledgment of the part played by Red Cross, voluntary donors and so on. From the time it became a Commission, one gets the clear message that CSL sees itself as apart from other entities, operating as if in isolation, needing no one else. In 1980 the annual report contains an uncharacteristic mention of NBSL 'collaboration studies' on Whooping Cough Vaccine, Influenza Vaccine, and Interferon[260] which, it even admits, solved CSL's problems after changes in manufacturing procedures by CSL's research and development and production teams. Such a reference is rare. More often external parties are portrayed as a hindrance, irrelevant or just not mentioned at all.

The polio case study, despite its age, is a good example of the relationship between CSL and the national authority from the late fifties up until the new TGA regime of 1991 onwards. Regulation only occurred when failures reached crisis point and so came to the notice of the Department. Then regulation was marked by CSL obstruction and failure to take responsibility for regulating themselves. However, some informants told the author of times when junior staff quietly ignored irrational directions from senior CSL officials and co-operated with regulators on the quiet to straighten out manufacturing problems. A former CSL official reported to a regulator that years before NBSL stepped in to solve the polio vaccine problems, he had raised concerns internally about the state of the scintered glass filters used to strain matter in manufacturing. He claimed his efforts were rebuffed and he found himself 'on the outer' - because of speaking out against an unsound manufacturing practice, he held.

14.9 Pituitary hormones

Over two thousand Australians received contaminated human hormone drugs made by CSL under a Government program between 1967 and 1985.
In 1993, the Federal Government announced an independent inquiry into the pituitary hormone program.[261] This was before writs were issued. At this time, over one hundred writs claiming negligence have been filed over deaths from CJD contracted from the products or alleging stress and anxiety in hormone users anticipating future suffering and death. The Federal

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[260] *annual report 80-81 p 12*
[261] *see Bibliography, Allars*

Government granted CSL a blanket indemnity which even covered the prospect of deliberate recklessness, the first of its type issued by the Federal Government; its scope is believed to be unprecedented in asset sales of former Government run institutions.[262] The indemnity was granted on the basis that CSL allowed the Government to have conduct of the cases.

14.10 Independent inquiry not to look at CSL

In respect of CSL's part, Government limited the independent inquiry to looking at 'guidelines relating to the manufacture of the hormones' rather than at the manufacture itself. Judging from her Report, Professor Allars took this to mean that she should not examine CSL's manufacture of these products, nor their distribution, packaging and so on, in any depth. For example, in para 8.32 of the Report, speaking of information in a leaflet and on labels for these products she says 'since it is not within the Inquiry's terms of reference to examine the product liability of CSL, the information contained in the leaflet or on the labels is not assessed in this regard.'

This limitation was superbly convenient for CSL and the Federal Government, as the Allars Inquiry co-incided with the Federal Government's sale of CSL. Professor Allars was commissioned in May 1993 and required to report to the Health Minister by June fourteenth the next year. This gave her a massive task, which she completed on the ninth of June, less than two weeks after trading in CSL shares commenced.

A number of issues arise from the timing and ambit of this Inquiry. Why should not CSL have been subject to the same degree of scrutiny as the other parties involved in the pituitary hormone program? Secondly, how could Professor Allars arrive at fair and just findings concerning the culpability of the other parties involved in the program if she was not permitted to fully explore the circumstances under which the program was set up and conducted?

The first of these questions is important for a number of reasons. While the Federal Government is not bound by Corporations Law governing disclosure of material matters in the course of a sale of Government assets, it has been the policy of the Government to proceed as if it were bound, and there are good reasons why it should. Potential investors have a right to know what they are buying. If material matters are not disclosed, their only recourse is the unsatisfactory one of suing. Second, to not disclose is a serious breach of public accountability in a political democracy, which prevented anyone with a stake in CSL's viability from expressing their views or influencing Government's actions. Such a course could only breed distrust of Government. Third, the Sale Prospectus was a joint publication of the Federal Government and CSL, whose Directors *are* bound by Corporation's law. To not disclose material matters in it would seem to put the CSL Directors in

[262] *Sydney Morning Herald 21.5.94, p 3, Jennifer Cooke*

breach of these laws, especially if the matters are ones which CSL was in a good position to disclose, such as its manufacturing procedures.

The second question is also important. Unless an independent inquiry defines what was done and should have been done by the various parties, there is a risk of attributing too much responsibility to some parties while overlooking the responsibilities of others. This seems to have happened in this case.

While Professor Allars produced a tremendously informative and valuable document, which fathoms extremely well many facets of the complex situation surrounding the pituitary hormone program, the terms of reference appear to have resulted in her neglecting the fundamental reality that the responsibility for the quality and safety of products rested all along with the manufacturer.

The Health Department and its various specialist committees definitely had a role to play in regulating the experimental usage of these products and should have had a greater regulatory role over CSL's manufacture. But the Report appears not to appreciate where the actual responsibility for safety and quality lies and does not explore how the Health Department came to exercise inadequate control over CSL. Inadvertently, Allars concluded that TGA's predecessor, the National Biological Standards Laboratory was at fault. The limited terms of reference gave her an impossible task in this respect and this resulted in some inappropriate findings as to fault. Professor probably would have had to fathom CSL's attitude towards scrutiny by NBSL, and better understood the limits of testing then and now for CJD, to have fully appreciated the demarcation of responsibilities between the two agencies.

The massive media coverage of this scandal centred around the laxity of some doctors who administered some of the products and around actual and perceived failings of the Health Department, while CSL was barely mentioned, even when the Report does reflect upon CSL's role. Media set off down the familiar path of targeting doctors, with the odd shot at the Health Department. 'The doctors ... were a law unto themselves'; 'nation's worst case of medical negligence'; 'eminent gynaecologists broke laws'; and 'the Human Pituitary Advisory Committee had wrongly allowed pituitary hormones to be administered'. A talkback program asked 'can you trust your doctor?' One might have thought that CSL was merely an innocent handmaiden to these villains, just following instructions, giving of their best.

CSL's role involved a series of questionable practices, some of which could easily be judged more serious than the polio production failures of a few years earlier which are addressed earlier in this chapter. Some of these questionable practices may reflect on the production of blood products which were being made at the time from Red Cross plasma and from human placentae.

The growth hormones were processed in a 'fractionation column', apparatus designed to separate out fractions of hormone from extraneous matter such as the infective particle causing CJD, hepatitis virus, bacteria, pyrogens and so forth. At the time there was no separate blood products division at CSL. Staff involved with research on the hormones, with the collection of pituitary glands and their processing into hormone products, also worked on research into blood product manufacture and its processing. Quality control was administered by the same personnel for blood and non blood biologicals alike.

Whether the processing apparatus itself was used to make blood products is not known, but if it was, this might explain how blood products contaminated with CJD, dealt with in chapter five of this report, may have become contaminated. Allars criticised the fact that there were no tests run to see if there was contamination going through the column. Hepatitis certainly survived the process. If hepatitis particles could survive the fractionation, so could CJD, expert informants told the author.

CSL wore a number of hats in this matter. It was represented on the Department's Human Pituitary Advisory Committee (HPAC) from 1967 until 1975 and was member of the Fractionation Subcommittee which was responsible for the manufacture of the hormones from its initiation until its disbandment. HPAC was where new research findings were aired and disease and other safety risks discussed. CSL had been interested in research on pituitary hormones. CSL Scientists, including Val Bazeley, had been working on the extraction and properties of growth hormones since the early fifties. Members of the blood products division were actively involved in research on kuru, the fatal CJD-like brain disease which was considered a virus at the time and was a recognised disease in Papua New Guinea, the first country from which CSL took plasma for fractionation, some time before 1961. CSL had published papers on kuru in association with key researchers.[263] CSL had a Virology Research Section and by the sixties NBSL's Viral Products Division was stationed within the grounds of CSL at Parkville in Melbourne, even if CSL people were not supposed to visit it after the polio fight, discussed at 14.7 of this chapter.

CSL must have had a good deal of information relevant to the concerns of HPAC. In fact, they would have been one of few organisations in the country with both the knowledge and potential awareness of what CJD could have meant to the Australian blood supply. Whether they passed vital information in a timely way is unknown. Certainly there is no evidence that warnings about CJD possibly passing in blood ever came from CSL to HPAC, or to the infectious diseases section of the Health Department, or to the National Blood Transfusion Committee via the CSL representative, who was closely involved

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[263] *eg Genetic Studies in Relation to Kuru, Am. J Human Genetics, 24, S39-S71, 1972 .*

with CSL's research and manufacturing of both pituitary hormones and blood products.

Despite not having had access to CSL files on matters relating to pituitary hormone processing, Professor Allars makes some rather surprisingly definite statements about CSL's role. For example, she says that glands which had been graded 'poor' or 'rejected' were not processed (3.83) and that glands imported from Mauritius were not added to hormone batches. (3.74). On the other hand, she says she was not clear about who was responsible for the exclusion criteria governing which glands should be used. These criteria were designed by CSL for their National Pituitary Gland Bank, which was established before the human pituitary program, to overcome the virus problem.

CSL was aware of the dangers of releasing product containing hepatitis as this was a major problem in blood product manufacture. Allars identifies some batches that tested positive for hepatitis. One of these was fertility hormone batch 128. The report says that this batch was not released because it was found to be contaminated with hepatitis B surface antigen.[264] However, informants have alleged to the author that ampoules of hormone from batch 128 were distributed in the mid eighties. The Health Department was informed of this in 1992 by a recipient of the products and the former Health Minister acknowledged this in writing in February 1992.

Release of batches was approved at the highest level of CSL's quality control. That hepatitis evidently did survive, would seem to invalidate the claim that the virus inactivation method used by CSL worked for hepatitis, CJD or any other virus. CSL continued to produce hormones which were contaminated with hepatitis until 1984, just before the program was stopped.

A manufacturer must be ultimately responsible for the purity, safety, potency, consistency and reliability of its products. This is because no other party is in a position to exercise that responsibility. There is no point trying to assign the responsibility away to NBSL or other external regulators, since no outsider is close enough to the manufacturing processes to exert the necessary control.

As chapter two and earlier parts of this chapter show, CSL chose not to follow good manufacturing principles in significant areas, both before and after they were set down in the Code. Biological products were excluded from the Code when it was first released because NBSL was not at that time able to address a number of specific aspects of biologicals manufacture. However, this was a minor matter. The principles and practices in the rest of the Code were still fully applicable to biologicals, especially the requirements on sterility.

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[264] 3.91 *p* 101

The report states that 'CSL products, including [the hormones], were manufactured according to the Code of Good Manufacturing Practice'.[265] The footnote for this statement refers to evidence given by two CSL officials. Given that Professor Allars was not empowered to inquire into CSL's hormone manufacturing processes, it might have been more judicious to present this statement as a claim which was not tested by the Inquiry. However, Professor Allars had no cause to question the evidence.

14.11 Manufacturing faults

It is clear from other evidence in the Report that before going into production, CSL did not satisfy Code requirements for verifying the manufacturing process. The products were not clinically trialed. Batches were made by a variety of methods, some of them experimental, so that uniformity of manufacture was absent. The first four fractionation 'runs' were experimental.[266]

Quite often the finished batches were unsterile, contained pyrogens and hepatitis B, and varying amounts of extraneous hormones. They could not be assayed validly or reliably for the hormone content. The Report merely mentions a whole range of other problems with the product, such as adverse reactions, pyrogens, discolouration and errors in labelling and packaging. Sometimes, unsterile, pyrogenic or otherwise faulty batches were reprocessed and blended with other batches. Some batches consisted of blends of hormones processed by other fractionation methods either at CSL or elsewhere. All of these represent GMP Code breaches.

In some instances CSL sought 'permission' from HPAC to release batches made by unusual methods and not meeting quality control requirements. A manufacturer has no business at all asking a Government committee to approve their faulty manufacture.

14.12

As manufacturer, under the Code it was CSL's responsibility to organise and supervise collection and storage of the pituitaries. Surgical standard cleanliness is required in collecting pituitaries. The GMP Code requires that starting materials come from approved and identified sources and comply with quality control needs and specifications for release. Allars' Report shows that CSL often did not know the source of glands, but was willing to take glands from Papua New Guinea (where kuru was a recognised disease), Hong Kong, Mauritius, Singapore, Malaysia and New Zealand, as well as from mental hospitals and geriatric hospitals, where dementia and other neurological diseases specifically excluded for gland harvesting are far more likely to be present). The criterion of 'neurological diseases' was 'by oversight' omitted from the exclusion criteria in 1977, Allars says.[267] Informants say

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[265] *3.84 p 96*
[266] *3.71, 7.15 and Table 3.3*
[267] *3.25 - 3.38*

CSL had no quality control specifications for the glands. Evidently the quality was often poor, as it caused low yields and many other problems in manufacture.

Allars found that CSL didn't adequately disseminate the exclusion requirements for collecting glands. Most of the pathologists and mortuary attendants contacted by the Inquiry were unaware that any written exclusion criteria issued by HPAC existed. CSL representatives who dealt directly with mortuary attendants did not provide copies of the successive versions of the exclusion criteria. Pituitaries were supposed to be removed for the purpose of post-mortem examination, according to human tissue legislation passed in the States and Territories between 1978 and 1985. Allars formed the conclusion that glands were generally removed not for this purpose but for supply to CSL and says the use of the glands during this period was therefore unlawful. CSL paid twenty cents and later fifty cents for each gland, Allars notes. Oddly, though, she does not point out that the human tissue legislation prohibits commercial transactions in human tissue; CSL's purchase of the glands would appear to have been unlawful during the periods after the legislation was introduced.

14.13 Quality control

The lack of quality control on these products is scandalous, since it was known that if the glands contained live virus there was no treatment which could be certain to destroy the virus - without destroying the hormones themselves. Nor was there any way of testing the glands or finished product to rule out the presence of live virus.

If the production unit had been following GMP on quality control, they would also been reporting to top management at CSL. But product release was not even being done by Quality Control uniformly. It was being approved in the production department. CSL did not subscribe to the concept of independent quality control, as shown in chapter two of this report.

In these circumstances, one would expect deficiencies in quality control, and there were plenty, some leading to safety hazards in the goods. One was the use of a filtering membrane to remove bacteria which was too course for the purpose. Other deficiencies existed in premises, equipment and the scientific skills of personnel. Batches which failed pyrogen testing were released and the pyrogen problem wasn't solved. When problems arose, there is evidence that production did not cease as it should have, until the problem was clearly rectified.

Even the live virus which, in theory at least, preceded the hormones , could still contaminate the column material and so get into the hormone preparation. Hepatitis clearly did survive. This observation in the report makes it rather difficult to understand why Professor Allars did not at least challenge CSL's claim that the products were manufactured according to

good manufacturing practice. Perhaps she inferred that a certain standard of product safety was acceptable to GMP without knowing otherwise.

Attempts at bioassay were never successful and were abandoned in favour of immunoassay, whereas these tests should have used to complement each other. Allars appears to have overestimated the ability of members of the Fractionation Committee and CSL to perform valid assays.

Perhaps the most fundamental question was whether it was even possible to produce quality hormone preparations of known potency from human cadavers either in Australia or overseas. A former NBSL scientist, Dr. W K Whitten, commented in an NBSL report in 1966 which was brought to the attention of the Inquiry, that:

> 'There does not seem to be any way of limiting the collection of pituitaries to 'safe' cadavers.'

In other words, had NBSL been let loose on CSL, the entire pituitary hormone program could well have been terminated. Dr. Whitten's opinion came only a handful of years after another NBSL scientist, 'V' had insisted on basic safety requirements at CSL or, as CSL management liked to see it, tried to pull the mat from under the polio program. Even if it had been possible to test the hormones for CJD, which it is not since no test exists for this disease, NBSL was hardly likely to have received an invitation to visit CSL and inspect their pituitary hormone program. In all probability, NBSL was sidelined - again- because they saw the matter straight.

14.14 Conclusion

The amount of evidence which could be presented in this chapter was limited by a number of factors - resources, the need to protect certain informants whose evidence was so specific it might have identified them, and exigencies of space. But it may safely be concluded from the line of inquiry which led to this evidence that the questionable practices and attitudes towards regulation which were found in the blood products division of the organisation, are not limited to that division or activity and have been chronic over a long period. (It should also be noted again that no similar phenomena were found in the veterinary area or in anti venom research and production.)

The significance of these findings is that regulatory remedies and standards proposed for the blood product manufacturing activity will also need to be applied to other parts of the organisation, otherwise they could be eroded or defeated by factors such as a contrary or non supportive culture in the wider terrain of the organisation, or by opposing practices and habits by personnel who may be transferred into the Bioplasma Division, or by executive action made difficult by non uniform agenda for the organisation as a whole.

CHAPTER FIFTEEN: CSL's CORPORATE ETHOS - A PREDICTOR OF REGULATORY SUCCESS?

The ethos of an organisation can be a challenging thing to identify and describe, however the attempt is valuable. Ethos can be a vital determinant in the success of regulatory schemes and particularly of self-regulation, and as well of the success of less directly or formally empowered players in the regulatory game, such as parliamentarians, unions, the media, consumer groups, shareholders and the public. Since these latter types of stakeholders have less access to the process than more formally empowered regulators, the attitude of the organisation towards them can make a major difference to the success of their efforts at being involved.

Studying the culture of an organisation can permit judgments to be made about the entity's attitude towards law and law breaking, external regulation, parliamentary and public accountability, its place in society, the values assigned to profit making, manufacturing standards, product safety, consumer information, disclosure, honesty, and willingness to assume responsibility for the actions and products of the organisation.

The most affordable and effective regulatory systems are ones which incite the corporation to regulate itself in the direction of agreed goals, while laying down a system of external sanctions which will be progressively implemented to enforce compliance if the corporation cannot itself get compliance through self-regulatory measures. No corporation functions well when it feels its movements and decisions are dictated by others, just as no individual flourishes under the control of others.

A common dilemma posited for external regulatory schemes is: how can they be effective as regulators of actions by players who deliberately seek to flout the trust element, or who are too incompetent or inefficient to be capable of responding positively to external controls? The first answer is to let self regulation flourish as far as it can. Yet self-regulation will not flourish in a environment unsympathetic to its success. It flourishes best where all employees are educated for their jobs, fit to do them and motivated to do them for reasons they understand and which at least align with the desired goals of regulation, and where employees are trusted within the corporation by those to whom they must account.

Evidence of organisational culture or ethos may be found in many of an entity's activities and attitudes, not all of them necessarily having implications for regulation. This chapter focuses on a number of elements which may be relevant to the success of regulation - the nature of the organisation's activities, its organisational goals, its attitudes towards regulators and government, its attitude towards parliamentary and public

accountability, its ability to detect, admit and respond to failure, its attitude towards its own people and its commitment to effective self-regulation.

This list is by no means comprehensive. Nor could all items on the list be studied to an acceptable extent. For example, the commitment of CSL to effective self-regulation could not be tested as access to the company was denied, leaving only the company's own public claims, and a small amount of anecdotal reporting, available for consideration. The role of CSL in its numerous alliances with other companies and research bodies would have been valuable to study as it could have shed light on possible informal peer review mechanisms. Resource limitations and lack of access made this fuller study impossible.

The evidence concerning the other indicators of organisational ethos suggests that CSL has prevented many stakeholders from gaining access to information about it, that for a long time it assumed a victim mentality when called on to account for its failures, that it has low commitment to parliamentary and public accountability, low tolerance for non-conformists who challenge these elements of organisational culture from within, and for long has regarded regulators and Government as an unwarranted intrusion on its affairs.

Whether these long-standing attitudes and practices have changed significantly in recent years could not be judged in this study. Senior management above the Bioplasma Division of the corporation responded to requests for interview in order to assess the corporation's likely responsiveness to regulatory measures with complete non-co-operation over five months, which unfortunately tends to suggest that the culture of CSL may not have changed. This impression may be misleading. If real change has occurred, then that could be demonstrated by the company or by independent inquiry.

15.1. Nature of the organisation's activities

CSL's activities and goals have often been poorly understood outside the organisation - particularly the nature and place of research and development as opposed to manufacturing products under licence or distributing the goods of other companies. The following observations are confined to human use product activities of CSL.

15.1.1 Origin of CSL's products

For a number of reasons it is relevant to be concerned with the origin of products which CSL markets and sells. A company selling locally-made products which it has discovered and developed may be easier to regulate than one acting as agent for foreign products, or even manufacturing another company's product under licence. As seen earlier, blood imports are particularly hard to control at the moment, because of failures in overseas companies and their regulators on whom Australia seeks to rely for product certification. There are many ways in which a company using licences and

patents from abroad may be restricted from using them in certain markets, including local ones. A Trade Practices Commissioner interviewed for this study cited the example of BHP using a patented system of applying zinc; the patent holder has stopped them exporting to south east Asian countries. 'This would be unauthorised as a restraint of trade under the Trade Practices Act were it not for an exemption which covers the operation of international intellectual property,' he said.

CSL's Intragam immunoglobulin product, Intragam, the alternative to the Swiss Sandoz product discussed in chapter seven, is made under a licence from the Cutter biologicals company. Official B, was asked in 1992 if CSL would like to issue Intragam beyond Australia and New Zealand.

> Yes, where we are fractioning plasma for say Hong Kong we would very much like to be able to issue Intragam along with the other AHF [antihaemophilic factor] plasma volume expanders etc [but we are] ... limited by the agreement with Cutter which limits us geographically ... we [hope] it will possible at some future date if that could be changed but at the present time they are reluctant ... they are distributing into these areas where we might like to do contract fractionation ... [there is a] pretty universal shortage for material for intravenous gammaglobulin as the demand grows.

Second, a company has more control over products which it has originated or at least has developed from others' work, as opposed to completed products which enter its warehouse from other companies and are merely relabelled and distributed, or products it imports in raw form and packages, or products which are manufactured under another's' licence.

Third, shareholders, potential investors and other stakeholders should be informed of the nature and origin of a company's product, as the information may be relevant to their decisions. For example, investors may wish to support local production. Some might not wish to invest in a company that deals in foreign blood products, given the extreme sensitivity of blood products at this time.

Fourth, when Australian regulatory controls of foreign products are as inadequate as at present, consumers and potential consumers of blood products have a right to know which products are derived from foreign blood.

15.1.2 Role of Research

Over the years CSL has claimed to be a research-based manufacturer in a market dominated by multinational companies.[268] CSL talks very loosely about R & D without saying how slight the research part is. Financial

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[268]eg *CSL annual reports 1978 &1992-3, inside front cover*

accounts, annual reports, the 1990 history[269] and documentation submitted to the Health Department don't separate research from development or define what either means. The 1992 to 1993 annual report says on the inside front cover 'Research-based, [CSL] is dedicated to the development of biological products'. Page seven boasts of a 'substantial growth in research and development to $19 million.' An informant claimed that a very significant part of the R&D budget is spent on regulatory affairs.

The general public assumption of CSL as doing mostly 'real', original or innovative research had been largely untrue since the sixties. There are a few exceptions, such as the anti venoms. These attracted a good deal of publicity because of their innate appeal to Australians and the promotional work of Struan Sutherland, but they were a tiny part of CSL's work, as the company was ever eager to point out, especially after Sutherland blew up about cut resources.[270]

CSL also provides a warehouse facility for foreign drugs bearing CSL labels, and manufactures products under foreign licence. This author when trying to locate a biologicals company, rang its 008 number. 'CSL' answered. When the company was finally located, a representative said it was one of many distributing its products through CSL, who was 'not supposed' to answer the company's number that way.

After the sale the author asked a CSL product information officer for a breakdown of home versus foreign products. She was told there was no such list and it would take too many resources to prepare one.[271] Another staff member estimated that approximately ninety percent of CSL's products are their own. (The product range was reduced in the early nineties from about two thousand to a few hundred). One employee said that CSL's emphasis is now on Australian production, especially 'value-added' labour. This refers to imported materials or products which are further processed, packaged and labelled here. Under the Federal Government's Factor (f) scheme of financial incentives for Australian production, CSL is granted price increases of up to $$66,840,250 between 1993 and 1999, so long as it meets certain production targets for approved value-added projects.[272] This scheme was established following recommendations by the Department of Industry, Technology and Commerce Working Party on Pharmaceuticals of which CSL's current managing director was a member.[273]

Basic research by CSL leading to new products has always been slight, when compared to development. The most outstanding exception is the range of antidotes to local venomous creatures such as snakes, spiders, ticks and sea animals, which has achieved constant innovation and product applications

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[269] *p 40*
[270] *eg Brogan p 213, & annual reports.*
[271] *telephone interview June 1994*
[272] *Sale Prospectus, p 86*
[273] *Prospectus p 13..*

since the twenties. This activity was transferred to Melbourne University after the sale.

By the eighties, CSL occasionally began to admit being more involved with development and application than with research.[274] But since many people long before formed the view that CSL does a lot of research, this impression could be kept alive, wittingly or otherwise, by continuing, vague public statements like 'we've been involved with many of the major ... therapeutic advances over the past seven years'.[275] Certainly the media has obtained a quite misleading picture of CSL's product origins. Journalists interviewed by the author while the company was being floated told the author that CSL does 'a lot of research'. The following extract from the Australian Financial Review in 1988 is typical of the loose language which can create the impression that CSL's products are researched, or at least substantially developed, by CSL:

> In its 70 year history, CSL has ensured the availability of such vital drugs as insulin, penicillin, numerous vaccines and human serum fractionation products ... it's growth has been linked to the major advances in therapeutics that have taken place this century ... insulin 1923, diphtheria toxoid 1927, snake anti venoms 1929, tetanus toxoid 1938, interferon 1981... the range had grown to more than 2,000 separate products.[276]

CSL ceased **penicillin** manufacture long ago, and now sells others' product. **Insulin** extraction began at CSL in 1922, a prompt manufacturing response to its discovery overseas in 1922, but in 1957 CSL went to the multinational drug company Eli-Lilly for know-how on insulin and penicillin, and for more insulin technology in 1978, and again in 1984 to the Danish company Novo Therapeutik for access to their insulin patents. In 1984, unable on its own to develop insulins in competition with genetically engineered products coming on the market, or chemical modifications of animal insulin, CSL formed a joint venture with Novo. This gave them access to a range of new forms of insulin, and it was this foreign contract which enabled them to continue and increase their manufacturing. According to Brogan, six years later when Novo merged with another company and CSL was pushed out, the manufacturing basis disappeared and CSL had to close its insulin extraction plant.[277] Now human origin insulin has been overtaken by a recombinant product, which CSL did not have the skills to produce.

As to **vaccines**, the first polio vaccine was Salk's technology and CSL's production, as seen in chapter fourteen. CSL's Sabin polio vaccine which replaced Salk is fully imported. A whooping cough vaccine was developed

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[274] *eg CSL annual report 1981-2;ABC Radio, The World Today 3.3. 1988, former MD.*
[275] eg ABC *Radio, The World Today 3.3.1988.*
[276] *Financial Review, 4.3.88*
[277] *Brogan p39 , a CSL official in 1994 said production stopped in December '93.*

from original work at CSL in the fifties and showed promise but failed a test required by regulators.[278] Later work showed the test was inappropriate, says Brogan, and the product developed by Keogh and others at CSL should have been released. CSL continues working to eliminate the side effects of its whooping cough as a mono component and as a component of triple antigen. In 1994 the Federal Government indemnified CSL for pertussis-related damage claims from product issued up to the time of CSL's sale. The 'flu vaccine is an Australian product as is a range of other vaccines including diphtheria, triple antigen, tetanus toxoid, cholera, typhoid, yellow fever and plague vaccine. CSL also distributes Merck's vaccines after packaging and labelling, and is competing to produce more vaccines under alliances with foreign multinationals, such as a multi component vaccine which it hopes its multinational partner will distribute in Asia. CSL's serum-based hepatitis vaccine was a foreign import, which has also been replaced by a recombinant product. The company has been working for some years to develop a malaria vaccine.

Snake **anti venoms**, as already mentioned, were built on original research at CSL, but the company claimed they didn't make money and are a very small part of their work.

CSL's **blood products** for distribution in Australia must be made from Australian source plasma, because of government policy on national self-sufficiency, although some have been made under foreign licence. Recombinant factor VIII is a foreign product. It or foreign-made alternatives will likely take over the market for blood clotting products as plasma-derived versions attract more liability suits, as the haemophilia patient advocacy movement lobbies for levels of usage higher than can be met by Red Cross under its existing funding allocations, and as the price of recombinant factor VIII comes down. As things, stand CSL hopes to handle both the local and much more lucrative foreign recombinant product.

CSL has never looked like being a player in blood product research or development. Their main achievement was not in product development but in rare blood grouping work by Roy Simmons, Jack Graydon, Noel Semple and others in the fifties and sixties, eventually working within a WHO reference laboratory established at CSL. In fact this work was not a CSL achievement as suggested by the official history. It was done on Simmon's and Graydon's initiative, not in a research department but simply as an interest in addition to their production work.[279] The blood product division also developed a product to treat Rh disease following collaboration with Australian Red Cross bloodbankers. In the eighties CSL developed confirmatory tests for HIV, but manufacture was stopped in June 1986 when commercial manufacturers issued their own testing product.

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[278] *Brogan* 222-3
[279] *author interview*

In 1980 R & D on blood comprised only seven point sixteen per cent of the national interest research component proposed by the CSL/Health Department joint working party, costed at $200,000 out of $2.4 million.[280] Research into blood, including the serology and blood grouping studies referred to above, attracts less than two pages in CSL's official history.[281] Lists of published research papers from annual reports between 1961 and 1992 show blood research featuring decreasingly and in some years not at all. The 1986 reports shows four on blood grouping out of a total of fifty four papers. The 1987 report shows none, 1990 shows one on blood out of fourteen, and it covers blood group serology work. 1991 shows five out of forty seven. Many of the published papers originate from work at the WHO centre. The 1992-3 CSL annual report omits the traditional list of the organisation's research publications.

15.1.3 Role of Development

In the Laboratories' early years there was speedy product development, such as insulin mentioned above, and penicillin during the second world war. In 1966, CSL was the first in the world to use anti-D serum to prevent rh disease.[282] Molecular biological research into peptides, for use in the development of anti-viral drugs, was initiated in the late eighties with an external research grant of $1.35 million and was hived off into a CSL subsidiary called Coselco Mimotopes, which sold out to Chiron in 1991.

According to CSL, R & D projects determined by the Minister for national interest products,[283] diminished from 1980 when the funding basis changed, requiring Government to pay for the research. In 1988 to 1989 the organisation claims it spent $14.4 million on R & D, of which $2.2 million came from the Federal Government. The uncertainty and inadequacy of research monies has been given by some as a major reason why CSL should be privatised.

As for the development of blood products, evidence in chapter six, 6.5, shows difficulties in recent decades, although one could not elicit this from CSL's published statements. Annual reports to Parliament contain vague statements on progress in development, such as 'studies of human plasma proteins'[284] or 'the programme for the development of several other products derived from plasma continued according to plan'.

A Health Department official told the author that CSL was 'said to have been reactive to Red Cross requests for new products [including product development] in the past.' CSL's annual report in 1990 says of modifications to the blood product prothrombinex 'it is expected that the modified process

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[280] *Extrapolated from Report of the Standing Health/Department/CSL Commission Working Party on CSL's National Interest Functions.*
[281] *Brogan 227-8*
[282] *Ref various annual reports, The Fight Against Disease CSL; etc.*
[283] *annual reports, official history 1990*
[284] *CSL annual report 1980 p 11,*

will be adopted routinely during the first half of 1990-91.' Company product sheets given the author in November 1992 say under 'New Product' that 'Prothrombinex-HT is expected to be available in 1992'.[285] Yet it was still not approved by TGA for general use when this part of the study finished in April 1994. The report also said CSL was considering early replacement of Stable Plasma Protein Solution with a five percent Normal Serum Albumin, because of persistent unwanted effects in SPPS. As seen in chapter six on product recalls and manufacturing failures, the replacement product was also found to cause the same problem of altered blood pressure as had been caused by the older product.

CSL used to provide the Red Cross blood banks with fibrinogen, a clotting agent, but they ceased taking the product about fifteen years ago because it was too unsafe. Serological testing equipment for blood grouping in Red Cross laboratories, such as red cell lines against which they could test their laboratory reagents, was also provided by CSL but overseas companies such as Ortho largely took the market with newer technology for making these products.

Red Cross informants said in 1994 that after the company obtained a licence to sell recombinant factor VIII from the US Baxter Healthcare Corporation a CSL insider summed up the company's intentions for blood R&D:

> CSL is not interested in R & D in blood any more.

15.1.4 Regulation and scrutiny of R & D

The independent Reid Nossal Inquiry into CSL said in 1978 that the organisation should strengthen its external peer review structures and treat its scientists better. The Head of the Health Department should become the focal point for advising the Minister on the definition of the public interest and determination of public interest activities, including blood processing and blood product development. CSL had been determining the national interest activities itself, the Minister initiating a direction only on rare occasions, despite this being a Ministerial responsibility under the CSL legislation.[286] An Australian Science and Technology Council report in 1980 said R & D for the public interest projects should be subject to 'external review and assessment'. A joint CSL/Health Department working party met annually from 1980 to address these projects, which CSL claimed 'recognises community expectations and ensures that R and D at CSL is planned, implemented and controlled responsibly'.[287] The purpose of the working party was to restore the role the Minister was supposed to have had all along. While it may have worked well in general, it was scarcely an adequate accountability measure for blood products, because the Health Department had little expertise to evaluate proposals in this field.

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[285] *Coagulation Factor, CSL Blood Products Division.*
[286] *Report of CSL/Health Department Working Party 1980*
[287] *p 28 1981-2 annual report*

15.1.5 Role of agencies and foreign alliances

A Red Cross informant said 'We ask [X] and [Y] at CSL if they are going to licence [this new product]. They say "no, just act agent". ' Agency arrangements can give a company even less control over the quality of products than manufacture under licence, and may lessen the effectiveness of regulation. Sandoglobulin, the immunoglobulin made by Swiss company Sandoz, and Baxter's recombinant Factor VIII, are examples of foreign products CSL handles. Sandoz sales are slight since CSL's subsidised equivalent, Intragam, was issued under a foreign licence, but no one is willing to delist Sandoz' product and CSL complains of plasma shortages for its own domestic version. They insist that even if they were able to increase the yield by manufacturing refinements, supply of the home product would remain a problem. However true this may be, CSL clearly has a motive for wishing to maintain distribution rights for the expensive foreign product, which doesn't inspire confidence in their future production of the variety made from Red Cross plasma.

CSL's alliances are increasing, and will continue to.[288] Most will likely be with foreign companies. A number of international alliances with multinational drug companies is enabling CSL to develop and market human vaccines[289] and antibiotics.[290] When CSL went up for sale it was CSL's alliances with SmithKline and other foreign drug companies which were considered to need protection 'in the national interest'!

15.2 Organisational goals

Regulators and other stakeholders cannot deal effectively with an organisation if they do not understand what it is trying to achieve and the nature of its activities. CSL's goals and activities have often not been clearly understood.

The goal of CSL is to make profits from the business of pharmaceuticals.

What does this mean for national interest activities such as blood products, vaccines, and other biologically-derived products for purchase and distribution by government - activities which many people think of as synonymous with CSL? Essentially it has come to mean that these products are vulnerable to becoming casualties to the goal of profit maximisation.

Way back in 1925 CSL was definitely committed to public interest goals. A CSL price list proclaimed proudly that American and British biological products had been 'largely displaced from the Australian market' by CSL's products and said the laboratory was 'not tempted to follow a mercenary

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[288] *eg Biogen USA< Genentech, Novo Nordisk Denmark, Leo Pharmaceuticals Products Denmark , Gynex Pharmaceuticals, HyClone Laboratories,, etc.*

[289] *Merck, see p 86 of CSL Sale Prospectus*

[290] *SmithKline Beecham see p 87 of CSL Sale Prospectus.*

policy which places questions of Public Health in a secondary position to those of commercial profit'.[291]

In 1961, CSL ceased being a division of the Health Department and became a statutory authority under the CSL Commission Act. In 1990 Health Minister Howe claimed[292] that CSL's charter at that time had focussed on national interest functions, in particular biological pharmaceuticals and serum. Ministers and the public may have focussed on the national interest aspect of CSL's functions in the sixties and seventies but CSL did not appear to.

From the sixties onwards CSL spoke and acted almost exclusively as an aspiring autonomous profit making drug company, or sought conditions that amounted to the same thing.[293] However, assisted from time to time by apparently contrary public statements[294] and probably by the public's aversion to having their settled view of CSL overturned, Australian media, parliamentarians and the public continued to assume that CSL was primarily committed to public health goals, a purely benevolent national institution engaged in considerable research in the public interest. A former employee said it had acquired the image of 'a national icon, a protected species, associated with national interest products like spider and snake anti venoms, allergy tests - products no one else would make'. The image lived on after well after the substance behind it had been quite transformed.

There were occasional aberrations in this trend, such as in 1978 when CSL printed the 1975 WHO resolution on voluntary blood donation in its annual report, praising Red Cross and the 'magnificent donors';[295] or the 1987 plea on public health grounds against the running down of public interest activities at CSL, made by Acting Chairman Wade;[296] .or when CSL was under the Directorship of the late Bill Lane in the mid sixties, supported by CSL's Chairman Davis. Then, annual reports bore statements like this: 'The Commission has never questioned that the fundamental function of the Laboratories is to act in the national interest'. In the official CSL history Brogan puts such wayward nonsense into perspective:

> Not only is that last statement absolutely untrue, for the Commission had very definitely ruled in favour of paying its way, but in addition, it must be observed that nowhere in the CSL Act is there a reference to either 'public health' or 'national interest.'

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[291] *quoted by Brogan p 22.*
[292] *7.9.1990 The World Today, ABC Radio.*
[293] *eg MD 1974-1990, statement of CSL's needs, chapter two*
[294] *eg, advertising lift out in The Australian newspaper 1975 : "The main function of CSL is to safeguard the health of the community by ensuring Australia is not dependent on overseas sources for essential medical requirements."*
[295] *p27*
[296] *1987 annual report*

CSL's assumption that serving the national interest is incompatible with making money is an important factor for regulators of Australian blood products to bear in mind.

Even its closest and most prestigious supporters appear not to have realised the extent of CSL's commitment to becoming a profit-making body at the expense of public health enterprise if need be. As recently as 1990 Sir Gustav Nossal in the Foreword to the official history said that his earlier independent inquiry into CSL had convinced him of one thing above all - the public interest component needed to be valued and assessed in its own right. 'Viewing the organisation purely as a profit centre does not do it justice' he said.[297] But Sir Gustav seems to be addressing Government more than CSL. He continues 'it is time the Government made up its mind about what it wants from and for CSL, which cannot flourish amidst uncertainty in the mind of its sole shareholder.' Whatever the rights and wrongs of Government attempts to regulate CSL, these attempts were mostly in the direction of CSL as a public interest enterprise ahead of anything else, at least until the eighties. On the other hand, CSL itself manifests from 1960 to 1990 as an unruly colt forever kicking at the stable door in its frustrated desire to gallop unbound across the fields of free enterprise.

Ironically, given its important role in relation to CSL's blood products, the TGA's stance towards CSL is based on a more accurate picture of the organisation than most. Officials described it as 'just another manufacturer' and 'a drug company'. Some officials would add judiciously 'though with a public interest component'.

As time went by, CSL was at some pains to impress on key stakeholders its commitment to profit-making, even while its spokesmen played on public approval for its public interest activities when this suited. The 1978 annual report refers to a CSL attitude survey amongst major groups concerned with community health, medical and veterinary practice, retail pharmacy and wholesaling. The results showed that CSL was 'expected to play a major public health role, but there was little awareness of our *duty under the Act, to be profitable'* (emphasis added). CSL decided the survey results should form the data base for a campaign to re-educate the public to its true calling.

The 1980 annual report, in discussing the national interest activities, tells us that the Senate Standing Committee on Finance and Government Operations in 1977 had 'reaffirmed the status of CSL as a Business Authority'. In 1985 the managing director told the Melbourne Age newspaper that CSL was told to be 'commercial'. (The 1961 legislation required a reasonable return to the Federal Government from CSL's activities.) CSL recast this provision in their minds to support the removal of all types of restraint which they associated with 'non commercial', including staff ceilings,[298] having to show the

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[297] *Brogan vi*

[298] *Chairman's Report, 1978 annual report p 2,*

Minister their corporate plan, keeping Red Cross plasma separate from plasmas of foreign countries, and so on.

CSL managers have even treated public interest activities with a degree of contempt at times. Why is unclear, but it is just possible that widespread public support for activities that didn't make them a lot of money gave CSL a problem which then matured into resentment of the activities themselves as symbols of CSL's captivity.

The much publicised case of anti venom resource cuts in the eighties is exemplary. Dr. Struan Sutherland, head of the project at CSL, was a perpetual sting in the side of management because he had the audacity to fight on every front for retention of a quintessential national interest service at a time when management wished to all but knock it out of existence. Sutherland was already a folk hero. His life-saving range of products against snakes, spiders and other venomous creatures of land and sea, his popular field guides, his twenty-four hour 'talk-to-the-experts' hotline, not to mention his openness with the public and media, his dedication, his refusal to be silent or to go away, and the support he attracted from other CSL staff, made him a dangerously loose cannon for a management which displayed every bit as much commitment to public service traditions of rank-and-file compliance and silence as the supposedly old-fashioned Canberra bureaucratic managers which CSL loved to stereotype and hold up to ridicule.

In this author's opinion, the worst thing Sutherland ever did from the perspective of CSL management was to publicly proclaim that CSL was much more a profit-oriented drug manufacturer than a scientific research establishment bent on serving the public interest. It was not that CSL would have disagreed with this in private. The affront was in having it said in public, in a manner that made profit-making seem an unworthy goal. CSL wants the public to think that they have been both these things, and could be both these things quite harmoniously, even while they were intent on stripping Sutherland's unit of most of its resources as a cost-cutting exercise.

In responding to public pressure to state his case, Sutherland exposed management to full public gaze as they went about their rightful business (as they saw it) of stripping his unit. The MD tried to stay out of the public firing line which made matters much worse in public accountability terms. He refused to discuss in public matters such as the publicised brawls between Sutherland and CSL managers, or CSL's QC-assisted trial of Sutherland under the Staff Rules for disgraceful and/or improper conduct when he chucked paper clips and pins at an executive bearing the fateful news and called the MD a swine. Cornered by a Sixty Minutes reporter wanting him to speak, the MD said he thought it was 'unethical' to speak on the TV about

such matters.[299] Whatever this meant to the managing director, (and he could have been protesting at Jana Wendt springing the 'Sutherland issue' on him) it was evidently lost on the public. Sutherland had already taken the field because his idea of ethics and reason co-incided with that of 'ordinary Australians'. Sutherland responded 'I'm just asking for a reasonable share of the research cake, and what's the value of a child's life?' CSL simply could not win, and what a way for the public to discover that, after all this time, CSL itself didn't really value these activities in the way the public had thought. The Sutherland case attracted more publicity than any CSL issue before it. Senator Gareth Evans, whose life at the time was probably saved by Sutherland's antidote to the deadly sea wasp sting, accused CSL of 'mind-numbing pettiness' over their handling of the Sutherland affair and ridiculed the 'Monty Pythonesque nature' of some of the exchanges.

CSL could have made life more bearable for itself by giving Sutherland back his resources and thinking of the anti venom unit as their good-guy public relations unit. Media files from the time show that instead they went on demolishing their PR front. They talked down the company's anti venom work in public on grounds that it didn't make them money. They voiced disdain for journalists who were keeping the public informed on a topic evidently dear to many Australians. Even in 1990 the talking down was still occurring.[300] For example:

> The identification of CSL with Australia's venomous creatures and the development and distribution of antidotes to their venoms distorts the significance of CSL's work. The function is a relatively small one, and its importance, whether judged against financial or public health criteria, is minor by comparison with the more far-reaching fruits of CSL's labours.

Statements like these aren't necessarily intended as a slap in the face to ordinary Australians, for valuing the production of life-saving anti venoms so highly. It is just CSL saying 'Look, we have a different agenda now and why can't you love us for our profit agenda and our lean management style rather than those cursed spiders, jumper ants and sea wasps that don't make proper money?' And saying it in the worst possible way, from a public relations point of view. It was only over months of reading, studying and reflecting on CSL's words and actions that this author came to appreciate the measure of the disparity between CSL and its public image, and the stress this generates for the organisation as it tries to go about its business of being a profit-making drug company in the face of such widespread public misunderstanding about its goals and motivations. It suited CSL well to be seen as a public hero, but not at the price of having to perform according to public definition of the national interest.

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[299] *transcript of interview , Sixty Minutes, 8.2.82 with Jana Wendt and Sutherland, with CSL's MD present.*

[300] *Brogan, p 235-9, p 213.*

It is relevant to recall the evidence of a BTS Director in chapter six on discovering that CSL was mixing blood plasmas of different country origin to maximise financial returns. According to Red Cross interviewees, CSL blood product officials as well as senior management were genuinely baffled because Red Cross would not concede their right to continue the practice. To them it was essential for the conduct of a lean economical blood processing business. The BTS Director said CSL's attitude was far more troubling to Red Cross than any other aspect of the affair, causing shock and distrust.

By 1988, CSL's commitment to profit and its understanding of the national interest were clearly acknowledged by the Commission in it's annual report. Quoting from 'Dicey' who evidently said 'Men come easily to believe that what they do is in the public good', the report says:

> 'national interest' across the range from 'everything we do is in the national interest because it is done under enabling legislation' to 'making profit is our national interest function'. We suspect that serving the latter objective is the most enduring contribution to the nation's broader needs.

In other words: what's good for CSL - making profit - is good for the nation. This is a significant public declaration from a statutory authority owned by and accountable to the state and charged with community service obligations of making vaccines, blood-based therapeutics and other public health consumer items for state purchase and free distribution, especially when it was the Government-subsidised blood and vaccines, rather than gee-whiz one-offs or high-tech products, that were the key human use products keeping CSL afloat all along.

How then did CSL see those public or national interest functions fitting into its ethos? The annual report continues:

> Our attitude to national interest activities has long been that they are a contract between CSL and Government. This enables them to be carried on and within our *culture of commercial operation*.. To provide these services within a *public service* or academic institutional environment lacks the dynamics of industrial and commercial imperatives'. (emphases added).

CSL's long-standing resentment of Government for imposing national interest activities on the organisation, and their neglect of these activities when they were imposed, was not necessarily grounded in any particular attitude towards the activities themselves, but in the unacceptable level of remuneration granted for them and the perception that they detracted from the main goal of making profit, especially in the years when losses from national interest activities had to be made up from overall profits. This is

what lies behind such apparently contradictory words in the report cited above: 'Each year a range of things *they wouldn't do on commercial grounds* is selected from proposals by CSL and the Health Department and evaluated by a joint working party.' CSL would of course do them - if funding was made available. If the money from vaccines and blood wasn't all CSL thought they warranted, at least it could be counted on. This was not the case with some of CSL's other human products, as chapter fourteen shows.

The senior orientation of the organisation towards profit-making explains why, having heard so little about CSL's plasma work, the public suddenly heard so much just prior to the Government sale. In January 1994 CSL had signed a ten year contract with government to buy the products on terms at last acceptable to CSL, a jump from twenty percent to eighty percent of world prices.[301] This made their projected income look even better. That was worth talking about to potential investors. So was the new state-of-the-art fractionation plant financed almost in full by Government; in CSL's eyes it offered the prospect of overseas plasma processing contracts on proper commercial terms.

It also explains why, when all was said and done by the Due Diligence team and the Department of Finance readying CSL for sale, vaccines and blood came out of the wringer as the two key core expertises of the corporation, despite blood having been treated by CSL as the runt for so long, barely worth a mention in public statements. Vaccines and blood always *had* been CSL's strongest lines. Both were for long highly subsidised, and protected by monopoly conditions or long-standing market penetration, with sales being assisted by timely statements from the National Health and Medical Research Council encouraging vaccination.

Not that profit-making matters, necessarily. Profit-making is a perfectly fine activity. In a commercial environment, profit should follow if business is conducted well. But this is, of course, not the same thing as having profit or money as a primary *goal*.

There is one important way in which the placing of a profit-seeking goal ahead of other organisational aims might pose difficulties for the regulation of CSL's blood product activities. Simply, the goal can function as a harmful distraction. For the activity of blood processing, as with blood banking and supply, there is a peculiarly high need for singularity of purpose, and the appropriate ranking of goals.

The commercial blood sector loves to cut up the charity or non commercial blood sector organisations in public whenever one of its members lapses or fails, because these companies are ever keen to take over the noncommercial business for themselves. Commercial plasma harvesters in some countries even contrive to poach voluntary donors, knowing their blood is likely to be

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[301] *other sources say 30% to 60-80%.*

superior. This author's analysis over some six years of the reasons why blood businesses go bad, finds that the reasons centre around the introduction into the business of purposes which are ranked higher by the organisation than the goals of an adequate supply of safe blood, rather than that the problem is purely profit versus non-profit.

Usually these introduced purposes or motives are commercial, but not always. In the case of the French blood scandal, in this author's assessment, a kind of perverted nationalism, imperialism, and in the case of the Director Garretta, megalomania, came into the picture as well, along with uncontrolled profit-seeking. This configuration of conditions was compounded by a scandalously corrupt or negligent plethora of regulators and mixed motives at the highest levels of Parliament about the purpose of the blood service. In the case of American Red Cross, from this author's study so far[302], a combination of charges to the end user, payment for plasma by commercial firms, lack of accountability by Red Cross together with excessively generous staff remuneration and conditions, compounded by periodically weak regulation and significant regulatory gaps, all combine to increase the likelihood of distraction from the senior goals of blood safety, quality and availability.

One can say that to the degree an organisation puts a higher ranking on goals other than the quality, safety, adequacy and availability for clinical need of human blood, to the same degree they are vulnerable to disaster. This is not because blood is fundamentally different from any other product. There are no absolutes; it is a question of degree. Blood, because of its nature and the way it is introduced into the body, has a terrifically high potential for harm if something goes wrong.

Therefore one can also say that it is in the interests of everyone concerned with the supply of blood and blood products to remove as many cross purposes, non-aligned purposes, distractions and potential or actual conflicts of interest from the domain of those responsible for the pursuit of quality, safety, adequacy and availability of human blood supplies and its regulation. Were this author a regulator, she would on principle expect trouble from an organisation processing human blood in a commercial for-profit environment, in the same way that she would expect trouble if charity or non-profit organisations showed indicators of a higher commitment to other goals than the supply of good product, whether they were commercial goals or not. Probably the main reason money gets targeted so often as the problem is because of the widespread belief that lack of it is the root of all evil.

15.2.1 Anti-competition

As to CSL's activities and business style in furthering its principal goal, the record also shows anti-competitiveness, as well as a trend towards agency,

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[302] *US May 1992*

licensee and joint venture arrangements rather than original research and sole manufacturer activity. As a statutory authority of the Federal Government between 1961 and 1994, CSL sought government protection, bounties and subsidies and at the same time constantly lobbied government for conditions compatible with competition. CSL's anti-competition activities in this period are consistent with a commercial drug company eager to enter world markets[303] and inconsistent with its public image as a government public health institution working in the national interest. CSL constantly felt let down by Government if it did not receive favoured treatment, such as when the federal Government granted Abbott Australia a bounty on production of penicillin V and CSL a bounty on penicillin G which had a lesser market. CSL shut down its penicillin plant altogether when this happened. Brogan claimed 'the bounty scheme denied CSL a justification for operation of its plant, which had the greater versatility, capacity and economy of scale'.[304] An informant told the author that CSL's penicillin had been heavily subsidised all along; its yields were roughly twenty percent of what overseas manufacturers were getting.

In 1987 after CSL had failed to produce a clinically safe immunoglobulin and government sought to import an alternative, the Managing Director told this author that government's action was 'a retrograde step [which] strikes at the heart of Australia's much valued independence ... a direct threat to the non-paid voluntary donors.' Really it was a threat to CSL. (The author had not then learned how to analyse CSL's actions and statements and may have been perceived by some at CSL as a useful mouthpiece.)[305]

While positioning itself in the same public interest camp as Red Cross on the issue of foreign blood imports, CSL was simultaneously prepared to act as Australian distributor for the company marketing its rival immunoglobulin. Asked why, the MD said: 'Sandoz said they were not in the business of distributing blood products so we said we'd take it. Off the record' (no such agreement had been made) 'it won't do us any harm and we have first hand feedback about what they are doing. On the record, they are special products - transport arrangements, warehousing and distributing - we have good friendly relationships with clinicians ... It's true their product is competing with ours but we still have to see if the sales are truly competitive with ours'. In fact, any acceptable version CSL produced would immediately take the field from Sandoz because it would be available at no cost to the clinician, hospital or end user. There was no competition with Sandoz actually.

After Health Minister Blewett gave CSL the conditions they'd been seeking in order to compete in the marketplace, the Government brought in a French 'flu vaccine. Its price matched CSL's, and it was packaged in a ready to use syringe whereas CSL's came in a vial for transfer to a syringe. CSL said the

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[303]*see Corporate Crime in the Pharmaceutical Industry, for example Chapter Five, p 159-204*
[304]*Brogan p 92.*
[305]*ref. Red Gold - The Price of Worldwide Commercialisation of human Blood, 1991*

import put continued local production at risk[306] and complained of 'irrational competition'.[307] A spokesperson for Health Minister Blewett said CSL had the ability to compete and should do so.[308] CSL complained to the Industries Assistance Commission, unsuccessfully. Then they claimed to Australian Customs that the French company was dumping, in that the vaccine was selling for less than its effective price in France. Professor Ian Gust said from Fairfield Hospital in Melbourne that we shouldn't have to rely on overseas imports as they might become unavailable. The MD said any reduction in CSL's sales resulted in higher unit costs, reduced employment and less profit. Even when such measures to wipe out competition failed, CSL continued to protest in its annual report to Parliament.

A former CSL competitor in the serum business maintained that CSL would approach small Australian companies as if to explore collaboration and then use the information gained for their own purposes. He described CSL as 'a large dead hand on development in Australia. They washed around in a research orientation, a huge scientific bureaucracy, which had no real application and believed no one should question them. What they had because of their closeness to Government, was the inside edge to get funding, and they took the lion's share - for example the Industrial Research and Development biological grant of half a million in 1978 - in addition to all the other supports and subsidies they received. You would start out, and they would copy you. They went on TV saying they were going to produce a kit to test for contamination in meat, to beat meat substitution, but we were already producing the kit, and selling it to State and Federal authorities.

'Not that they ever got ahead of us by doing this sort of thing. It would have been a joke if they had. I would have been ashamed. They were just spoilers. You would open up an avenue and get along the track and they would come along, like blotting paper, soaking up the information, getting insight into your work. But they would never sell the idea - like with enzyme labelling. They made such a lot of noise about this - said they were going to do it.

'But the Great White Elephant had to have the first go. Politicians were used to saying 'Shouldn't CSL be doing that?' And they **should** have been! But they weren't. They were the official producers of blood bank materials, which they supplied free to the blood banks. But the blood banks started using overseas stuff.

'They couldn't perceive what was important to do in relation to the market. They would get lost in science and never get into application. As a competitor you wouldn't count them at all. Their idea of developing a product for the market would be to go and ask a famous scientist 'What should we do as our latest test?' and he would tell them to do something

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[306] *Melb Age 7.6.86*
[307] *CSL annual report 1984-5*
[308] *Melb. Age 7.6.86*

from thirty years ago. They had a lot of quite important people loosely associated with them. It doesn't work - they ask [them] the wrong questions.'

'[CSL has] had a few clean ups in recent years But they probably wouldn't change if you put new people in at the top, in my opinion. There isn't [enough] mechanism for change there. CSL is like those ambitious post-war projects. We were going to make it all ourselves, after the war. It could have been done. But we were too far from the action. And we couldn't collaborate. Australians just can't collaborate well enough. In the sixties and seventies we just let the ball drop. Now the Australian way is to be agent for everyone else. May be they will be able to change enough, but I doubt you could do much with a group like that'.

15. 3. Attitude towards regulators/government

CSL, as it sees it, has a long history of being suppressed by Government and government regulators. There was CSL, forever tying to make more money, and there was Government forever trying to - well, not helping it. Government regulated CSL little but its attempts were seen by CSL as an impediment to the main goal of becoming a profit-making drug company. CSL, management at least, seem to mostly hate politicians and evidently hated regulators as well. Ministers and politicians never adequately appreciated CSL's arguments for more money and less regulation. Regulators did the bidding of Ministers or their own bidding - either was bad for CSL. Finally in 1992, despite the loss of favoured status, relatively secure contracts and other such conditions of Government ownership which privatisation would entail, it became easier for CSL to co-operate in getting Government off their backs for good.

Has this history of suppression (as perceived by CSL) left within the organisation a reactive hatred of regulators *per se* which might tempt personnel to evade regulation, accountability and reporting requirements to the detriment of blood product processing, or to use their new found freedom from government restraint in an irresponsible fashion? Could CSL behave like a state supported medical student who accumulates a growing sense of bitterness at being impoverished during the long haul of training and thereafter seeks compensation indefinitely by false claims to the Health Insurance Commission for medical benefits? Or an 'economic' refugee whose determination to never again be poor is used to justify wealth by any means in the new country? This is the phenomenon of the 'can't have' condition that turns into a 'must have' condition. It is not an inevitable progression of course, because reason, strong management, and many other factors can overtake a tendency to react this way.

The answer will partly depend on what CSL was reacting to in its dislike of Government regulators before privatisation. Was it just because the hand that regulated them was the same hand that dealt them money so parsimoniously, meanly or not at all? Was it because of perceived or actual damage, neglect and disinterest by those regulators? Or does it indicate fundamental

disagreement with the concept of regulation and accountability, a we-know-best intolerance of scrutiny and the costs involved? Was it because of guilty secrets? Was it resentment at being regulated, poorly or otherwise, to ends the organisation doesn't believe in? At least one factor appears beyond dispute. CSL saw much of the regulation imposed on it as being at cross-purposes with its main goal of becoming a competitive, profit-making pharmaceutical company. That is bad enough when it comes to predicting the future success of regulation for Australian blood products.

The recent achievement of increased prices for the company's blood products may improve CSL's temper where Government and regulators are concerned. The company seems happy enough so far with the terms of its Australian government blood fractionation contract. How far it will realise its goal of expanded commercial fractionation in Asia, how the vaccine market will pan out, and whether Government will subsidise synthetic factor VIII to CSL's satisfaction, all remain to be seen. It also remains to be seen whether the coffers of the dedicated insurance subsidiary are full enough to pay for CSL's liability share if further product liability claims arise for blood products made or distributed by CSL after the sale, or if hidden product liabilities from before the sale arise and are not covered by Government indemnity. Hopefully, the company will feel it can make enough progress towards its money-making goal under private ownership, and regulators will not be treated as in the past.

It is both difficult and in some respects too early to try for definite answers to the question of whether CSL will be refractory as in the past concerning external regulation. Yet it is still worthwhile to study CSL's attitude so far. As with all of the elements of organisational culture discussed in this chapter, it is unfortunate the Managing Director was not responsive to requests for interview. One is obliged to rely on the public record, which fortunately contains copious indications, although only a minute sample can be cited here.

15 .4. Attitude towards public accountability

On the major Reid-Nossal Independent Inquiry into CSL, ordered in 1978 by the Prime Minister, the only one of its kind in CSL's history, the Commission's annual report summed up in characteristic style its stance toward government regulation and accountability:

> ... whilst accepting that inquiry and accountability are healthy indicators of democracy at work there must eventually, and perhaps sooner rather than later, be a point at which the cost ... in serving these worthy concepts, exceeds the actual or presumed benefits. It was therefore ... reassuring that an Inquiry, whilst delineating and making positive recommendations for the relief of problems *recognised by the Commonwealth Serum Laboratories for more than a decade*, ... recommended also that CSL be spared the burden of further *reviews*

and inquiries which are a diversion from the achievement of fundamental objectives.. [309] (emphases added).

In fact, however, Nossal's recommendation against further review was conditional upon CSL implementing all of the recommendations. CSL's claim that the Inquiry told them what they'd known for ten years is quite implausible, and more a sign of the organisation's inability to be wrong than anything else. The recommendations told CSL to improve external review of their research activities, show more initiative in recognising and rewarding first class scientists, not scale down their R&D, consult with the National Biological Standards Laboratory on standards before building plant, and immediately submit to NBSL inspection of their good manufacturing processes. If they had recognised these as problems before Nossal p;dinted them out, why did they not implement solutions themselves? Inspection of their manufacturing plant by NBSL could have been arranged with one 'phone call, judging from evidence presented in chapters two and fourteen of this report.

(The dismissive attitude shown in the above quote doesn't necessarily reflect views of non-management. Nossal said that its members received good co-operation from CSL officials during the six months investigations.)

The Commonwealth Auditor-General found fault with CSL for not including the depreciation of its buildings in financial statements and directed them to correct this. On complying, the Chairman said in the annual report that the measure 'achieves nothing other than reducing the book value of assets'[310] and went on with a slab of complaint that illustrates well CSL's strong sense that it was a victim of unnecessary accountability measures and of regulators and government.

The same report says a comprehensive submission on R & D activities had been prepared during the year for the Australian Science and Technology Council and adds superciliously 'It is to be hoped that the amount of time consumed in providing information to this and many other enquires is allowing better social and scientific decision-making. We continue to watch for evidence of the benefits of such exercises.'[311]

In 1985 the Commission expressed its view about the Government Green Paper on accountability of statutory authorities and Government business enterprises, which led to the formation ministerial oversight guidelines in 1993. The Commission said 'we support the principle and seek the attainment of increased efficiency. We have no confidence whatever in a system which confers an overriding role on the bureaucracy. On what grounds can it be argued that the bureaucracy could have the time or competence to adjudicate

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[309] *CSL annual report 1987, p 19*
[310] *CSL annual report, 1973 p 3.*
[311] *op cit p 7.*

on business decisions in an industry which is foreign to them and for an organisation which is run on business lines? The proposition is a clear slur on the competence and relevance of the Commission.'

15 .4.1. Attitude towards Ministers and Parliament

This author read the official history only after studying and analysing the public record and evidence acquired through interview. In nearly every case, it expresses CSL's attitudes far better than an outsider could, which is why it is quoted so often in this report. Of the Executive arm and Parliament the author says:

> It would be pleasant to be able to say something complimentary about politics and political statements, but nothing comes to mind.[312]

In 1988 an ABC radio journalist asked the former MD 'What's the attitude, then, of yourself and people with CSL, to privatisation?' He replied 'Our first statement is that were delighted to have any expression of interest in what we do by parliamentarians and particularly by the Prime Minister'.[313] This style of the former MD is not shared by his successor, the current Managing Director. Nor does he speak of CSL as a victim. He maintains he told staff when he joined the Company 'our future is in our hands'.[314]

After studying CSL's annual reports to Parliament when a statutory authority from 1961 to 1994, with other CSL official publications and comparing these with records and evidence from interviewees, this author formed the opinion that, rather than being an exercise in parliamentary accountability or a useful resource for regulators, annual reports and other CSL publications are more a useful outlet for **self-praise** and self-promotion, generalised bitterness and criticism, **promotion of markets and products, obfuscation and misrepresentation**, big colour photographs, **whipping the media and their critics** (see 4.3) and **bagging regulators, investigators, and politicians** - although their heavily critical, self-excusing attitude began to fall away after 1990. Only a small sample of supporting material can be reproduced here.

The latest CSL annual report devotes the equivalent of seventeen out of its fifty four sides to coloured pictures and gives less information than ever before.

Annual reports and other publications are teeming with examples of self-praise, such as: 'it could possibly be argued that there has been more demonstrable benefit to public and individual health in terms of lives saved and sickness avoided from every dollar spent at CSL than from any other form of medically oriented spending in Australia.'[315] The organisation

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312 *Brogan p 253.*
313 *The World Today 3.3. 1988*
314 *Bulletin 5.10.93, p 86*
315 *annual report '81-2*

applied to have a commemorative postage stamp on one of its anniversaries. Brogan disdainfully reports how they were told to try again on their hundredth and Ginger Meggs got the stamp instead.

Obfuscation and misrepresentation abounds in annual reports to Parliament. The 1980 to '81 report says *'The routine inspections* by State Health Department officials and by members of the National Biological standards Laboratory (NBSL) took place as part of the conformity to the Code of Good Manufacturing Practice.'[316] (emphasis added) seen, CSL actually side-stepped the inspections, though they were routine for all other pharmaceutical manufacturers, and had to be ordered to submit immediately by government after the Nossal Independent Inquiry in 1978, and thereafter was inspected only infrequently until the new therapeutic goods legislation became operative three years ago. Inspections were *not* routine in 1980, although they were meant to be. This paints a extremely misleading picture for the Minister and parliamentarians, who may have been looking to the annual report to satisfy themselves that CSL was well scrutinised and regulated.

The 1991 Annual Report said 'Process and product development continued with the aim of providing new or improved products to meet emergent clinical needs in terms of safety and efficacy. Attention was also given to developing a range of new plasma derivatives which should become available as human use therapeutics during the next ten years.' This contrasts with the evidence of exasperated hospital pathologists, Blood Transfusion Services and the Haemophilia Foundation executive who claimed that CSL's plasma product development record was extremely unsatisfactory.

Just before CSL informed the public that blood products formed one of two core product groups and was the company's great future in Asia and the southwest Pacific, the blood fractionation business was covered in the 1991 annual report by five paragraphs.[317] One says 'The need for a new facility was advised by CSL to the Australian government in the mid 1970's ... in the years since then, the Parkville facility has been improved and upgraded on a regular basis to reflect ... increasingly stringent requirements of the GMP with respect to pharmaceutical products in general, and blood products in particular.' This suggests indirectly that CSL shared no responsibility in the failure to specify plasma plant requirements, which does not sit with evidence presented in chapter thirteen.

Reporting on blood products is often vague and non specific,[318] containing complaints about external factors such as alleged adequacy of plasma or poor plant, impliedly not CSL's fault.

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316 *p12*
317 *p 17*
318 *annual report 72/73 p 19*

CSL rarely admit troubles of their own making in production, preferring to suggest the cause lies somewhere else. Searches found an occasional single-line acknowledgment, often followed by a spin into technicalities unfathomable to lay readers, which leave the impression that the problems are with science rather than CSL. For example: 'The newly formed Pharmacology Group has concentrated its efforts on the cause of reactions to CSL products. It is investigating the vaso-active properties of Stable Plasma Protein Solution, with particular reference to the prekallikrein activator activity as measured by the generation of kinin-like activity with intact plasma.' This refers to CSL's chronic inability to produce an acceptable albumin which recently led them to develop a replacement product, as discussed in chapter six.

The same year's report mentions problems with 'unwanted or toxic components' in whooping cough vaccine.[319] The Federal Government has indemnified CSL for damage from this vaccine. This is how CSL explains the problem to the national Parliament: 'Difficulties were again encountered in the testing of the pertussis component of triple antigen, in that the inherent variability of the intra cerebral challenge assay system made interpretation of some potency test results difficult and obscured the effects upon potency of refinements in processing technique designed to reduce the residual toxicity of the vaccine'. This means the mice they injected with the vaccine were getting disease symptoms from time to time. This would have been either because the vaccine was toxic or because it failed to protect the mice from future 'challenges' with toxin. The official CSL history version at least doesn't implicate the mice, though it is silent as to the cause of the problems, saying merely that the vaccine has a 'reputation for a higher-than-desirable reactivity in recipient children'.[320]

No mention was found in the annual reports of the fracas over pooling plasmas of different origins, nor of the consistently poor yield of factor VIII from starting plasma - except to say 'yield improvements are being continuously realised' which sounds admirable, nor of the company's serious troubles with their intravenous immunoglobulin Intragam. CSL does say, however, that there is no reason why Australia cannot continue to be self-sufficient in supply of blood products. They suggest that Government only need give Red Cross more money so they can send more plasma to CSL.[321]

Annual reports mention difficulty with breakdown in plant, but claim 'Although plant breakdowns were frequent, product loss was minimal ... As at October 1991, the design and construction program ... remains close to the originally estimated target. Notwithstanding the limitations for the existing

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[319] *1978 p6,8.*
[320] *Brogan p222*
[321] *annual report 1985-6 p 9.*

plant, we maintained our required output of plasma products'.[322] The Haemophilia Foundation executive interviewed for this study said in 1992:

> Because their plant is in that [poor] condition they have had break downs in the plant which have meant that they have had holdups in production, which has meant that people have been so short that home therapy for instance here in Victoria was suspended for a number of months ... It has really affected their lives ... constant problems with [availability of product for] surgery.

In 1990 CSL planned to become a public company and expand its operations under a Commonwealth Reform Package. The Chairman's report for that year says that for these things to occur a 'significant improvement in operational performance' will be required.[323] This statement is an extremely rare admission that CSL had not always been perfect and that all its problems were not caused by external factors.

Annual reports and other 'advertorial' opportunities have also been used to more or less subtly promote it own products:

> CSL has not advocated that the ['flu] vaccine be made available in the same sense as polio or triple antigen but believes that the weight of medical evidence available from 'authoritative sources' throughout the world substantiates widespread vaccination'[324]

Widespread vaccination is not what Australian authorities advocate. The allusion to unidentified authoritative sources is common. The next year's annual report contains another generalised advertisement for CSL's vaccine range: 'studies indicate that there is a real danger that due to complacent or apathetic attitudes to various disease, the immune status of some sections of the population may fall ... Most of these diseases had not been eliminated from the Australian community'.

In 1979 the former MD promoted immunisation in a public, reported speech and said that the National Health and Medical Research Council was aware of the need for immunisation 'but it did not have the power to enforce schemes'.

In 1992, statements by the head of research at CSL in the Medical Journal of Australia were reported in the Melbourne Age and Canberra Times[325] He held that all babies should be vaccinated against hepatitis B instead of only the at-risk groups, all pregnant women should be screened for the disease and teenagers should be vaccinated.

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[322] *1990-1 annual report*
[323] *annual report 1989 - 90.*
[324] *annual report '71-2 p 12*
[325] *15.6.92*

The house publication 'Inside CSL' which found its way to many parliamentarians during the sale process, carries a piece in March 1993 on influenza vaccination, saying 'It has been estimated that up to three million Australians meet NHMRC criteria for annual vaccination against influenza - including two million over the age of sixty five'.

The author found no evidence of any attempt by government to restrain CSL from promoting its products direct to the public, but in 1976 Senator Grimes claimed certain doctors were profiting from the media publicity about 'flu epidemics to persuade factories and schools to conduct mass vaccinations, making two thousand dollars in one morning. The Senator, a medical doctor, said the vaccine should be given only to those at risk, especially those with chronic respiratory disease.

15. 4. 2. Attitude towards public disclosure

If stakeholders are to be involved in the regulatory process, the first thing they need is access to information and the second is the information itself. As seen in earlier chapters, much information which could be useful to consumers, shareholders, parliamentarians, media and other stakeholders wanting to influence the regulation of CSL's blood product manufacture is secret. This includes the contract with Government for blood product manufacture, (after the sale, qualified access was given as discussed later), the authority's corporate plan ratified by the Minister under the new 1993 Guidelines on Accountability and Ministerial Oversight arrangements (the Guidelines themselves are obtainable),[326] the findings of inspections by TGA, the Food and Drug Administration of the US, other government inspectorates, and so on. The author and her research assistant were not permitted to see the laboratories blood processing plant (although we were permitted to see the new plant under construction). Red Cross officials were prepared to release their contract with CSL to a reporter but then said CSL might not like it being disclosed.[327]

The blood business of CSL is difficult for public individuals to penetrate .The products are normally described in technical language. They are ordered and administered by doctors. The manufacturing processes are complex. A deliberate policy on public information backed up by programs, skills and resources would be needed to inform lay publics, but CSL has none of these in evidence, except when the anti-venom project was housed at CSL. CSL offers information to the public when it is involved in self-promotion, such as an anniversary, or share selling. It uses cultivated silence, selected targeting away from the general public, and bought and free publicity to manage its image in the media and elsewhere.

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[326] *Department of Finance*
[327] *author interview 1994*

The previous MD's target audience from 1974 to 1990 comprised 'health professionals and influential public figures in all levels of government, science and industry' says Brogan, but not the general public. He gives as the spurious reason that the 'ethical (prescription) nature of CSL's products is such that there is limited scope for institutional promotion to the public.' If this is the case, how does the organisation explain its statements promoting vaccination?

Informants for this study commonly claimed that CSL does not think of its blood product clients. The following report suggests the phenomenon has affected other clients. When several hundred people had reportedly died of 'flu in the United Kingdom and Australians travelling to 'flu ridden northern hemisphere countries wanted 'flu type A vaccine from CSL's supplies, the Director wouldn't release it. He said CSL had found that if they upset the 'complex distribution system' things start to go wrong. He said CSL couldn't 'play favourites', suggested people get vaccinated on arriving in foreign countries, (although some do not have the vaccine), or otherwise they could cut their trip off.[328]

When it is impossible to avoid responding to media coverage, CSL deals more often in generalities, opinion and reassurances rather than opening issues to objective public or media scrutiny. The following is a typical example from a Melbourne newspaper headed "Rest Assured; the Nasties are Locked in"[329] '... the Commonwealth Serum Laboratory is confident it can retain its image as a lifesaver ... despite a troubled few days for the Parkville laboratory. First, a steam leak last weekend in an area involved in diphtheria research worried firemen ... [then] the disclosure that Lloyds of London had refused to cover the CSL against claims from AIDS victims.' This was followed by the MD's assurances that labs are 'thoroughly cleaned, workers well trained ... we have procedures laid down in all these areas ... all the appropriate precautions are taken and I don't think anybody here feels any qualms about working here'. Then he dived into a general public relations speech, talking about activities 'unique to CSL', citing as usual only the anti venoms, which, he said, nobody else would be 'silly enough to produce.'

In addition to free self-promotion through annual reports and its in-house journal, 'Inside CSL', which puts a gloss on 'internal' events and reaches parliamentarians starved of factual information, CSL also buys advertising. In The Australian newspaper a lift-out advertising supplement for CSL's 60th anniversary says the public doesn't know much about CSL - and admits this is because CSL hasn't been telling. It goes on to give highly managed information. CSL also put out an advertising supplement to promote the plasma plant and forthcoming sale in 1993.[330]

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[328] *Melb Age 1.3.76*
[329] *Melb Herald 16.1.1986*
[330] *Business Review Weekly*

The Fight Against Disease is a commissioned PR history written by two journalists for CSL's seventieth anniversary in 1986. It is even less accurate than the 1990 text. The history speaks of the Bundaberg incident, in which twelve young children died after being injected with diphtheria toxin-antitoxin contaminated after it left CSL as being 'by far the most serious product-related event in CSL's history'. The Fight Against Disease, on the other hand, says:

> A Royal Commission totally cleared CSL and Dr Morgan [the Director] personally, yet 'from that time on, Dr Morgan placed a special emphasis on quality control of all CSL products ... As one doctor put it: "As a result of the Bundaberg tragedy, the safety of CSL products reigned supreme for evermore".[331]

Yet Brogan's text, just four years later, states that the Royal Commission of 1928 found CSL's Director had omitted antiseptic from the preparation (on reasoned grounds) and supplied it in a multi-dose container, which could be breached without all the contents being used. The Director warned Brisbane Health authorities that once opened, all the contents should be used, but he didn't make clear that a shipment to Bundaberg would contain no warning note. The doctor concerned received no warning. The contamination entered in during use of the preparation. The Royal Commission found that omitting antiseptic and using rubber capped bottles suitable for repeated use were both unsound practices.[332] This is quite different from saying the Royal Commission 'totally cleared CSL.'

On the eve of becoming a public company, CSL had one of its own staff, a former company secretary, write its official history, the 1990 publication 'Committed to Saving Lives', referred to frequently in this report. As mentioned earlier, it states that the author was given 'free and full' access to CSL records. As a company secretary he would also have had access to the Board and would be in a position to know a good deal about the organisation. Yet the 1990 history makes no mention of any questionable practices involving blood processing, and deals only partially with serious manufacturing failures such as Salk polio vaccine. This official history of 'the country's major public health institution'[333] could intensify public misconceptions of CSL. By appearing to fully acknowledge earlier failings, and omit reference to more recent ones, the history can lead one to suppose there have been none. It contains so much detail the reader may infer that it is a comprehensive account. The lack of an independent history as a point of comparison gives it even more weight.

There is no doubt CSL wanted the official History to be taken as reliable. In 1990 the former MD said in a farewell speech to staff at CSL:

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[331] *p 39*
[332] *Brogan, p 24-6*
[333] *Brogan -p 241*

> 'I did complement Brian Howe [Health Minister] on Tuesday night that he gave the most accurate rendition of elements of the history of CSL that I've heard ... one reason why he was so accurate ... he was reading notes that Alf [Brogan] had prepared on the history, and that certainly gave it the stamp of correctness and accuracy. And amongst all the things that have been done in [my] time ... [the History] is going to be perhaps the capstone.'

CSL has consistently declined to disclose to Red Cross its cost per unit for factor VIII production in Australia, despite their constant requests to know if CSL is using their plasma economically. The figure was given by CSL to this author orally seven years ago. It could not be verified and was never published. (The Haemophilia Foundation executive interviewed for this study in 1992 said that their organisation deals closely with CSL. She claimed, interestingly, CSL had given them a figure of thirty eight cents for production of each unit, which compares with thirty seven given the author in 1987). She said that if the costs of blood collection were added it would probably be 'closer to a dollar like it is overseas'. She added that when she put this to CSL official A, he agreed the cost was probably eighty cents to a dollar per unit.)

As an exercise in accountability, it would be interesting to see if CSL would grant an independent historian the same access to their files which was given to the internal author of 'Committed to Saving Lives', published prior to the sale of CSL, when the Freedom of Information Act still applied to documents in CSL's possession. CSL documents or documents relating to CSL in the Health Department's possession are still subject to that Act.

Although the Administrative Decisions (Judicial Review) Act no longer applies to CSL, it does apply to government decisions made pursuant to legislation, such as the Sale Act and the Therapeutic Goods Act. Documents could be needed to comply with an AD(JR) request which sought to know, for example, Government's role in CSL's sending Australian-sourced blood products overseas or the reasons for not disclosing in the Sale Prospectus the questionable practices in CSL's blood products division.

For six months following lodgement of the Prospectus, CSL made the contracts referred to in the Sale Prospectus,(minus information which could result in 'unreasonable prejudice to CSL') and some other documents available for inspection between 9am and 5pm in its Melbourne office.[334] The author asked the Company Secretary what access was being granted to people outside Melbourne. He said he was aware of the Blood Regulators Study. He then asked the author why she wanted access to the contracts. He was told the CSL/Federal Government contract on supply of blood products

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334 *ref CSL Sale Prospectus p95, Additional Information 8.12*

could not be more relevant. He undertook to return the author's call when he had considered the request. No further communication was received.

A Health Department official informed the author that the blood product contract being made available from CSL did not include the Appendices containing prices the government was paying and the amounts of product CSL was to supply. He believed CSL was not permitting viewers to copy the contract which he described as 'bland and innocuous'. He believed CSL's granting of access was in compliance with a Corporation's Law requirement. He said his own agency's refusal to disclose the contract was based on a decision by Attorney-General's, presumably because the data 'could give some commercial advantage to some other party - although CSL is a monopoly'. He agreed to look at the validity of this, and later revised his view, saying there was no reason why the document, including the prices being paid by government for CSL's fractionation services, should be kept secret. They might be disclosed in response to a written request, which was filed as this report was in production.

15.4.3. Attitude towards media

Much of CSL's success with media depends on inability of TGA to speak out, inability of journalists to analyse what CSL tells them, and longstanding lack of public information on CSL and blood products.

CSL hasn't liked dealing with media and has done so very little. As we saw earlier in this chapter, the previous MD would not discuss charges against Struan Sutherland even when Sutherland was willing. When the Bulletin published a long piece on the Sutherland affair and CSL's research and resource cuts, the MD indicated he would sue[335] for defamation seeking damages and trial by judge alone.

As managing director from 1974 to 1990 he pursued a definite policy of not promoting CSL to the general public, according to the official history. This has been applied to ridiculous lengths. When the Melbourne Age newspaper found out about the major inquiry into CSL by Nossal, the Director-General confirmed its existence, 'senior government officials' said CSL was 'gobbling up millions of dollars and the Prime Minister wants to know what is happening to the money' while the Director of CSL, typically, would neither 'confirm nor deny' if a review had been ordered.[336]

One of few CSL issues routinely appearing in the media has been the shortage or absence of vaccines, such as influenza or triple antigen. Typically stories originate from health authorities, or a parliamentary question, rather than CSL admitting the situation or offering a plausible explanation.[337]

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[335] *Melb Age 30.7.82*
[336] *Melbourne Age 4.2.78*
[337] *eg Adelaide Advertiser 28.10.76;Canberra Times 10.5.73.*

In 1990 routine tests by NBSL, TGA's forerunner, found roughly a third of the blister foils on CSL's imported oral typhoid vaccine were faulty, allowing moisture in to kill the living bacteria which make the vaccine work. Thirty thousand doses were recalled. CSL's spokesman said the recalled vaccines were 'not dangerous' but their potency was 'reduced'. An ineffective vaccine would of course be very dangerous for someone exposed to typhoid. In the same report the NBSL scientist said 'The bacteria are dead, and so it's ineffective'.[338]

Rather than directly answer specific media inquiries, CSL has used its annual report to bash its critics generally:

> 'during recent months various aspects of the activities and policies of CSL have been criticised in the media by *persons* who are either ill-informed or who chose to present biased views in an endeavour to promote sectional interests. They attempted to denigrate the laboratories' contributions to human and animal health in Australia. The commission is concerned that its public image, staff morale, and relationships with the medical and veterinary profession are being impaired, although it *has not entered, and will not enter into , public debate on these matters'* .(emphases added)

As press gallery journalists usually skim government annual reports for reportable snippets, this sadly noble statement was of course likely to be reported, and it was. It was CSL's response in part to criticisms from the Australian Pharmaceutical Manufacturers' Association, who said the public was entitled to know why CSL's 'flu vaccine supply was failing and that CSL may have been using the bait of adequate supplies of 'flu vaccine to encourage chemists to give preference to other CSL products.[339]

15.5. Ability to admit, accept and respond to failure.

For much of its history CSL has had a pronounced tendency to explain its own failures by reference to external factors, what Braithwaite calls 'a culture of excuses'. This makes it difficult to establish the actual cause of failures and formulate effective regulatory remedies. The poor quality of the monkeys for polio vaccine; the hens that won't lay fertile eggs in which to grow 'flu vaccine; the effect of drought on sheep population; the depressed state of the beef and dairy cattle industry; Government's meanness as funders, its caprice as purchasers of CSL product and its burden as regulators; the indifference of Ministers; the unreasonable and misplaced expectations of the public; the ungenerous research funding bodies; the delays of bureaucrats; the freight of taxes; the pointless demands of the Auditor-General; the gall of critics; the glib ignorance or mindless provocation of the media; the tedium and difficulty of the work; the restraints of the market; the competitiveness of the international drug industry; the difficult pricing environment in Australia;

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[338] *Melb. Age 31.5.90*

[339] *eg Daily Mirror,9.5..73*

the lack of adequate supply of plasma from the blood banks, the time-wasting of those who call for CSL's accountability, or the general failure of just about everyone to treat CSL with the respect it was due - "the disappointing lack of understanding by various government agencies and advisory committees of CSL's resources and national and international status as a manufacturer and marketer'.

When CSL has been found wanting the reasons lie with almost anyone other than themselves. This is a remarkable achievement of mental agility on CSL's part, since in this study it was found again and again that of those people who had a view of CSL at all, it was both favourable and rarely based upon fact, or based on knowledge of only one aspect of the organisation's work, especially the anti venom work.

An example of CSL's tendency to blame others is well illustrated by the following case study arising from the blood products manufacturing section. According to a Red Cross source, for some years CSL had been alleging that a considerable proportion of the starting material, possibly up to twenty five percent of the bags sent to CSL proved unsterile on testing. Allegedly they contained bacteria. Red Cross were reasonably convinced that this was untrue, but reported the allegations to NBSL and asked them to test a sample. The laboratory undertook sterility testing on five hundred blood bags and they all passed. CSL's response was allegedly to accuse NBSL of incompetent testing. So NBSL tested another five hundred. They found one bag capable of growing bacteria - this can be considered a 'false positive', that is, the contamination presumably introduced during testing. In other words, Red Cross blood bags passed the tests one hundred percent. Reportedly, CSL refused to use the blood bags which NBSL had tested and found sterile, so a thousand bags of donor blood had to be thrown out.

The Head of NBSL then directed his staff to investigate the testing procedures used by CSL. NBSL found that CSL was testing every bag before fractionation by clipping off a small section of tubing leading from the blood bag and testing the material in that. Not surprisingly, they were finding a considerable number of the bags unsterile. 'No competent person would do that' said an expert informant. 'It was the testing procedure which accounted for the results they were getting'.

These testing failures would have cost Australian donors and the taxpayer a good bit more than the cost of the nine hundred and ninety nine bags tested by NBSL. Assuming they were acting 'responsibly' in relation to the blood bags which they said were non sterile - they would have been discarding all the bags of blood which 'failed' their testing over the years in which this 'running sore' of allegations and denials continued between the two organisations.

Later CSL tried to obtain a Red Cross contract for the supply of sterile bottles to the Blood Transfusion Services around Australia. Red Cross asked NBSL to test some of these bottles. The results were that some were non sterile.

There are countless other instances where CSL explains its own failures by reference to external factors.

When 'flu vaccine dried up in 1980 the Managing Director said one reason was 'late advice' from government about the 'flu type they wanted vaccines against. This 'late advice' as he called it, refers to Government's deliberate policy of specifying the 'flu strain as close in time to onset of epidemics in order to ensure that the vaccine provided an antibody response to the right strain. Besides, Health Department sources told the author that the choice of strains was made by a committee on which CSL had more than one member, as against only one person from their own agency. They claim that in fact it was the Health Department who were constantly urging CSL to cut their *own* delays in starting up the vaccine production and that they even used Health Department resources to try to reduce the time CSL was taking to get into production.

The Managing Director's list of excuses for lack of 'flu vaccine also included 'unforseen' delays, such as not enough fertile eggs to grow the vaccines in,(a foreseeable problem in every other year) low yields of some of the virus strains (caused by?) and a contamination problem which ruined some of the doses (cause unspecified).

A CSL official in 1992 explained that they had paid mortuary attendants for pituitary glands because a specialist college had advised them that the attendants wouldn't provide the glands without some inducement. Paying for tissue was unlawful under State and Territorial tissue legislation passed from 1978 to 1985.

In relation to biotechnology grants CSL said in 1983 that 'Both our statutory authority status and own expertise seem to be grounds for being passed over than preferred'.[340] The 1986 annual report complains 'we have not been helped by the attitude of a number of granting bodies which have held the view that we should not need to come to them as they *perceive that* we have our own line of funds from Government. Indeed an argument of remarkable convenience but to our disadvantage.' (emphasis added).[341] Others say CSL had the inside edge over most other contenders for government grants.

The annual report of 1987 to 1988 complains that 'The rebuilding of the serum fractionation plant ... has been dogged by a series of *unforeseeable difficulties* since site clearing .... in 1983-4. These have included significant changes in technology, inflation, currency devaluation ... regulatory and disease

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[340] *annual report 1983 Melb Age 2.7.85*
[341] *p 10.*

containment standards, and the need to plan with limited resources'. To CSL these matters may have been unforeseeable; equally the constant justifying of non-performance in this way can be read as evidence of a culture of excuses within an organisation not ready for the real life of private enterprise.

When there is no real flow of information, one cannot easily judge which of the torrent of excuses is valid and which not. Common sense tells us CSL cannot be faultless, yet where precisely does the trouble lie? One can resort to believing all their excuses, or none.

The previous MD told the Melbourne Age newspaper 'to the extent that you might argue that we've been run down, it's because we were never allowed to gear up'.[342] Some informants agreed with this construction of the situation, others, both within and outside CSL, said that CSL got more than its fair share of help and rescuing from Government and would have got more if it had warranted it by performing better. It is difficult for outsiders to establish which factor came first. However, no excuses will do for many of the practices and regulatory failures at CSL, many of which can easily be seen as contributing causes to the conditions it complained of.

These days CSL is constantly asserting that Red Cross doesn't supply them with enough plasma to meet current needs for factor VIII. The Haemophilia Foundation of Australia echoes the claim in the media and when lobbying parliamentarians and others. The is being put to the Health Department by both parties in support of claims that the expensive recombinant factor VIII - which CSL now has a licence to distribute - must be permitted as an alternative and made available by government subsidy. But does one hear that CSL has been chronically obtaining factor VIII yields from the plasma which are between thirty and forty per cent lower than those of overseas processors?

After this study a TGA official said that CSL had begun to admit that some of the things they had done at the old plant were wrong. This is mentioned in chapter nine. He said that CSL had asked TGA for help. This would no doubt be because CSL knows it must comply with TGA and overseas regulatory demands to stay in business and succeed in the international market. It can no longer insulate itself from its mistakes. Maybe some are realising that the games CSL played with Health Department regulators were hurting themselves as much as anyone else, and that the enemy wasn't 'out there' after all.

Does it matter, in regulatory terms, that CSL appears to have found it hard or impossible to admit to mistakes and that it so often targets external factors to explain its actions? If the mistakes or deficiencies are so widespread that value for money is being significantly lost, if the mistakes have safety or vital supply implications, then it does matter. If the mistakes arise from

[342] *Melb Age 2.7.85*

incompetence or inefficiency, more than from the normal and considerable range of difficulties inherent in production of biologicals and pharmaceuticals, then it does matter.

Does it matter that they withhold information about their errors from stakeholders, the public included? If the difficulty in admitting is more than a public pose, if it indicates an inability to accept failure and correct it, or that they believe their own rhetoric, then it does matter. Mistakes which aren't acknowledged or are justified may well be repeated or followed by other like transgressions, to prove the first transgressions 'right' as it were, or just through sheer lack of a sense of accountability.

But the conundrum is this: how are we to judge, if the corporation does not routinely disclose, nor admit where the failures originate? And if they do not disclose, how can they maintain the trust of regulators and the public when, inevitably, indicators begin to show? And if they don't routinely disclose, what is to stop us overreacting to the indicators? There is the kind of mindless withholding that can turn a peccadillo into a reason for divorce or a third rate burglary into a constitutional crisis or a corporation's slip-ups into a forsaken reputation. And then there is the kind of secrecy that appears to work. And this is probably the most harmful, since successful withholding can lead a corporation to conceive that law and ethics are for others and thus it can lose its frame of reference in society. How then does it determine social as against antisocial conduct?

15.6. Attitude to staff

During the Whitlam government, moves were made towards staff representations on the boards of statutory authorities. Various unions with staff at CSL sought the election of a staff member to the Commission but it did not eventuate. Government later appointed a former CSL staffer and union figure to the Commission, who held the post for thirteen years. Brogan says the appointment was viewed with consternation by some Commissioners but proved a 'valued addition', although he does not say how.[343] An industrial chaplain was appointed in 1980. Staff surveyed concerning their desire for such an appointment mostly didn't care, but the managing director, 'an avid churchgoer' wanted it. Brogan said the chaplain has been 'of considerable value to a significant number of employees.'

CSL was targeted by unions early in the campaign for a reduced working week. Industrial action followed after the Government amended the guidelines which CSL and unions were working to. A CSL Commissioner protested to the union person on the Commission, wanting him to have the industrial action stopped - something he hadn't the power to do - and was put out when it didn't happen.[344]

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[343] *Brogan p 200.*
[344] *Brogan 200*

Struan Sutherland described his fight with management over resources for the 'apparently profitless' anti venom project as:

> comparable to being in a school yard ... when you found yourself taunted. ... I called my Director a swine ... and was subsequently suspended. On the second occasion, I tipped a bowl of paper clips over my immediate superior. Both foolish things to do, but ... upon reflection I really had very little choice but to do what I did ... some of my colleagues have said I should have used road blocks instead of paper clips.[345]

He claimed the running down of research on anti venoms and poor treatment of staff continued throughout his employment at CSL, a cold war which ended this year when Sutherland and the anti venom project departed CSL. Though much of CSL's fame derived from Sutherland's efforts, management treated him as the enemy within.

The Struan Sutherland 'sideshow' as the official history describes it, is not the only example of CSL trying to stamp on staff who speak out in the public interest or of being at serious odds with its employees. Some one hundred members of the Professional Officers' Association and Commonwealth Medical Officers' Association met in protest over the treatment of Sutherland and demanded his reinstatement. A Professional Officers' Association poll showed sixty four percent of members believed there was bad 'vertical' communication at CSL; six per cent thought it was good. Forty six per cent reported a bad level of confidence in senior management and eighteen rated it as good.

The phenomenon of employee discontent extends back into the sixties and forward to the present, though its precise extent now is not known. In 1960 a CSL officer named Leo Rowan wrote in a private capacity to the Medical Journal of Australia criticising a paper published the previous month by CSL staff on the benefits of mass 'flu vaccination. Rowan said the vaccine should not be used in the face of an outbreak unless real danger threatened. CSL's Director was furious at the criticism of CSL staff and the implication that CSL improperly promoted the use of 'flu vaccine. He received little support[346] from the Health Department in his efforts to censure Rowan, nevertheless Rowan was 'quietly transferred'[347] to the School of Public Health and Tropical Medicine in Sydney. An informant for this study spoke of a blood products employee being vituperatively attacked by CSL in recent times and over time, allegedly 'treated with scorn' because he abided by values outside the CSL culture of, as he saw it, placing too high a value on profit maximisation and shirking public accountability.

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[345] *Sixty Minutes, 8.2.82*
[346] *Brogan 142*
[347] *Brogan p 143*

The 1987 annual report contains a report on human resources which claims 'many initiatives to improve the flow of communications between the Commission, management and staff, including bi-monthly meetings between staff representatives and management'. In-house training and graduate development were said to be emphasised and fostered, with roughly fifty staff receiving assistance with external studies at tertiary and post-graduate levels and sixty percent attending in-house courses to improve technical and personal skills. 'A new era in staff participation' was heralded under the banner of total quality management as its introduction extended through the organisation. The 1989-90 annual report says that TQM programs continued to flourish, having a 'pervasive effect on the culture and practices of the organisation ... key elements are the ability to reduce costs and increase productivity'.

In late 1989 CSL ratified a structural efficiency agreement with the Australian Council of Trade Unions and the majority of unions representing the CSL workforce. Other union negotiations followed, for a single CSL General Conditions of Service Award. New arrangements for work place management of employee conduct issues and discipline were trialed and revised arrangements for assessing managerial performance were developed.

The same report refers to CSL's first report under the Equal employment Opportunities Act of 1989 which, it says, describes a range of initiatives to 'realise CSL'S commitment to the principle'.

In 1990 print media[348] reported a week long dispute, in which five hundred members of the Public Service Union - nearly half CSL's work force - imposed month-long bans over alleged 'primitive' health and safety conditions at the blood products plant. The Director of the Blood Products Division reportedly said bans of this duration would pose threat to the health of haemophiliacs, which may well have inflamed the employees. The PSU wanted an independent inspection of the site by an occupational health and safety officer. According to this report, the MD called the bans a nuisance, denied they were having an immediate effect, and said the unions had deliberately misinterpreted previous negotiations and that he was willing to allow an independent inspection.

The annual report of 1987 first raises the possibility of an employee share scheme. These schemes can be a useful way of building staff commitment to a corporation, although it doesn't necessarily mean the commitment aligns with desirable regulatory outcomes. The CSL sale terms included an employees share scheme for two and half percent of stock on offer. 'CSL Employees now own nearly one percent of the Company', the house newsletter Inside CSL said in June 1994.[349]

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[348] *Canberra Times 2.3.90; Australian 28.2.90*

[349] *Inside CSL June 1994 front page*

Following the sale of CSL this year, immediately dismissed, departing or retiring staff have been required to sign secrecy agreements. Some have objected, or are seeking modification of the terms of these agreements which last indefinitely according to a number of sources. One said 'CSL is as closed as it ever was'.

A staff survey six months before the sale found that of the sixty percent who responded, thirty two point five percent said the morale of CSL employees was good, thirty five point five said it was bad and twenty nine point seven were 'neutral'. However, most respondents reported a sense of achievement with their work and job satisfaction. Most reservations were about management performance. Most employees expressed satisfaction with management's support of GMP but many were unsure or lacked information about Total Quality Management and MRPII. This is perhaps not surprising, as these regulatory measures are new to the corporation, and cannot be expected to take effect overnight. They require ' a way of thinking' to really become 'owned' by the organisation, that is, by the individual employees who make it up.

Many employees expressed dissatisfaction with management's performance in showing leadership, treating people fairly, delegating decision-making and promoting the best person for the job. A majority were satisfied with management's technical competency in areas like planning ahead, getting things done according to plan and encouraging new and better ways of doing things.

While some of these scores are not good, one can easily imagine that not so long ago they would have been considerably worse. The same survey run at six monthly intervals could furnish some meaningful data. It doesn't matter how low a score is in one sense, so long as it is moving up.

15.7. Commitment to effective self-regulation

Self-regulation may be defined as 'the adoption of codes of practice which embody the mutual obligations of competing members of an industry or profession. These obligations are generally designed to complement federal and state regulations'.[350] Purposeful and effective self-regulation, whether implemented under the implied threat of regulatory escalation by external agencies or because of enlightened self-interest on the part of management, can be far more effective than mere intervention in the affairs of a corporation by outside regulators.

15.7.1 Quality control

As seen elsewhere in this report, CSL for long refused to comply with the code of good manufacturing practice developed by the National Biologicals Standards Laboratory of the Health Department. An essential ingredient in

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[350] *Eric Mayer, in Business Regulation and Australia's Future, ed Grabosky and Braithwaite, 1993 at p 101.*

good manufacturing practice, according to this code, was that there be a quality control department. The head of quality control was to report directly to the senior executive and have independent oversight of all stages of the manufacturing process. In the normal course of things there would have been a set of production instructions, manufacturing documents, and, similarly, documents specifying procedures for labelling and packaging. These documents had to be agreeable to the quality control department. There would also be a set of quality control standards or other specifics with which the product had to comply when tested, such as an ambit for the percentage of a solution which must be albumin, or in what circumstances a batch of blood product which didn't pass testing could be reprocessed, and so on. 'That was the philosophy all the way through [the code]' an expert informant told the author. 'CSL refused to adopt that philosophy, from the late sixties through to the most recent times. And yet all other pharmaceutical manufacturers were doing these things in the early sixties'.

According to evidence given this author, a CSL quality control manager constantly complained about being isolated and bypassed within his own organisation. As seen in chapter fourteen dealing with Salk polio vaccine manufacturing failures, a CSL scientist reported having queried the quality of glass filters used to separate the live virus from the vaccine and said he was ignored and passed over. One quality control officer reports having objected to the issue of human pituitary preparations containing pyrogens. Evidence relating to quality control at CSL under Government ownership consists mainly of reports of individuals attempting to prevent breaches through individual protest. It suggests there was no overall official commitment to quality control with appropriate authority vested in designated officers who were permitted to do their jobs on any routine basis.

15.7.2 Total quality management

Total Quality Management is a program conducted within an organisation to increase its efficiency and productivity, and to ensure the quality of the goods produced.

Brogan claims CSL was 'among the pioneers of TQM (total quality management) in Australia'. In 1984 CSL undertook a pilot TQM project in its packaging section which was facing enormous problems from inefficient work practices and ageing machinery. (The Nossal Inquiry had recommended six years before that it be immediately upgraded). According to Brogan, the initiative for the TQM trial came from the section's director, Graeme Kaufman, who sold it to the managing director. He says it led to total elimination of batch failures for one product, restoration of an old machine to better than previous performance, reduction in reworks by a factor of ten, a thirty per cent reduction inventory and the same percentage increase in efficiency, all without major expense. The MD then extended it to other parts of the company, including marketing, distribution, production and administration, according to Brogan. 'But not for the code of good

manufacturing practice!' insisted an NBSL informant to this author, and others agreed with this.

15.7.3 Self-regulation in the nineties

There is considerable information in official CSL publications concerning its initiatives in self-regulation, particularly in the last three years leading up to the sale.

The business of the organisation was separated out into divisions in the late eighties. In 1987 a Blood Products Division was established, now the Bioplasma Division.

For the Bioplasma Division, in addition to TGA licensing subject to GMP inspection, a CSL representative said they follow GMP themselves in regulating manufacturing, as well as using total quality management (TQM) and a planning and scheduling strategy called MRP11 which is used by various other companies in Australia. The company also has a separate regulatory affairs section now. Fifty six percent of respondents in a CSL staff survey in late 1993 said they were satisfied with their manager's and supervisor's support of TQM. Half were satisfied with the level of support for MRP11 and sixty eight for GMP. This could support the idea that self-regulation backed by the threat of regulatory escalation in the event of failure may be the most effective formula for compliance, as TGA licensing is undoubtedly the strongest external regulatory influence on CSL.

According to Official A, interviewed by telephone in 1994, clearance of each batch of product is now required by the independent quality control manager for the Bioplasma Division, who also reports to senior management. As an indicator this is a vast improvement on the past.

There were 'heavy investments in plant enhancements to meet the increasing demands of both domestic and international markets' from 1991.[351] (The entry of CSL onto the international pharmaceutical market has brought a regulatory benefit in that it has to submit to international inspection in addition to TGA inspection. CSL was recently inspected by the Food and Drug Authority.)

As mentioned in earlier, CSL was chosen at random for an Australian National Audit Office project which looked at internal audit standards in a range of Government instrumentalities.[352] An official at the ANAO believed CSL's performance, based on that project, was found to be 'pretty good'. ANAO interest in CSL, other than through annual audits, was otherwise not found.[353]

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[351] *annual report 1991-2 p 7*
[352] *ANAO Report no 50 of 1991-2 .*
[353] *interview ANAO 1994*

In July 1991 a three year audit plan was adopted which widened the activity from the traditional financial watchdog role to that of an independent reviewer, according to CSL's house journal. 'When reviewing how things are done, we are looking for ways to minimise costs ... We assist in improving performance and efficiency in much the same way as CSL's TQM and Manufacturing Resources Planning MRP11 programs but with the central focus on reducing costs and increasing profitability'.[354] From a regulatory viewpoint, one needs to be more interested in whether the TQM and MRP11 programs were working well alongside internal audit. Cost-cutting measures alone could lead CSL down the wrong track, as seen with the mixing of plasma to increase profits. As seen earlier, the blood products division was granted an MRP11 award at the same time that clients gave extensive evidence concerning the company's failure to meet their needs.

All these developments are good indicators of commitment to self-regulation. As to their actual effectiveness in achieving desired outcomes, that could not be assessed by this study. For example, TQM requires demonstration of 'continuous improvement', evidenced by graphs and the like. Does CSL's GMP auditing in fact show this? It would be valuable to CSL and its many stakeholders if the company were to co-operate in future with an external compliance audit. To quote two interviewees for the Australian Blood Regulators Study:

> 'In the eighties CSL was seen to be the lost Ark, still working with sixties technology. Now they have gone through a revolution, with the new plant, new people, total quality management ... Some say they are capable of doing it, some say it hasn't changed. It is difficult for an outsider to say.[355]

> The people who are involved have to own the process - that is TQM to a tee. Can you instil that? You need leadership to get it across - and its very difficult to achieve.[356]

15.7.4 Conclusion

It is a risky business to allow for-profit trade in human blood, whether at the level of donation, blood banking or processing and distribution. CSL is a for-profit organisation and operated as if a for-profit organisation over a long period. In the past it was paid less than market prices for its Australian fractionation service but in early 1993 it secured prices from the Federal Government approaching world market costs. CSL has long conducted commercial fractionation for foreign companies alongside Australian manufacture.

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[354] *Inside CSL March 93*
[355] *medical research scientist*
[356] *State regulator, in interview with author 1993*

Over a long period, it has not been required to routinely account for its blood production activities and has not done so. It appears to have developed a culture of secrecy and of justifying its failures by reference to factors other than its own doing. All these factors make it unsuitable to fractionate Australian product.

If the organisational ethos described in this chapter were shown to be no longer current at CSL, or dying a rapid death, the regulation of its blood processing could stand a better chance of success. However, regulation as it presently exists, while it may be resulting in improvement, is still weak judging on evidence given this study, particularly in the area of the company's accountability to its clients, the public and the Health Department in its role as a purchaser of blood products. A solution to both situations may be found in the one course of action.

R.77 CSL's Bioplasma division and management senior to that Division should be required by Government in consultation with the Directors of the Company, to comply with a series of external accountability exercises designed to test their responsiveness - within the framework of the national policy on blood supply - to clients, suppliers, shareholders and the community of blood product users and potential blood product users - that is, the Australian community, and governments or communities of users in overseas countries for which the country fractionates plasma into blood products. Government is in a position to secure compliance from CSL on the basis that it is the company's sole client for Australian blood products.

CSL should table for a consultative committee a plan to ensure the transformation of its corporate ethos. This should be designed to overcome secrecy, ensure government and public accountability for the manufacture of Australian blood products, and implement credible internal compliance and ethics programs. The primary emphasis and purpose in this plan should be to enable the realisation of the eight regulatory goals postulated in chapter one of this report. The plan must include positive measures to rule out the compromising of these goals by CSL's commercial and international activities. The plan should be modified in light of consultation with relevant stakeholders. CSL should report to the consultative committee on progress with the performance indicators in the plan.

The company should commit to continuous publication of quality assurance policies and quality outcome indicators.

The nuclear power industry is now 'pairing' comparable facilities in different countries who then audit each other for compliance with regulatory programs. This global peer review scheme in effect makes each corporation hostage of the other, since the auditing facility shares responsibility for the

compliance of the corporation they audit, and can be made, for example to help pay for a cleanup in that corporation in the event of a failure which should have been anticipated.

R.78 CSL's should consider pairing the Bioplasma Division with a 'sister' organisation from another country, preferably a state-owned fractionation facility, to permit continuous mutual peer review of its compliance with regulatory programs.

CHAPTER SIXTEEN: THE UNBINDING OF CSL

In this chapter two issues with implications for the regulation of blood products are examined. The first issue is the manner and terms of CSL's privatisation. The second issue is its likely effect on blood products regulation. This chapter is more a series of observations than a thorough study of the sale and the regulatory effects of privatising CSL. The sale had not been anticipated when the Australian Blood Regulators Study was devised, and the author, also the Principal Investigator, was inexperienced in some areas necessary to make a fuller study. These included Government assets sales, due diligence, the Corporations Law, and the role of the Australian Stock Exchange and the Australian Securities Commission. The role various officials in assisting her understanding of these matters is gratefully acknowledged. Nevertheless, it still seemed best to not venture too far into analysis in these areas. Much of this chapter is therefore descriptive only.

16.1. The sale

What was it that the Federal Government sold to CSL shareholders: a pup, a pig, a bargain, or the crown jewels? No prospective shareholder was in a position to know. The divestment of CSL was in all respects a very private sale. The Federal Government is not bound by the Corporation's law which governs standards for disclosure and other conduct. Although it has adopted a policy of acting as if it were bound, its level of disclosure was very low, vital information was highly manipulated and the sale process was conducted in great secrecy. Stakeholders who might have taken part in a debate on the subject were kept out.

16.1.1 The decision to sell

The decision to sell CSL, including its blood product manufacturing activity, was made by Cabinet in secret and announced in the context of the 1992-3 budget. The decision was in response to a submission from the Health Department, strongly backed by the CSL Commission, according to sources. Before going to Cabinet it was considered by the Estimates Review Committee, the key Ministers in Cabinet responsible for framing the budget. Former Health Minister Neil Blewett was on the Committee. The Department of Finance framed another Cabinet submission concerning foreign ownership and the Minister for Finance had carriage of the Sale Bill. The decision to sell CSL was announced in a Government news release.

A Ministerial aide told the author of his concerns about the future of community service activities once CSL was sold. Three days later he had backed off talking about it and referred the author to the Deputy Secretary of the Health Department instead. Finance controlled the sale very closely. A Health Department official said Health wanted a public float but few matters were up to them. 'We have brought these matters to bear on Finance but we

were not in any position of strength because Finance rules the roost'. He also was censored from speaking further.

Because of the way the decision was made, there was no opportunity for stakeholders to debate its merits. What would be the effects of placing blood fractionation or vaccine production, both of them Government community service obligations, into a private commercial setting? Could they not have been retained and better regulated? Why could Government not have hybridised the company, selling the pharmaceuticals and retaining ownership or at least control over the blood products,vaccines and anti sera?

There was also no possibility of debating the merits of privatisation itself, even though: 'there is now - in the late 1980's and early 90's - increasing awareness that privatisation is not an unmixed blessing, so that there is some lessening of its appeal (though, arguably, not yet in Australia, which seems to be in the guard's van rather than the engine of the privatisation train).[357] Thatcher got away with privatising water, why shouldn't Australia privatise human blood?

A Health Department official said 'we couldn't tell people [about the decision] because CSL is very highly structured; it has agreements with forty-six companies including multinationals'. CSL's commercial interests had to come ahead of accounting to the Australian people. Telling the people might jeopardise the sale, in other words. And the sale was going to happen; what the 'great unwashed' out there in the electorate thought was just too bad.

Even once the decision was announced, there was no debate. The two year sale process was conducted in great secrecy. It was as if, by refusing ever to speak about the public interest, officials thought they had obliterated the concept. Computer links between the Sales Task Force and other agencies were shut down. Entry to the Task Force offices was by key only. The author's name was passed along the inter agency grapevine as someone to be fobbed off. When she kept asking questions, some even tried to fathom who she *really* was. One version had her Very Involved with a particular political party. (Hopefully the Task Force investigations into CSL were superior to these divinations.)

16.1.2 Reasons for selling

Why sell CSL? Was it just another divestment in the flood of privatisations? Was it to recoup some costs of the recession and overspending, or to fill up the 'once only budget bucket'?[358]

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[357] *Wettenhall p 6*

[358] *Wettenhall, Why Public enterprise - A Public Interest Perspective, Canberra Bulletin of Public Administration, No 57, Dec. 88, p 44-50.*

Was it because CSL was inefficient? No one in Government thought that. If they had, they would have been better placed than anyone else to conceive solutions, had they wanted them.

Was it because CSL was efficient? Measured in profit and loss terms, it's trend was upwards, meaning Government stood to gain moderately increasing returns by retaining ownership, and income of twenty million dollars annually for leasing the new blood processing plant to CSL. Most observers assumed that because CSL's profits were up, it must also be efficient. However, efficiency is not a reason to sell, only a selling point after the decision is made. despite what some commentators believe.[359]

Senator McMullan, representing the Minister in the Senate during the sale legislation debate, said he understood the chief reason for the sale was the incongruity in Government being CSL's owner, customer and regulator. This reason was also cited by a Health Department official. However, as Senator McMullan also observed, such issues should be looked at on a case by case basis.

There are parallels for this situation, and solutions to it as well, short of selling the enterprise. A large part of Australian security services are undertaken by police, although the States are a major user of services. Some police regulation is being separated off into the hands of the Ombudsman, but most is internal. The argument that can go both ways. Government could have kept CSL, regulated it properly through a separate mechanism and put price setting in the hands of an external authority. This was far too reasonable a motive to explain the sale. Government had never cared about the incongruity before; why should it suddenly sell the entire organisation to satisfy such a fine, theoretical point?

Was it because CSL, in the end, wanted to be sold? One official said, when asked reasons for the decision: 'CSL has had a gut full of Government interference, of restraints on raising money, and being told what to do in the R&D area, and thinks it can compete [in the private sector]. There was also some push from other companies.' But why should the Federal Government suddenly start giving CSL what it wanted - unless it also suited the Federal Government? The alleged push from other companies was not pursued by the author. There have been intimations of this sort of influence in major decisions about the future of CSL over many years. If there was such a push, Government would still have needed it own reasons to proceed.

On the face of it, CSL stood to gain far more from the sell-off than did Government and some of its gains were at Government's considerable expense. The sale gave Government three hundred million dollars, take away six million for the cost of selling the authority, take away the one hundred and seventy to one hundred and eighty million put into the new blood

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[359] *eg Sydney Morning Herald 7.3.88*

processing plant, take away twenty million a year in forsaken lease payments, and take away annual dividends from CSL's business. Government also had to declare some indemnities. Under a new ten year Plasma Fractionation Contract they now pay CSL twice to three times the previous price for blood products made from Australian donor blood. CSL's Board is keeping the new prices secret,[360] but they are said to be roughly eighty percent of the commercial world average.

The sale Prospectus shows that most of the eight percent increase in revenue for the financial year ending June 1994 is attributable to an expected sixty-five percent increase in 'Bioplasma Division sales' arising from the new contract. Interestingly, it commenced before the sale, on 1 January 1994. The output from the new plant hasn't increased enough to account for that. Thus the revenue increase can be assumed to come from increased prices paid by the Government.

CSL also has the prospect of achieving, with the help of Haemophilia Foundation lobbyists, future Government subsidy for costly recombinant factor VIII which CSL plans to market as a 'complement'[361] to Australian plasma-derived factor VIII made in the Melbourne plant.

CSL wasn't supposed to get the new fractionation plant. By the end of the sale bargaining process, however, the arrangement had changed from lease to handover and CSL came away with another glittering prize: CSL's investment in the world class facility had been forty million as against Government's of up to one hundred and eight million, as mentioned above. This really *was* the crown jewel. As one official put it: ' [CSL] was really only a fractionation plant in sale terms'.[362] The handover added an estimated one hundred millions dollars worth of sweetener to the sale.

In just fifteen years of leasing, the Federal Government could have banked the same amount they got from selling the entire statutory authority, plus the annual returns. The Federal Government paid to give CSL away in the end, and handed over the best and technologically safest fractionation facility in the world. The move prompted incredulity, bewilderment and disgust in numerous quarters, especially those knowledgeable about the commercial blood industry. Yet people felt protest would be pointless in the face of the powerful privatisation mania that seemed to be sweeping through Government. Few people looked beyond the mania to ask if government had rather more to gain than lose by washing its hands of CSL.

Eight weeks after the sale went through, Deputy Prime Minister Howe broke Cabinet ranks and questioned Government's commitment to privatisation

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[360] *Prospectus for Sale of CSL p 96*

[361] *CSL official B, interview 1992*

[362] *and see, for example, Financial Review 22.10.93, p 30, MD's statement about timing the float to completion of the plant.*

and the tide began to turn. Soon after, it was reported that leasing Government airports in preference to sale was being seriously considered by Cabinet:

> The Federal Government may not go ahead with its plan for a full sell-off of major airports and will more likely offer them for lease or partial sale. A major study ... is likely to suggest leasing rather than selling. ... The preliminary advice to ministers is that offering the airports for long-term lease rather than sale would not reduce the expected return to the Government. ... The Cabinet has also asked [the study] to advise it on the alternative of leasing the airports. ... The decision to sell them in breach of the ALP platform ... has sparked a major Labor Party row and a threat to block the sale at the national conference in September.[363]

Why the set on making CSL the first one hundred asset sale, giving Government no way back in, short of a costly buy back? The Commonwealth Bank and the Australian Industry Development Corporation had been hybridised when fresh capital was needed. Overseas, partial sales are common. Singapore Airlines became a mixed enterprise in 1975 when a first tranche of shares was sold to employees and a subsequent tranche to overseas investors to raise capital for aircraft purchase. The Government retained sixty three per cent. Singapore Airlines, ironically, was one of two finalists to tender for a major part of the privatised QANTAS.[364]

Why did Government not retain control over the community service products of blood, vaccines and anti venoms, which needed and could have closer scrutiny than in a commercial setting, and could also be purchased more cheaply if State-owned? Government could have allowed CSL to accept endowments. Did Government know absolutely nothing about the disastrous regulatory failures unfolding in the world blood industry? With CSL determined to internationalise, did the Federal Government really believe 'the market' and TGA together can prevent that type of failure ever happening in Australia?

Perhaps 'Why sell CSL?' is the wrong question. What happens if one asks a different one: 'Why keep it?' Officials interviewed for this study often said that CSL was being sold because it was 'a cost to government'. What did they mean? The cost of CSL's R&D bill? The cost of regulating it? Hardly. In the explanatory memorandum to the Sale Act, the Minister for Finance rounds off his three-paragraph Financial Impact Statement with:

> In addition, ongoing costs of monitoring CSL faced by the portfolio department [Health] and the Department of Finance will no longer be incurred following the sale.

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[363] *Sydney Morning Herald p 3 27.7.1994*
[364] *Wettenhall Public Enterprise etc (see later)*

This sounds impressive, but the job was being done by two officers.

Perhaps, in the beginning, Government was merely scouting around for saleable assets to boost revenue short-term. However, if the decision to sell CSL was more than a mindless impulse that then had to proceed for face-saving reasons, the most likely reason for persisting was probably the wish to rid itself of liabilities for biologically-derived products. This is where the real cost was unfolding.

Rarely profitable in any case, biological products are, 'liable to some disaster' as regulators and Government lawyers often pointed out during this study. The proof of that was mounting as never before in the years leading up to the decision. Did Government officials have reason to believe that in the hands of CSL, these products could be expected to visit even more cost on Government than the normal liabilities for biologically derived products? How much government officials knew of CSL's questionable practices is not clear, but something is rather wrong if Government didn't know, and key officials were keen to avoid talking with the author about her own discoveries, especially as sale time drew nearer.

The agency most aware of these mounting hidden costs was the Health Department, the same agency which submitted the sell-off proposal to Cabinet. Recall the evidence of the Department's senior legal official in 1992: 'why should the Commonwealth put itself at risk when a manufacturer could be done?' Recall the same agency's attempt to have blood products exempted from trade practice amendments creating a new route for civil litigants, and its flat refusal to consider no-fault liability for consumers harmed by bad blood. Recall the agency's handling of medically-acquired HIV suits, addressed in chapter twelve. Recall the indifference to regulating blood products and other biologicals over many decades, and imagine the liabilities accruing to Government from the fruits of that indifference, should more defective products come to light. Bear in mind that a new wave of suits over hepatitis-infected blood was on the horizon, that hepatitis D, E and F are expected, that CJD infection in placental blood products was known about in some circles at least.

Some may say this doesn't explain the sale. Why close the stable door after the escape? That is too logical an argument. The Health Department had already shown in the case of pituitary hormone product failures, and HIV-infected blood, funding of blood testing and other associated issues that its first response to trouble was to avoid paying as long as possible, whatever the long-term consequences of that policy might be. The indemnities Government gave CSL are limited only to products already known to be defective and supplied only before the point of sale. They do not apply to harm from hidden defects in existing products, harm perhaps from products which were a mix of Australian and foreign plasma. The motive for selling was more likely to be based on the general observation that CSL was costing

the Government too much in product liability and rather than wait for the liability to grow, it would be easier to get rid of the perceived problem altogether and bank a bit of cash at the same time, which might pacify Finance for a while.

16.1.3 The Indemnities

In May 1993 the Health Minister established an independent inquiry into CJD and the government/CSL pituitary hormones program, under which women received hormones and, evidently, the fatal CJD prion at the same time.[365] The report was due to be tabled in parliament just two weeks after CSL expected to commence trading shares on the stock exchange.

> Government sources, while confirming that the potential liability has been fully taken off CSL's books, played down the effect it would have on the planned sale of the organisation. A spokesman for the Minister for Finance, Mr Willis, said the government had made no contingent liability for any claims against CSL. These would show up in the Government's own accounts only if legal actions were successful.[366]

The Government had reason to be confident that the Allars Inquiry wasn't going to harm the sale as the report was scheduled to be released by the Minister on the last day of the financial year, the same deadline for the sale of CSL. Despite all the hiccups, delays and flaps with the sale, CSL started trading twenty seven days ahead of the report being tabled on June thirtieth.

Former Health Minister Richardson had already promised an indemnity, on grounds the Federal Government would manage the defence for them and CSL. As mentioned earlier, the Government recently applied to have roughly one hundred stress and anxiety claims over CJD from CSL's products struck out.

Richardson also referred to ailments picked up via allegedly defective blood products.

> CSL does have a difficulty in this regard. To make sure that potential investors are *well and truly reassured about what might happen* , the government will be giving an indemnity to CSL. That will be public. It will be known to all those who seek to invest in CSL before the float. So **no-one will be in any doubt whatsoever as to the state of what they are buying'. CSL 'is a viable, excellent company that will go from strength to strength.'**[367]

The Government indemnified CSL for AIDS claims resulting from plasma products which CSL manufactured for New Zealand and Papua New Guinea

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[365] *Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease,*
[366] *Fin Review 21.10.93*
[367] *Fin Review 15.12.93 p 7*

and post-sale claims against CSL arising from hepatitis and HIV contamination from local donor blood, for claims over vaccine distributed before CSL is privatised, and for whooping cough vaccine claims.

16.1.4 The CSL Sale Act

The 1993 legislation contains 'national interest restrictions'[368] which seek to:

- control foreign influence;
- restrict the disposal or encumbrance of the new plasma facility without Federal Government approval; and
- provide a mechanism for enforcement of the Plasma Fractionation Contract.

16.1.5Control of foreign influence

Under the legislation, an Australian body corporate[369] must be no less than sixty percent Australian owned and, in the opinion of CSL's Directors, effectively controlled by Australian individuals, government or corporate bodies or fund managers, according to a set of criteria laid out in the Act.[370] However, the Directors can ignore these criteria if they are satisfied, on 'reasonable grounds', that the corporation is still effectively controlled by Australian interests. That deals Directors considerable discretion when judging issues such as whether foreign persons and their associates are 'in a position to exercise control over a significant proportion of the operations' of CSL. How much research should they undertake to satisfy themselves? May they be satisfied with mere belief, or reassurance from others? Are the Directors equipped to unravel interconnected shareholdings, company chains and shareholder's agreements in deciding these matters?

CSL must also maintain a register of foreign-held voting shares[371] be made available to the Minister on request.[372] The Minister may apply to the Federal Court for an injunction to enforce this and other requirements, such as the requirement that at least two thirds of the Directors must be Australian citizens, including the presiding Director. However, to exercise this power, the Minister has to know of a situation requiring correction, and would therefore have to be informed to a greater degree about CSL than Ministers have in the past.

The government limited foreign ownership to twenty per cent of shares.
The decision was made in the 'national interest', 'to put a fence around CSL's great strengths - its strategic alliances which have built up Australia's research base'.[373]. These strategic alliances are with transnational

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[368]*PART 3A*
[369]*19B*
[370]*subsect 6*
[371]*19E (I)*
[372]*19E (2)*
[373]*statement by Parliamentary Secretary to Health Minister*

pharmaceutical and biological companies, SmithKline Beecham, Merck Sharp and Dohme, Cutter Laboratories, Hoechst, and with Biotechnology Australia.

16.1.6 Disposal of fractionation plant

Unless to a wholly-owned CSL subsidiary,[374] neither CSL nor its subsidiaries may dispose of the plant, grant an interest in it, nor use it as security without approval from the Minister.[375] The Minister may delegate this approval to an officer of the Department.

16.1.7 Plasma Contract Performance

If CSL engages or plans to engage in conduct that would breach the Plasma Fractionation Contract, the Minister may obtain an order restraining or directing the Company[376] or an interim injunction if needed.[377] The Court may also make orders against CSL as well as granting an injunction.

The Plasma Fractionation Contract was not available to the public until CSL was sold, when its general nature was made available in the Melbourne office for shareholders to peruse, but not copy. The Company Secretary undertook to respond to the author's request for a copy of this and other contracts on display but did not do so. The Health Department was considering a request for access as this was being written. An official described the contracts as bland and innocuous and could see no reason why the public should not see them, including the prices Government is paying CSL for fractionating Australian plasma.

Regulation of CSL via this contract essentially amounts to the use of financial incentives. If CSL meets their quotas the Department will be satisfied, basically, said an official. The use of financial incentives as regulatory tools is not much used in Australia, according to Braithwaite and Grabosky.[378] If ever there was a good case for regulators to break new ground in the use of this mechanism as a regulatory tool, the Plasma Fractionation Contract is it.

R.79 As a contractor to the Federal Government, CSL should be covered by the Freedom of Information Act 1982 to the extent that information collected relates to blood product contracts. A condition of contract should be CSL's commitment to a code on information access.

16.1.8 Disclosure in the Prospectus

As part of the 'due diligence process' associated with CSL, the Assets sales Task Force is required under Corporations Law to fully inform any potential buyer of the *financial* and *legal* position of the Company. Corporations laws

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[374] *19P (2)*
[375] *19P(1)*
[376] *19Q(3)(4)*
[377] *19S.*
[378] *See Of Manners Gentle, Bibliography.*

requires that prospectuses contain all information that investors would *reasonably require and expect to find.* The laws apply to CSL but not the Crown.

In practice, material matters requiring disclosure are generally matters which could affect the company's financial viability or cash flow, such as product liability suits. Thus the Government was obliged to declare indemnities. However, because CSL manufactures goods on behalf of the Federal Government which are supplied as community services, material matters could readily include issues such as manufacturing practices, if they have bearing on safety, continuity of supply and other public interest concerns. This raises the question as to whether the Prospectus should have disclosed 'questionable' practices such as the ones referred to in this report. Besides, these practices could adversely affect the company's financial viability in a number of ways.

Would mums and dads, as prospective share purchasers, think it enterprising of CSL to send Red Cross products off to a foreign country? Would they share CSL's view that the mixing of plasma from different sources was justified on economic grounds? Would they be unconcerned that major clients were dissatisfied with CSL's service? Or might they wonder whether CSL should be trusted with the blood of Australian donors?

The Government didn't give the public a chance to form an opinion on these matters. How did the Task Force, and CSL's Directors, form a view that these kinds of matters did not need not be disclosed?

In overseas countries the public has not taken kindly to organisations engaging in questionable practices with human blood, even in nations where commercialisation is a fact of life. In the eighties, Thatcher's running down of the UK national system paved the way for foreign imports, some of them illegal. This was exposed, beginning with a letter to the British Medical Journal, and widely criticised. The expose even reached Australian media.

When the Socialist government lost power in France, its failure to check the behaviour of the blood industry was a major factor in its defeat. Feeling still runs high in France, made even more intense by revelations of government failure to withdraw hormone preparations despite knowledge of the CJD risk. Portugal's ruling Social Democrats also faced tough elections in 1993, in part due to charges that officials ignored warnings about imported plasma carrying HIV.[379] The recent German UB Plasma scandal prompted widespread public criticism and the same phenomenon is building in Switzerland over the conduct of the Central Blood bank in the eighties in delaying the introduction of HIV tests. In the seventies revelations began to unfold about the workings of the notorious Bonn clinic, where treatment of seven hundred haemophiliacs cost between one and three million deutschmarks annually. In 1980 the Berlin antitrust office charged

[379] *Time, November 15 1993,p 28*

pharmaceutical companies with fixing factor VIII prices. The companies dropped their charges by thirty percent 'for fear of further investigations'.[380] Citizens in Germany established a consumer watchdog group on questionable practices in blood.

In the United States, when an investigative journalist on the Philadelphia Reporter told how Red Cross capitalises on blood from US donors, and US plasma collection centres on the Mexican border are inadequately regulated by the FDA, Americans were incensed. The journalist, Gilbert Gaul, received the Pullitzer prize for his investigation. The legal defence of the US Food and Drug Administration and US blood companies for their decision in the early eighties not to use a hepatitis 'surrogate' screening test to detect donors at risk of HIV saw them successfully through the rash of lawsuits that followed, but now those same defences are crumbling as another round of public suits is mounting around those same decisions.

In Canada, it took eight months for old factor VIII to be replaced by heat-treated product after the decision to change over was made by the Department of National Health and Welfare's Bureau of Biologics in November 1984. A principal reason why public outcry hasn't been great the way is that the Canadian Haemophilia Society was at the table with the government agencies and closely involved with the decisions they made. Even so, by early 1993 individual haemophiliacs had begun calling for a Royal Commission[381] and a judicial inquiry was appointed to investigate the delay.

Even in poor countries citizens have found ways of registering their disagreement with questionable blood practices. When a Nicaraguan newspaper editor named Chomorro was assassinated for exposing donor exploitation at a government plasmapheresis centre, mourners at the funeral proceeded to the plasma centre and burned it down.[382] Australians have long had much higher expectations of quality, safety and availability from their own blood supply system. Our closed non-commercial system has functioned as something of a model for the rest of the world. Was the Government entitled to assume that potential investors would be content to base their opinion of CSL only on the state of its recent balance sheets?

Many regulators within Governments and the blood banking community believed the questionable practices mentioned in this study were serious breaches of trust which should be acted on. During the sale process the author tried gauging the Government's attitude towards them. She asked a Health Department official responsible for monitoring CSL what action should be taken if the company had sent Australian product overseas

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[380] *Hagen, Blood - Gift or Merchandise? Towards and International Blood Policy p 154*

[381] *Kate Dunn, in the Canadian Medical Association Journal, February 15 1993, 148(4), pp 609 - 612*

[382] *Red Gold, Beauchamp 1991 and other research by the same author.*

without approval. This official 'X' said he didn't know of such a thing but that he was willing to talk. When the author contacted him again to do this he said he had 'got his fingers burnt' talking to her and ended the conversation.

Later the author contacted the Australian Government Solicitor's office in Melbourne and asked the officer handling the CSL prospectus to explain the principles governing the drawing up of prospectuses, particularly in relation to disclosure of matters relating to a community service obligation such as blood product manufacture. This officer said it was the policy of Attorney General's to comply with disclosure requirements in Section 1022 of the Corporation's Law but:

This is a difficult issue. ... A lot of these questions are being looked at right now. It is awkward to discuss with you. ... I would like to talk to you but as things are happening now I couldn't.
KB: What about the due diligence process then? I am not seeking commercial information, but to know the general rules governing this process. By what means do you satisfy yourself that all is well?
We make our own due diligence inquiries ... we review government documents.
KB: Do you rely on these?
We make our own independent inquiries.
KB: What guidelines do you follow in doing this?
... They were very thorough. We spent a lot of time doing that.
KB: What if someone had information about a material matter. Where should they go?
If the prospectus gets it wrong in a material aspect, they can sue.
KB: I am not talking about a situation where the prospectus has been lodged ... but a situation where there was material information now which could go to the heart of the public confidence in the ability of the company to conduct its affairs, while the prospectus is in the making.
The due diligence process has been thoroughly conducted.
KB: What if a jam factory were to be floated and someone had evidence that half the batches had cut glass in them but the due diligence process was complete. Where should someone go with that concern?
The requirements for the prospectus are laid down. The due diligence process was an exhaustive job. ...
KB: [Jam jar hypothetical repeated]
[Same response].
KB How is the due diligence study conducted in general terms, not relating to CSL in particular?
It was very thorough. ... You have made contacts. ... You have been talking to people .... 'X' in the Health Department.... Talk to these people.

This was the same "X" above who had got his 'fingers burnt' after the author asked him about a theoretical questionable practice matching one which had come up in the study. He had been forbidden to talk with the author. From the interview conducted with the officer in the Australian Government

Solicitor's Office, the author formed the opinion that the officer did not wish to hear of any information which the author believed might be considered material to prospective purchasers of CSL shares.

16.1.9 Sale process

The process was a tripartite responsibility between the Departments of Attorney-General's, Finance and Health, conducted in utmost secrecy. Even the qualifications of the consultants used in the scoping study were secret, the Head of the Task Force said. 'All the information provided under the contract is commercial information. ...We are happy that [it is confidential] Someone would 'put some material together for [the author]'. Nothing came of that. Having said nothing on the record the Head of the Task Force then without warning went off the record to reveal that:

CSL is a *very* attractive company.

She was told the Task Force would 'rely heavily on the understanding' of the Health Department for their knowledge of CSL, and in the process of determining measures necessary to protect the blood products activity.[383] At some stage in the sale process the Government made a decision that CSL would continue in the same relationship with Red Cross for the next fifteen years. Red Cross was not consulted in the decision, as seen earlier. Nor was CSL, according to CSL officials A and B:

> KB: I'm interested in the origin of fifteen years as being the period in which CSL will continue in the same relationship with the blood program - that is, non commercial. Do you know where that figure came from by any chance?
> A: I've no idea!
> B: I don't think anybody does. It's interesting when you look at documents. Certainly there is a number out there - fifteen years - perhaps somebody who had wisdom greater than anybody, than *ours* anyway! looked at it and said 'Ah! The entire field of plasma fractionation will change in the year say 2005 or 2007. But for [A] and I who have been in the industry for most of our lives it's been interesting for both of us, we have talked about it occasionally, ... in the late seventies we really expected that by this time there would be a supplement, an artificial haemoglobin, everybody agreed that would be here and the need for albumin would diminish significantly, and for blood. It never happened ... at that time we thought that the fluorocarbons would have replaced the blood. So based on that .. many decisions were made and now prove to be incorrect ... I have no idea who settled on the number.
> ....
> A: Well, it's a good number, a gut feeling! (laughs)
> RS: It doesn't concern you at all? ...

[383] *author interview with official in charge of Asset Sales Task Force B, 14.10. 1992*

A: Why should it concern us? We've got to be very lucky to be planning up to fifteen years, its very un-Australian isn't it!
B: We've been dealing for years with the fact that blood, as an example , in the year 1990 was no longer going to be a major need, and here we find ourselves in 1992 and it is. So when people give us something like this we say fine, we hear you, but we must plan for the next five, the next ten. ... I cannot look beyond three to five years. So, no, it doesn't concern me. Rather than argue with them I just listen and go on and plan what has to be done.

One interviewee thought the reason for the fifteen year rule was self-evident: 'By then the economic rationalists will have wrung every drop of blood out of us'. After all the efforts of stakeholders to fathom the reasoning behind the fifteen year rule, it turned up in the Prospectus as only ten,[384] extendable to fifteen at the option of the Federal Government.[385]

Arrangements for determining the prices to be paid by the Federal Government for CSL's blood manufacture were also secret. A Health official said CSL had never had to work out prices before, since they had always been funded on their operating costs.

An officer in the Office of the Surgeon-General of the Australian Defence Forces was concerned about the sale:

KB: Did you have any concerns about the privatisation of CSL? Yes, in relation to the supply of blood, and it came up afterwards in relation to our commitment to Rwanda, [when] we had to give the forces plague inoculations. CSL's supplies were limited [after the sale] and this limited our flexibility. They could inoculate one lot of men but if they had had to inoculate them all at the same time, rather than wait for the second lot they could not have deployed the necessary numbers in one go. The second shot is just coming through now [September]. The stocks were also more expensive than before. In the past CSL held the necessary reserves because Government met the costs of this. Now the company has to pay for storage and so on and the costs have gone up. We had to revise our war reserves because of the sale, it is costing us more, if it wasn't a direct consequence of the sale it was an indirect consequence. Because of our increased involvement with the UN we are exposed to more countries with these diseases, malaria prophylaxis treatment needed.

KB Were you given the chance to express your concerns before the sale? Yes. Each utilising department was asked for their views.
KB What happened to the views you expressed?

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[384] *p 5.*
[385] *P 21*

> We just assumed our concerns were outweighed by some of the other perceived advantages in selling. We feel we were ignored.

16.1.10 Parliamentary scrutiny

There wasn't the will to have a debate on privatisation. The opposition supported it anyway, and the government ranks voiced no real opposition. It wasn't the fashion yet to criticise privatisation - that came eight weeks after the sale. One Member said he entered the debate with mixed feelings, having opposed the sale, and added: 'when I look around I do not seem to see too many fellow travellers, so I have to accept that the inevitable will happen later in the financial year'.[386] The Democrats opposed the Bill and raised important questions when it was in Committee.[387]

Nor was there enough knowledge amongst the members to evaluate its impact upon the quality of blood products. One of the gains to be achieved by privatisation was said to be 'cost reductions and hence lower prices'.[388] which was the reverse of what happened with the blood products range. Debate did not focus on the biological products except for indemnities. As one member said: 'There is no reason for the government to own a pharmaceutical company'.[389]

CSL was praised by most speakers. The opposition took the position that sale of CSL was inevitable and overdue. The Shadow Minister for Privatisation who led the opposition in reply, had said in 1990 when CSL became a Government Business Enterprise:

> We're looking at industries or government business enterprises that don't need to be in government, and this is a classic case. ... this is one that ought to be delivered up to the market ... so ... it can continue to expand and offer the service it has done so well in the past. ... There's no down side in privatising CSL. ... You can call it something other than privatisation if it sticks in your craw, but for goodness sake, do it. I've just had an interesting trip around many countries in the world. ... Privatisation is being embraced in about eighty three different countries. ... Consumers are benefiting, taxpayers are benefiting and more importantly, government of different political persuasion, from Austria to Somalia; to South Africa, to Israel, to United States - obviously - to Great Britain, have all benefited by pursuing this path. It hasn't been done in an ideological binge. etc.[390]

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[386] *Jenkins, Reps Hansard 27.10.93,p 2638*
[387] *Senator Coulter, Senate Hansard 23.1..93, p 3482 - 3484*
[388] *Senator Gibson Senate Hansard, 23.1..93, p 3477*
[389] *Connolly, Reps, 27. October 1993, p 2637*
[390] *ABC Radio The World Today 7.9.90*

There was an irony in this, because the Shadow Minister for Privatisation was the parliamentarian who did more than any other Member to bring to light the CJD scandal after making this statement. If he had doubts about the sale of CSL as a result of his investigations, they were not in evidence in the Parliament.

16.1.11 Australian National Audit Office scrutiny

The Australian National Audit Office was slightly involved with the sale process. An official told the author that they entered a joint arrangement with Arthur Andersen in which the Audit office went over Andersen's work and had meetings with them. As mentioned earlier, another official told the author that the ANAO tried twice to undertake an audit of the sale process under its Special Projects section. They were interested in examining the passing of the blood fractionation plant to CSL, the ramifications of the Federal Government insuring blood products, the implications of introducing charges for blood and other issues. On both occasions personnel left - one to the Task Force - and the project did not proceed although the will remained.

16.1.12 Claims during the sale process

CSL's claims during the sale process related principally to its research base, and its plasma processing prospects. A corporation's claims of current research and development are always difficult to evaluate as no one expects them to provide a lot of detail. Several blood products were mentioned as being in development, including fibrin glue, discussed earlier, in chapters seven, at 7.7 and chapter six at 6.5.4.

In general the company's claims were quite sober and moderately worded. Unfortunately, however, CSL furthered the line that viruses can be completely removed from blood products. A publication which covers the opening of the new plant says that new technology features 'extensive use of procedures to eradicate viruses in the manufacturing processes.'[391]

CSL claimed to be a research-based company and spoke often of its plans to expand into Asia, especially in the context of opening its new expanded-capacity plasma processing plant in Melbourne. CSL never said the Asian market was secured. They expressed confident expectations which the media inflated in the course of making them newsworthy. In an advertising supplement in the Business Review Weekly CSL said: 'In the next three to four years CSL intends to build its presence in Asia and the Pacific region, and its core activity of producing blood fractions from human plasma will play a major part in this process'.[392] The message that came through the media was 'have-plant-will-process'. Australian media coverage reviewed by

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[391] *CSL Limited Update, Issue NO 4, FEB 1994, "Broadmeadows Plasma Processing Plant Opens" p 3.*

[392] *advertising feature, Business Review Weekly, 1993*

the author did not question whether CSL would succeed in Asia and the Pacific, except for Peter Maher in the Bulletin.[393]

A typical report was AAP's on the opening of the new plasma processing plant in Broadmeadows: 'Victoria is poised to triple blood exports to South-East Asia after the opening today of the largest blood processing plant in the Southern Hemisphere. ... 'This is world's best, this is Australia at the forefront, at the cutting edge, this is us leading,' Senator Richardson [as Health Minister] said at the official opening today'. This report also said the company would be floated on the stock exchange 'later this year'. CSL's PR company included it in blurbs sent to other journalists just before the float.[394] The author tried to obtain a tape of the Minister's speech to see if his statement's were within the limits set by the Australian Securities Commission for talking up a government sale. The ABC, who covered the opening on 'PM', could not provide it and suggested the Minister's office. Richardson's office said they would try to provide one but then they said it had got lost and was floating around the backstreets of Melbourne, and no one had a copy.

In the run up to the new plant being opened, the company was fractionating for New Zealand, Hong Kong, Singapore and Indonesia[395] fewer countries than previously. Overseas plasma constituted twenty percent of CSL's throughput.[396] Red Cross sources said CSL was keen to secure Vietnam's business. In 1992 the company was pursuing business in Malaysia, Taiwan and the Philippines.[397] In March 1994 the Philippines blood supply was reported to be contaminated[398] with HIV, hepatitis B, malaria and syphilis. The Health Minister said some of the contamination was in blood from unremunerated donors - CSL only fractionates for noncommercial plasma harvesters.[399]

CSL's 1992 annual report said 'Arrangements have been made for Malaysian Red Cross Plasma to be fractionated by CSL with the derived products returned to that country'. When Health Minister Richardson opened the new plant, the MD told the ABC the company believed it could succeed in markets such as Malaysia.[400]. But Malaysian plasma isn't coming in any more, according to this author's sources. Rumours were circulating during the float that Malaysia is planning its own fractionation facility, at least for government-controlled blood.

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[393] *5.10.93 p 86*
[394] *eg ABC Lateline April 1994*
[395] *Business Review Weekly, Robert Gottliebsen 26.11.93, p 27 ; CSL Media Release 14.2.94*
[396] *Business Review Weekly, Robert Gottliebsen 26.11.93, p 27*
[397] *Melb Age 3.3.92*
[398] *see chapter eleven, Imported Plasma for Fractionation*
[399] *CSL official A, telephone interview 1994*
[400] *ABC "PM" 14.2.94*

At the back of the Prospectus it is mentioned that the only country in relation to which CSL has a written contract is Indonesia.[401] CSL fractionated for Papua New Guinea for over three decades, but recently ceased bringing plasma in because its quality was not pure enough for fractionation. PNG was said to be dependent on Australia and New Zealand for its blood supply now.[402] Health Department documents obtained by the author, supplemented with study of annual reports, show that CSL officials have travelled around Asia and beyond for many years consulting with countries over their fractionation needs. The head of the Bioplasma Division even visited an Australian Red Cross official on the subject of overseas plasma supplies recently, however he did not get very far.

It is difficult to see how the commercialisation and planned expansion of CSL's blood business can amount to much unless the fractionation plant can expand its business in the relatively short term, yet the foreign plasma contract aspect was meagre at the time of sale, judging from the Prospectus and other published sources. Perhaps CSL's confidence was backed by business prospects they elected not to detail during this period.

However, as Europe continues its plans to phase out foreign imports, the surfeit of plasma from North America will increase. How will CSL gain a bigger foothold in Asia and the Pacific in such conditions? Will it allow itself to be effectively controlled by the interests who distribute into this territory in order to make better use of the plasma fractionation plant? Will it have to allow other companies to obtain the contracts in this region and fractionate for them as a sub contractor? If this happens, could CSL be indirectly brought under excessive foreign control? A report in 1993 said that CSL hopes to commission the facility.[403] If bringing plasma in proves too difficult for safety reasons, will CSL use its property rights in the technology and engineering for the new plant to build other facilities in the region and operate them? Or will foreign corporations use their connexions with CSL and other means to prevent this? And how will Australian regulators ensure that Australian manufacture is not compromised?

16.1.13 The prospectus

Two senior ASC officials in Melbourne were interviewed before the CSL prospectus was lodged. The Commission had recently released 'best practice' guidelines for prospectuses. The guidelines point out that legislative policy requires an issuer to assume responsibility for the content of its prospectus and to ensure that both the primary and secondary markets for securities are adequately informed so that investors may make informed decisions. Point twenty two says where there has been a failure to disclose all relevant information required by the Law, the issuer may be required to withdraw the prospectus or issue a supplementary prospectus.

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[401] *p 96*
[402] *Red Cross interview 1994*
[403] *Bulletin 5.10.94*

The Director of the ASC's Fundraising and Markets division said: 'if there are any inherent risks involved in blood products which would have an effect on CSL's profitability that ought to be disclosed'. The percentage of business represented by blood product manufacture should be disclosed. If at the time of the prospectus there was evidence which showed an activity which could seriously damage the company's reputation, or amounted to a breach of a Director's duty, it could be put before the ASC as a post-vetting exercise.

The broad aim of the prospectus requirements in the Corporations Law is to ensure that prospective investors are afforded the opportunity to make informed judgments in a calm and reasoned way.[404] An ASC official described it this way: the prospectus should contain everything a reasonable investor needs to know to form an opinion, especially on profit and loss, assets and liabilities, prospects.

CSL is described as 'a leading Australian pharmaceutical manufacturer' in a Dear Investor letter from the Minister for Finance on page two of the Prospectus, and further down as a maker of biologically-based pharmaceutical and plasma products. CSL's equivalent letter describes it as one of Australia's leading manufacturer of pharmaceutical products.[405]

The first mention of the general or innate risk in producing biologicals which this author could find was on page ninety one, under additional information: 'there are other risks peculiar to CSL and in addition to those faced by most pharmaceutical companies. These exist because of the possible viral hazards associated with products derived from human plasma and because CSL manufactures products which are used in large scale and long-term immunisation programs.'

This was the same page on which the prospectus revealed that CSL had been granted an indemnity for claims related to CJD contracted from blood products made from human placentae, which was picked up by only two people of whom the author was aware.

The prospectus slides around the point about the availability of foreign plasma. It says the new plant 'should enable the production of a wider range of high quality products and increased plasma fractionation activities for international markets, particularly Asia.'[406] None of the questionable practices which came to light during this study is mentioned. Whether they were known to the Task Force and CSL's Directors and dismissed as not requiring disclosure is not known.

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[404] *R G Walker, in Implementing Privatisation:the Case of the GIO Float, Sept 92, p 16 Public Sector Research Centre, Uni of NSW*

[405] *p3*

[406] *p6 Overview*

R.79 The Australian Securities Commission should inquire into the role of CSL's Directors and the Federal Government in deciding what were material matters that ought to be disclosed in the CSL Sale Prospectus with regard to irregularities in handling human blood products and plasma and pituitary hormones.

16.1.14 Media scrutiny

In the run up to the sale, CSL employed an external public relations firm which held media at arm's length from CSL. An ABC research journalist rang the managing director to discuss a major national program and was rung back by the PR firm. The managing director returned his call after some weeks.

Media spoke of CSL as a good sale prospect,[407] 'the "jewel in the crown" of privatisation candidates ... "a cinch" to sell';[408] with a 'beauty parade of likely underwriters'[409] 'and 'Painless path to public life',[410] and 'a pharmaceutical company which would have little difficulty selling itself ... because of its solid level of profitability and portfolio of core products.[411] Five years before the last newspaper told its readers that 'CSL could not be fully privatised because it ran some essential public services such as blood serum fractionation.'[412] That was the Government line at the time. Few Australian journalists were equipped to do other than repeat other's assertions on blood products. The common tendency to report assertions as their own findings made it even harder for the public to discern facts.

The Financial Review became rather more discerning as time went by, at least on financial matters. Shortly before the sale, it was described as 'problematic'.[413] other business writers went the other way. A Business Review Weekly journalist, who obviously got quite close to the company, produced a very favourable piece at the same time that other media were about to sound alarms over indemnities for pertussis and other claims coming before the courts.[414] Gottliebsen's piece in the BRW said:

> One of CSL's great advantages is that it has not had an accident with its blood operation, and it is important for this safety record to continue because it is at the base of its goodwill.[415]

Gottliebsen wasn't to know about the indemnity for CJD from blood products as this was written before the prospectus was released. Nor would he have

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[407] *Aust Fin Review 12.11.93;*
[408] *Melb Age 3.3.92 ;*
[409] *The Australian 3.11.93*
[410] *Bulletin 5.10.93*
[411] *eg Fin.Review 18.8.93*
[412] *4.3.88*
[413] *5.4.94*
[414] *SMH 11.12.93 The Grim and Growing Liability of CSL, Jennifer Cooke*
[415] *Robert Gottliebsen Business Review Weekly, November 26, 93, p 26-7-*

known of the plasma mixing - which wasn't an accident - or the sending of Red Cross product overseas.

A Financial Review journalist interviewed during the float[416] said he had done a few stories on CSL recently but 'had had no dealings with the company, other than getting some finance information from their finance contact ... they don't talk to us much. The Financial Review had taken the singular view that the offer is too highly priced. We have consistently queried the price.'[417]

> 'It's a bit misleading for the mums and dads, because it's a very specialist, professional type of investment. A cash flow multiple is good for institutional investors, on that basis it is cheap. The cash flow in the next few years will be good but the earnings growth won't be fantastic ... The mums and dads are only in there because floats are the flavour of the month. But Government was very misleading on the second tranche of the Commonwealth Bank, and this and CSL will create problems for them in future floats. $2.40 a share for the private investors is greedy. [The Financial Review described the second tranche sale as a monumental flop]. They have misled people about it being a pharmaceutical company, it is really a blood company that wants to become a pharmaceutical company. It is good on blood.
> KB: Why do you say that?
> The new plant, and business magazines have spoken of growth opportunities in Asia and contracts.
> KB: How many contracts are there?
> Don't know. Their R & D is quite good.
> KB: Which projects?
> The company hasn't given those sorts of specifics. The so-called independents say CSL is good. Institutional investors are more cautious, ... but all will take shares.

In Canberra the Financial Review monitored the politics of the sale[418] but could say very little about blood.[419]

Government's deliberations concerning indemnities were well reported in the media and the Opposition performed a very effective watchdog role on the process, though more on behalf of those at risk from CJD through hormones and vaccines than blood products. (Again, until the Prospectus was released, no mention had been made by Government of links between CJD and blood products, as seen in chapter five.)

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[416] *Financial Review , Melbourne 26.5. 94*
[417] *Fin Review 5.4.94*
[418] *eg 5.4.94 p 1,*
[419] *two lines 5.4.94 referring to indemnities.*

Otherwise, analysis in the media of the sale process and its ramifications was poor. Many journalists were impressed by recent income increases and projections for the next few years. They did not seem to realise the part played in these figures by circumstances such as the sudden increase in Government prices for blood products, which was a one-off event.[420] The implications of privatisation for blood products, the company's largest single activity at forty percent, was not discussed. Journalists fed off what other journalists said and, as seen above, CSL's hired public relations firm assisted that process.

No consumer groups in this country took up the issue. None had taken up the issue of blood products. The media had no information base from which to analyse company and Government propaganda. Parliamentary debate offered little relief from the information drought.

16.1.15 Investor scrutiny

Three potential institutional investors was interviewed during the float. They were asked how they assessed information given during the sale process. The responses were markedly different.

> KB: how do you assess information about CSL given by Government?
> We take the accuracy as given. We assume it is a true and fair reflection of the company. If some exotic disease hits the blood bank, that's an unknown you can't factor in. ... We are aware the directors could be sued if the prospectus is misleading, and that under the law the Commonwealth doesn't have to adhere to the laws other people have to adhere to. Then we asses it on its merits relative to other investments at the time.
> KB: How do you assess what is said by Government and CSL to the press and in other forums at the time of the float?
> Everybody know it's in the interests of the sponsor [the company] and the client [the Government] to paint a good picture and that they are constrained by wilful misrepresentation, and that they will be more optimistic.
> KB: How do you decide whether to invest?
> (Paraphrase) We look at earnings growth, essentially. Big jumps in profit are difficult to believe.
> KB: What about the company's line that its future lies in the Asian blood market, how do you assess that?
> I thought that was OK. ... the specifics are in the Prospectus. ... the Directors don't want to say too much as they can hang themselves.
> KB: Were you left with the impression they had contracts in that region?
> No.
> KB: Or were likely to get them?

[420] *eg. Financial Review 2.5.94 CSL Cashflow a strong lure*

You assume they have done their homework, to make a positive statement like that.

KB: What about the indemnity mentioned on p 91, linking blood products with CJD?

I didn't see that ... [I] hadn't realised the possibilities of it, that it could mean blood products were at risk. Oh, well, contamination - that's life ... it's not an investment issue. ... It might happen, but there's so much involved in companies you become a bit immune to it.

KB: Do you go beyond the prospectus in your inquiries?

You read the prospectus, you don't have time to do more. If it goes off the rails you vote with your feet. And you never forget the Directors.

The interviewee then spoke of a number of other investment offers, saying that they looked OK but a number of the directors had been associated with failures in other companies in the past, and so their company would not touch the offers.

KB: Are you buying?

Nope. Too dear. This competitive tendency [of early bidders getting favourable treatment] is going to die a slow death and CSL is one step in that. It is not such a competitive company that it can afford to do that. It's a boring company.

A second institutional investor, who intended to buy in, said:

We do things differently. Each financial group will have a different focus. First we make sure there are no discrepancies financially and then we focus on the industry itself, because it can be cross-checked. What is available is a general overview of the projected growth for that industry. We look at statistics from different sources, brokers' reports, financial reports of different companies, what's in the papers. Although CSL is part of the pharmaceutical industry it's founded on one part without a lot of competition. We might get something from Europe and the US on blood fractionation, a general overview, and compare it with CSL, based on their prospectus and speaking to the company manager at the time of the float. In this particular case I [did that] through the broker.

KB What about the Asian market?

This is the trend in many industries. South East Asia is growing so rapidly.

KB Did you get the impression they have contracts [in Asia]?

[It was] more prospective.

KB Did you ask if there were plans for another fractionation plant in Asia?

No. The US is on the other side of the Pacific and they have their own facilities - there is going to be competition anyway.

KB What about the indemnities for blood?

They are difficult to check because it isn't a public document.

KB Did you ask about placentae, what is the difference between placentae transmitting CJD and blood transmitting it?
No.
KB What about the Directors, were you influenced by who they are?
No. If anything that was a drawback as they are fairly old - despite their good qualifications.

16.1.16 Role of Australian Stock Exchange

A company being floated must apply to the Stock Exchange to have its shares listed. The company is subject to the ASX listing rules. These require minimum numbers of shares and that they be spread amongst various shareholders, making the float genuinely public. According to this author's advice, the Stock Exchange would be influenced by the standing of the lead manager for the float in assessing the validity of the company's application for listing. Generally the Stock Exchange will be satisfied if the Australian Securities Commission is. It appears that the role of the Stock Exchange was quite routine in the case of listing CSL.

16.2. Regulation post-sale

Avenues for public access and accountability through the Freedom of Information Act and the Administrative Decisions (Judicial Review) Act were in the transfer of CSL to private ownership.
CSL lost the protection of the Crown and acquired indemnities for some biologicals. It also acquired the new plant.

16.2.1 CSL Limited should establish its own whistleblower protection scheme.

In the course of this study the author became aware that some CSL officers in the blood products division disagreed with practices of the organisation and might have spoken out against questionable practices had there been a safe avenue. Other CSL staff have engaged in a limited and effective form of whistle blowing, by passing information to external parties able to act on it. Those who argue that whistle blowers always suffer for their actions fail to address the fact that it can be very successful if done the right way. The spectacular calamities that befall some whistle blowers can be found on inspection to be partly and often significantly traced to individual lack of sophistication or knowledge about how to proceed effectively.

Whistle blowing allegations are now a fact of organisational life. This is pointed out by an Australian authority of whistle blowing, John McMillan.[421] Legal protection schemes for whistle blowers may increase in Australia. Such people should undoubtedly have legal protection but the main value of such schemes is probably symbolic. There are considerable liabilities in their

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[421] *The Whistleblower Versus the Organisation - Who Should be Protected ? , John McMillan, Law Faculty ANU, for publication in Freedom of Communication in Australia, Dartmouth Press, 1994,(ed T Campbell and W Sadurski*

practical application.[422] However, a custom-made mechanism could be devised for voluntary adoption by CSL which would avoid many of the liabilities for the organisation and individual in highly public whistle blowing. While the Bioplasma division is of concern to this study, such a scheme should be implemented across the organisation because a countervailing corporate ethos could defeat its implementation in just one area of the total operation. Such a scheme could even evolve into a model for the pharmaceutical industry later and function to reduce the need for external regulation. Some other benefits of such a scheme would be to:

- Demonstrate to the public that the corporation recognises the need for employees to have a safe and effective channel to air complaints;

- Signal to employees that employment does not destroy the normal rights of citizens to speak out against unlawful, unethical, unsafe or improper conduct.

- Provide a channel for concerns without the trauma and harm that can follow for the corporation, other employees and the whistleblower when matters are thrown open to the media and public at large.

- Provide feedback for the corporation, especially workplace officers, to assist them in handling and anticipating problems within.

The establishment and conduct of such an office ought to be as separate from the corporation as possible, to diminish the chance of it being manipulated as a whistle blower detection scheme. The Board could ask an external consultant to determine the role of the office in consultation with CSL and to be responsible for selecting personnel from outside CSL. Personnel should probably not be employed on a full-time basis as this could make them too dependent on the corporation.

Such an office should be designed to avoid rather than promote conflict. Whistle blowers or would-be whistle blowers can have a wide range of concerns, reasons and motives for wishing to complain. Resolution may require numerous skills, such as workplace advocacy, dissent handling and personal counselling. Part-time officers could bring a wider range of skills and experience than full-time officers.

In-house publications and occasional reports could be used to promote the office, and an ethic of responsible use of it; to inform employees of the corporation's actual regulatory and legal obligations; to encourage employee

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[422]*The Whistleblower Versus the Organisation - Who Should be Protected ? , John McMillan, Law Faculty ANU, for publication in Freedom of Communication in Australia, Dartmouth Press, 1994,(ed T Campbell and W Sadurski)*

discussion about the consequences of condoning harmful behaviour and discouraging 'dobbing'; to explain and promote the importance of using internal mechanisms and to make recommendations for their strengthening; to prevent reprisals or direct remedies where reprisals against employees are clearly established; and to report in general terms on findings and on resolutions.

16.2.2 The place of blood products in an internationalised CSL

The world market for new biotechnology drugs is a world of patent litigation, acquisitions and mergers, intense competition and the unending need to raise capital. Since few investors can evaluate true scientific progress, any news about products under development can cause shares to plunge or soar. A research disappointment can constitute a major crisis. A few small start-up companies succeed, others go into contract manufacturing and the rest are bought out.[423] What will happen to the manufacture of Australian blood products as CSL tries to find a place in this world? The answer is unknown.

The sale occurred at a time when increasing pressure was being brought upon suppliers, funders and regulators of blood products to increase supplies whether from home or foreign commercial sources, to slacken regulation in some areas, and to tighten it in others. On the other hand, CSL is for the first time clearly subject to the regulatory control of the Therapeutic Goods Administration, and, as a result of its increased focus on international markets, will also be subject to regulatory requirements of some TGA equivalents overseas. CSL was inspected by the FDA recently. The need to meet new international standards and requirements
can be expected to have a positive effect on the general attitude of the corporation towards compliance.

R.80 CSL should be required by law to be ISO 9000 accredited.

This international standard is a TQM standard governing quality of management processes. Inspections under the standard look for continuous improvement. It is not a substitute for State regulation but a useful complement and there may be interaction between the two.

Federal and State Health Departments have long neglected addressing volume, usage and wastage in any systematic way. The privatisation of CSL provides yet another reason why they should. The Plasma Fractionation Contract is said to regulate volume. The Prospectus refers to:

> 'the strong national interest in ensuring the continuity of supply of these critical health care products' and refers to the Plasma Fractionation Contract as the mechanism.[424] The Minister for Finance in his Dear Investor letter on page two of the prospectus says 'A contract between the Commonwealth and CSL ... will ensure that CSL

[423] *Fortune,6.7.87 p48 The Big Boys are joining the Biotech Party*
[424] *Prospectus p 8*

continues to produce plasma products for use by the Australian community.'

But the contract only requires CSL to meet targets agreed between Health and themselves in order to get Federal payments. How Health decides what volume should or can be produced is another matter, relating to availability of supply, resources for collecting, the purposes for which the products are used, and the regulation of wastage and misuse. These issues are addressed in chapter eight.

16.2.3 Factor VIII supply

Just before the sale A Red Cross director claimed he was told by a CSL official 'CSL is not interested in R & D in blood banks anymore'.

KB Why?
Because they now have their licence to make the recombinant product from Baxter. They will sell in competition with their own product. It will allow them to bring in money with both hands.

However, CSL Official B described the products in interview as 'complementary. ... No country can totally afford recombinant ... so you want to develop the best product possible from your human source.'

Certainly the superior plant technology for factor VIII gives CSL a motive to manufacture factor VIII. But if Government agrees to subsidise the foreign product, CSL also has an incentive to progressively run down local factor VIII production, while the Haemophilia Foundation pushes the demand for recombinant. The plant could then be used to make factor VIII for foreign countries who cannot afford recombinant, or commissioned out to companies with big supplies of plasma. If factor VIII production *were* run down this could drastically affect the dynamics of the entire domestic blood service. It is only by collecting enough blood to meet factor VIII demands that blood banks have enough of the remaining fractions to service the others demands for whole blood and blood fractions.

16.2.4 Future of the processing plant

A Red Cross informant believed the Bioplasma business will be commissioned out to an international biologicals company, and CSL will split up into separate companies. Bioplasma was seen as a good first stepping stone as none of these companies have plant in Asia. The Head of the Bioplasma division comes from this international sector, having started out with Baxter and worked in other small and large biological companies. He is 'responsible for the strategies to further internationalise CSL's plasma fractionation business' according to CSL.[425] The Red Cross official said:

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[425] *CSL Limited Update, Issue 4 Feb '94 p 3.*

> He suggested to me very strongly that it would be easy for such companies to get onto the CSL Board, "Baxter and Cutter could easily get a Board position", he said. Within five years CSL could be working with international plasma suppliers.

Within existing regulatory frameworks, there is nothing to stop this happening. The possible effects on Australian blood supplies are considerable.

16.2.5 CSL as a private monopoly

The sale has transferred CSL from a public to a private monopoly for the manufacture of Australian blood products. Professor Wettenhall says 'The more objective of recent efforts to compare public and private sector performances have concluded that openness to competition is generally of greater significance in determining performance quality that ownership status'.[426] In some respects, privatisation will improve CSL's performance. The measures taken to fit the organisation for sale demonstrate that this is already occurring. It is the monopoly aspect of the blood products and vaccine manufacture that still needs address, and more so in the wake of privatisation because Federal administrative laws no longer apply to CSL and the company plans to expand its commercial operations in Australia and in the international market,

The blood products activity should be regulated more closely than before privatisation, to offset the possibility of the for-profit ethos compromising blood safety, quality and supply. In the United Kingdom, Prime Minister Thatcher discovered that privatisation and deregulation didn't go well together. 'Her enterprise sales were followed by the creation of new bureaucratic instruments such as Oftel and Ofgas (Office of Telecommunications, Office of Gas Supply) to act as the new public watchdogs.'[427] Wettenhall quotes Malcolm Wallis[428] as showing that:

> while privatisation may lessen somewhat the public sector's need for operational-managerial talent, it increases the need for legally-trained regulators, contract designers, supervisors and so on.

A device was developed for public enterprise but which might be used for CSL's Bioplasma Division is known as the signalling system[429] Professor Wettenhall describes the system as follows.

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[426] *see Public Enterprise in an Age of Privatisation Professor Roger Wettenhall, Current Affairs Bulletin, Volume 69, Number 9, February 1993.pp 4-12*

[427] *Wettenhall op cit p 6*

[428] *'Privatisation and Development Administration: Some Implications for Training', International review of Administrative Sciences, 56:1, 1990*

[429] *Wettenhall p 8) above, arising from work of Prof Leroy Jones' Boston Area Public Enterprise Group US, in association initially with the Pakistani Government.*

> Signalling recognises that public enterprise usually has a 'multiple objectives' problem. From this it draws an important distinction between 'public profitability' (taking social costs and benefits into account) and 'private profitability' (judged by purely commercial tests). It advances a set of performance criteria, with enterprise-specific values assigned to each, and prescribes also disclosure bonuses as incentives for accurate, unbiased reporting. The signals are located in the data coming forward from these indicators. Where they show significant shifts from past reporting periods, or surprising or disappointing results, they stimulate intensive discussion between evaluating agents and operating management with a view to pinpointing causes, attributing responsibility, and commencing corrective action.

A version of signalling could be introduced by a Health Department Unit responsible for policy and regulation on blood and blood products. The Department could require CSL to comply with a signalling program now, as a condition of the plasma contract, on the basis that CSL didn't tell them about the embedded inefficiency and lack of responsiveness to clients when the Federal Government contracted with them for the supply of blood products in early 1993. The contract could provide for CSL to report on;

1. Establishing effective complaint mechanisms.
2. Evidence of performance in complaint handling based on regular solicited client feedback and reports of unsolicited feedback;
3. Progress in developing and refining domestic products.

The regulatory legalists in Health may object of course. Yet the Health Department very successfully regulated the pharmaceutical industry for some decades without legislative backing. Pharmaceutical and biological companies will comply with regulatory demands if it is in their financial interests to do so, whether they are backed by law or not. They will also comply on other grounds, such as commitment to safety and quality, despite the conviction of some uninformed or cynical commentators,[430] assuming compliance doesn't also spell financial suicide.

Alternatively, a simpler way of achieving this goal would be to require CSL to report publicly on its compliance with the soon-to-be completed Australian Standards Association standard on complaints handling, as recommended earlier in this report.

R.81 The Health Department should make compliance with the Australian Standards Association standard on complaint handling a condition of its plasma fractionation contract with CSL, by stating in writing to CSL that it is a requirement.

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[430] *Corporate Crime in the Pharmaceutical Industry, Braithwaite, chapter nine.* -

R.82 CSL should be required by regulation to keep public complaint registers and performance indicators in a Quality assurance plan for improvement in complaint resolution performance in relation to blood and blood products, vaccines and other products which Governments purchase under their community service obligations.

16.2.6 Corporations Law

As mentioned at the beginning of this chapter, the author was not equipped to study the possible impact of corporations laws on CSL's blood product activities in any thorough manner. Only a few observations are made here.

Although the laws governing company conduct are more complex than in the eighties, making their usage more difficult, the courts are imposing heavier fines on individual company directors who transgress laws.[431]

According to Tomasic and Bottomley[432] corporations law, whether statutory or judicial, does not prescribe any affirmative criteria or prerequisites for appointment to the office of director. Apart from specifying age limitations and the need for a director to be a natural person, very little is legally prescribed by way of ongoing standards of skill and competence, these authors say. In their study on the role of Australian directors they suggest that Parliaments could legislatively mandate that corporation boards include a fixed percentage of independent non-executive directors. This suggestion is understood to be under Government consideration at time of writing this.

R.83 In the absence of legislation requiring that corporation boards include a fixed percentage of independent non-executive directors, the Board of CSL should consider appointing such a Director now, to assist the company in (a) appropriate regulation of the manufacture of biological products for government (b) the introduction of public and client accountability measures for the company's blood processing activities, (c) an internal whistleblowers office and (d) shareholder communication policies and programs which recognise the equal right of individual shareholders to the same information about the company's business as is given to institutional shareholders and pledge that individual and institutional shareholders will have access to the same information simultaneously.

Such a Director could be called the Public Interest Director. While this Director should have skills which suit him or her to direct the design and implementation of accountability measures, he or she should not,

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[431] *The Federal Court recently fined TNT Australia Pty. Ltd and Ansett Transport Industries (Operations) Pty Ltd $4.1 million and nine hundred thousand dollars respectively. Eight TNT executives were fined a total of four hundred and twenty five thousand dollars and the companies will pay costs of $1.07 million.*

[432] *p 21Directing the Top 500 , ref bibliography Australian*

however, be taken to be responsible for implementing or maintaining these measures as that responsibility should rest with the Board as a whole.

R.84 Corporations Law should recognise the role of a board as a body by providing that public company Board members are jointly and severally liable for the actions and omissions of any particular director.

CHAPTER SEVENTEEN: ENDWORD

> **That Cabinet decision [of 1949], that financing of this important undertaking be met by the Government, was responsible for putting in place a system by which plasma fractions derived from voluntary non-paid blood donors were made available to Australian citizens free of charge. It is a system that relies on collaboration between CSL, the Australian Red Cross Society and the Commonwealth. It is a system that has served as a model for the rest of the world, and of which Australia should be proud.**

Committed to Saving Lives, A History of CSL, Alf Brogan, 1990.[433]

In France, four doctors representing the State in what was believed to be one of its benevolent institutions, have been convicted for their part in distributing AIDS-contaminated clotting agents to haemophiliacs four years into the AIDS epidemic.

The fashion is to cite the 'French scandal' as an example of the voluntary donor system. This is to equate all nonprofit blood banks with the Centre National de Transfusion Sanguine, as if to say the same thing could happen in any voluntary system because of its nature as a voluntary system. The implication is that, by contrast, corporate blood must be better.

The suggestion is obscene, ludicrous and untenable. The French scandal is not an example of inevitable harm flowing from a voluntary donor system. It is a study in the consequences of regulatory failure, the perils of unaccountability and the consequences of secrecy. More particularly, unchecked commercialisation and profiteering was a key element in the Centre's downfall. To this extent, the debacle offers just as many cautions for commercial enterprises, as it does for the voluntary blood donor sector of the

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433 *p 96*

industry. Anti-social behaviour exists wherever it exists, and regulators must not refrain from regulating because of assumptions or beliefs about the trustworthiness of the bodies they regulate. It is not the job of regulators to trust, nor mistrust, but to regulate.

The Centre National, now Agence Francaise du Sang, was registered as a non-profit public trust. However, it was not functioning as a *bona fide* member of the voluntary donor sector in 1985, not in its goals, nor its financial dealings, nor its collection methods. For a start, unlike Red Cross here, the Centre sold it products. As the American journalist Jane Kramer tells us, aside from the revered and supposedly pure-blooded Parisian *benevoles* ,the Centre was also taking blood in 1985 from 'bums and junkies and hungry students and African workers and prison inmates' in exchange for a cup of coffee and a sandwich.[434] Its director, Garretta, was much less a doctor that an industrialist. He wanted to turn the Centre into the most important blood-production company in Europe. The government had built him a big new processing factory in Les Ulis just outside Paris. It wasn't built for heat treatment of blood, necessary to inactivate HIV. Garretta 'lacked the technology' to convert it, as Kramer puts it. Garretta wanted to put the Centre into joint ventures in Europe and America 'where it would make money developing collagen and transfusion kits and plasma concentrates for the growth of scar tissue ... Garetta's factory was going to turn France into a superpower of the blood world'[435] His empire was to stretch beyond Europe as well; Garretta visited Asian countries, looking for blood to process in his factory, selling technology transfer to the Philippines. He moved around the planet forging close ties with the international commercial industry, well beyond the reach of regulators, who in any case have not even begun to confront the internationalisation of commerce in blood, and way beyond public gaze. The Bellevue Palace at $300 a night, the mysterious income sources, the castle he built himself in France, the expensive monuments to his imperial enterprises in blood, which he proposed to build with other people's money;[436] Garetta lived an elevated existence of his own making, and no one succeeded in bringing him to earth until many others had been brought down with him. The best the system could do then was give him a brief jail sentence, but the others got death.

For the quality of his products Garretta was meant to account to the Director General of Health, (roughly equivalent to the Secretary of the Health Department), and to the National Laboratory of Health, which is France's TGA. Kramer tells us that the Centre produced its own research projects (including one where haemophiliacs were purposely given unheated product) and determined its own protocols, independent of any of the Paris university hospital research labs or clinics. It also produced its own

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[434]*The New Yorker, 11.10.93,, pp 74-95, Bad Blood, by Jane Kramer. Much of the detail in the author's account is based on Kramer.*
[435]*Kramer p 83*
[436]*personal interview with international blood banker ,*

contaminated products in the factory. And it went on distributing them well into the epidemic and long after they were known to be contaminated.

The government never ordered these products off the market. The Health Secretary said later it was up to the Minister for Social Affairs. The Minister for Social Affairs claimed medicine was not 'my specialty'. The Prime Minister said he didn't know. The Prime Minister was waiting on the Institut Pasteur to get its AIDS test marketable ahead of the Americans. If it was published that French haemophiliacs were receiving untested French blood, how could the government prevent the American test kits from taking the European field?

What did government learn from this? Kramer says that 'today, the Socialists admit they 'made a mistake' in 1985, but the mistake they usually mention has nothing to do with AIDS tests or contaminated ... products. They say their mistake was not paying off the hemophiliacs quickly, and "solving the problem" that way'. Their definition of the problem appears to be that the haemophiliacs will not be silent, and that a French journalist kept giving information to the public.

To some degree the research project and the distribution of contaminated material may beggar explanation in regulatory terms. It is tempting to say they happened because Garretta and the researcher were detached from reality and perhaps that they would have been anti-social in any setting. It may be true as well, but in regulatory terms it does not matter. What matters is how they were permitted to hold positions of trust and go on giving the contaminated products to patients. That has much to do with regulatory failures, lack of transparency and absence of proper peer review.

The main causes of the scandal appear to be lack of oversight by regulators and lack of transparency in the process from beginning to end. France has no freedom of information act. Australia has had one since 1982. However, the costs of using the legislation are becoming a significant barrier and in any event, the TGA has nearly all the valuable information about blood products corralled in a bull pen labelled commercial-in-confidence. Nor does the legislation yet apply to private companies, such as CSL. France is a country whose idea of disclosure or *transparence* ,, Kramer tells us, is to ask parliamentarians to deposit a statement of assets in the safe of the National Assembly when they get elected, and take it away with them when they leave. 'The public has little access to anything except opinion where the people running the country are concerned.' For opinion, Kramer means reassurance and euphemism. Australia has little more access in practice where blood products are concerned. The Administrative Decisions (Judicial Review) Act will not apply to CSL post-sale. On blood products, we have to be content with TGA reassurances, and TGA itself is reliant on reassurances and certificates from foreign parties to a considerable degree, as would the Centre have been had it succeeded in building its empire of foreign blood processing.

None of the questionable blood practices revealed in this author's report have led to discipline other such action, so far as we know, by official regulators. No action has been brought by any member of the public; not that this is surprising however. If harm did result from any of these practices, which of the users is able to identify its source and know which party to act against? Which Hong Kong user of prothrombinex, which Australian user of unidentified blood products made from human placentae, which consumer of untested New Zealand plasma mixed with Australian plasma, which patient suffering for lack of product due to CSL manufacturing delays , which patient 'consenting' to the use of a foreign blood product sourced from a donor in an unknown country?

Besides, legal action is valuable to the regulatory process and to prevention only if those litigated learn the right lessons from it. It is certainly no cure for the harm already caused. Kramer spoke of the haemophiliacs who signed away their right to action in exchange for a payout. 'Justice is a discipline, not a cure, and negotiating death did not buy life for any of the victims who sat in the Thirteenth Chamber of the Court of Appeals this summer and waited for a verdict. It only put a few of the people who could be said to have played a part in their deaths in jail.'

The French are paying a high price for failing to regulate blood and for keeping people in the dark on blood safety. A bomb was exploded in Garretta's car. He, a Legion of Honour recipient, and others, are in jail. The Socialists lost power in large part because they betrayed public trust. Minutes after the French Parliament ruled in May of this year that its cabinet ministers may be charged concerning their conduct in office where it may have had prejudicial effects, the haemophiliacs said they'd file suit against the senior Ministers they hold accountable for the scandal. Whether one thinks the suits warranted or not, this is more like revenge or punishment than the kind of differentiated approach needed to solve a complex set of regulatory situations and avert future failures. The former Prime Minister, Laurent Fabius, the former Minister for Social Affairs Georgina Dufoix, and former Secretary of State for Health, Edmond Herve, have been charged with poisoning, and with knowingly administering substances that, although nor necessarily fatal, are injurious to health, an offence which can carry five to ten years in prison.[437]

Blood can act as an agent for health or an agent for harm, an agent for life or for death. In this country is it given as a gift in trust. Trust is as much a commodity as the blood itself and every party who deals with the gift of blood once it leaves the donor must be worthy of trust, otherwise the purpose of the giving may be nullified.

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[437] *J-Y Nau, in the Lancet, volume 344, July 23 1994*

Bad blood can be passed inadvertently or by a lapse in procedure. The public will not necessarily turn on the supplier if trust has been maintained by means of sufficient displays of accountability, openness and honesty and if the harm is adequately compensated. Where parties dealing with the donor gift are involved for reasons other than or additional to the activity of providing health care, a far higher display of accountability, openness and honesty is required to maintain trust. Otherwise the donor will not give and the potential user will refuse the product, and no one will win, not even the litigation lawyers in the end.

At present there is unacceptable dislocation between the tripartite elements of knowledge, responsibility and control which are at the heart of the blood system in this country. The public, as givers and users, are the ultimate controllers of supply and demand, yet they are not being told enough truth about the innate risks of the product and about how it is being processed and regulated. Nor are they being permitted to share responsibility with agencies to whom donors entrust their blood. Naturally, therefore, some are seeking to cast responsibility upon regulators and suppliers through litigation, and others are beginning to voice lack of trust, based on both valid experience and invalid generalisations from overseas scandals. The threat and actuality of litigation have made some regulators wear their hats, (but it has had some bad effects as well) and besides that, little attention has been paid to earning and keeping trust.

It goes nowhere at all for regulators to keep the public ignorant, or to pretend the public are not there. The next steps that must be taken by the Therapeutic Goods Administration and by CSL Limited are positive steps to make their activities visible, so the public may decide for themselves upon fact rather than reassurance whether they should trust blood processors and regulators.

If they do not take these steps, they must live with the reality that round the world ordinary people are becoming increasingly doubtful about the integrity of the blood supply, will tend to fix their attention on any information scraps thrown to them, and will inflate the significance of data obtained - probably in the direction of less trust. Regulators may think public responses extreme, their lack of trust disproportionate, and their damages claims oppressive. Instead of worrying about these things, they should interest themselves in the gradual erosion of public access and participation that preceded the falling off of trust and produced the public backlash. Government and CSL should enjoin the public, through suitable representatives, in the process and regulation of blood manufacture and remove the overgrowth of unnecessary secrecy from the field.

Where human blood supplies from unpaid donors are concerned, trust is a far more valuable commodity than shares traded on a stock exchange or product approval papers from a foreign health inspectorate. It is harder to come by , higher in price, and much much harder to restore when lost.

GLOSSARY

albumin - sometimes referred to as **albumin solution,** the principal protein constituent of plasma. These terms often go hand in hand with the term **plasma** to mean a refined solution prepared from the non cellular component of blood used to replace blood in situations which are non-major.

antibody - a kind of blood protein synthesised in lymph tissue in response to an **antigen;** it circulates in plasma and usually renders or may render the antigen harmless

anticoagulant - an agent which stops blood clotting.

antigen - anything the body regards as foreign and causes it to produce an **antibody.**

antihaemophilic Factor - a **globulin** (protein) present in small amounts in human blood, the deficiency of which brings about **haemophilia.** See **factor VIII**

anti venom - antidote to venom of spiders, snakes etc; same meaning as antivenene .

Australian Blood Regulators Study - the study conducted between 1992 and 1994 from which this report issues. The study was housed at the Centre for National Corporate Law Research at the University of Canberra and funded by the Criminology Research Council. The Australian Blood Regulators is one part of a larger global study on blood regulation called the **Blood Project.** The administrative and descriptive title for the Australian Blood Regulators Study is 'Blood Pressure - The Ability of Australian Regulators to Respond to a Worldwide Trend towards Criminal Transactions In Blood'.

bailment - delivery for a specific purpose; delivery in trust, upon a contract express or implied, that the trust will be faithfully executed.

Bioplasma Division - current name for the division of CSL Ltd., which manufacturers human blood products; formerly the **Blood Products Division,** from 1987.

Blood collection centre - where blood is collected; in such centres blood may also be stored or processed but the term blood collection is used by the Therapeutic Goods Administration to identify the activities in the centre which it must regulate under its Code on Blood and Blood Products. A blood

collection centre may also be called a blood bank, or a Blood Transfusion Service, if it is Red Cross facility. Some blood collection centres are run by hospitals; not all are Red Cross run.

Blood Project - the name of an ongoing community-based global study on regulation of human blood of which the Australian Blood Regulators Study is one part.

BTS - Blood Transfusion Service of the Australian Red Cross, where individuals donate **plasma** or whole blood, and where some separation of blood into components is undertaken.

CJD - a terminal disease of the central nervous system with an incubation period of fifteen to thirty years, believed to arise by spontaneous mutation of brain cells in one of every million people; can be acquired iatrogenically via treatments derived from brain and pituitary gland tissue, and possibly by ingesting infected brain tissue, (as in kuru disease) or through blood products derived from human placentae or, presumptively, through blood.

CMV - **cytomegalovirus**, a common herpes virus causing liver infection, transmissible in blood.

coagulation - clotting

encephalitis - inflammation of the brain, caused by a viral or bacterial infection, or as part of an allergic response to a systemic viral illness or to vaccination.

Factor VIII - also known as **antihaemophilic factor** or **AHF** - the clotting factor missing from the blood of haemophiliacs in processed form for administration to prevent bleeding.

FFP - fresh frozen plasma - see **plasma.**

fibrinogen - present in blood plasma, it is acted on by an enzyme thrombin to produce an insoluble protein, fibrin, in the final stages of blood coagulation, or clotting.

fibrin glue - made from **fibrinogen**, used in surgery to seal wounds, in place of stitches or other means.

fractionation - the process of separating out blood components, deactivating viruses and further processing into blood components, undertaken in Australia by CSL Ltd. It is distinct from blood component separation which is mostly undertaken in this country by Red Cross **Blood Transfusion Services**. **Fractionation** and **processing** have the same meaning in this report.

Fractions Release Committee - the committee which approves the overseas release of Red Cross blood and products made from Red Cross blood. It includes a member of the **Health Department** who clears the material for Customs.

GMP - good manufacturing practice; the principles agreed upon between government and industry as acceptable standards for manufacturing; for blood products' manufacture and blood collection and separation at blood banks these are contained in the Code for Medicinal products with which CSL must comply and the Code on Blood and Blood Products, which governs blood collection centres and testing laboratories. (see bibliography)

haemophilia - an hereditary disorder, nearly always found in males, in which the blood fails to clot adequately or at all. Transmitted by females who are apparently not affected by the disease. Impacts can cause internal bleeding into body joints and joint deterioration as a result. Haemophiliacs are therefore not only at risk from external wounds.

Health Department - the Federal Government Health Department, currently known as the Department of Human Services and Health.

immunoglobulins - plasma proteins which act as antibodies, administered intravenously as blood products; these products may contain specific proteins or a range.

inactivate - make non-infectious; infection from viruses, bacteria and other disease agents in biological products may be inactivated (also deactivated) by heating, treating with solvent detergents or formaldehyde, steam vaporisation etc. A virus may be inactivated without being killed.

ITP - idiopathic (of unknown origin) thrombocytopenic purpura - lowered platelet levels that can cause internal bleeding.

MD - managing director

NBSL - National Biological Standards Laboratory, of the **Health Department**, which preceded the **Therapeutic Goods Administration Laboratories (TGAL)**. Responsible inter alia for inspecting pharmaceutical companies for compliance with good manufacturing practices, and for testing products.

NBTC - National Blood Transfusion Committee; an advisory body of the Australian Red Cross Society consisting of a national Chairman, the **BTS** Directors and two CSL representatives, currently the General Manager of the **Bioplasma Division** and Consultant Services Director, Blood Products.

Official A - formerly head of the CSL's Blood Products Division and before that in charge of research and development at CSL; now Clinical Services Manager, Bioplasma Division.

Official B - Head of CSL's Bioplasma Division, formerly known as the Blood Products Division when created in 1987. Official B joined CSL from North America in 1992 and has long experience at executive levels in small and large biological companies, working within the North American continent and elsewhere.

Official C - Principal Medical Adviser to the Therapeutic Goods Administration of the Health Department; Federal Government representative on the National Blood Transfusion Committee of the Australian Red Cross Society; nominated as principal point of contact for this study because of his knowledge of blood and blood products.

Official D - joined the Health Department as National Manager of the Therapeutic Goods Administration in December 1991.

plasma - 1. the liquid non-cellular elements of blood after red cells and other non-liquid components have been separated and before it has been **processed** for clotting factors and so on. It is potentially infectious at this stage and is known as FFP or fresh frozen plasma.

- 2. In North American literature, the same material after fractionation when it has been treated to render it unlikely to be infectious. It is known as SPPS or Stable Plasma Protein Solution.

plasma volume expander - **albumin** from blood; used in theatre, casualty, intensive care and trauma cases, to replace lost albumin, often in preference to products such as whole blood and packed red cells which have a greater potential for infection.

plasmapheresis - a method of extracting the **plasma** from a whole blood donation and recycling the remainder back to the donor at the time of giving the donation.

prion - a pathogenic (disease) agent consisting of a protein which has mutated, apparently spontaneously, causing slow viral diseases such as **Creutzfeldt-Jakob disease**, kuru, scrapie, mad cow disease and others.

processing - see **fractionation**; the terms have the same meaning in this report.

procoagulants - a new term being used by CSL for clotting agents such as **factor VIII**; means the same as **coagulant.**

prophylaxis - giving antihaemophilic factor regularly before bleeding occurs, rather than at the time of a bleed.

prothrombinex - a blood product containing a range of clotting factors.

quality assurance - the department in a manufacturing company which creates and also qualifies the company's systems which are designed to ensure product quality. Products are usually released for sale through this department. It should be on command channels which are independent of the other departments it must regulate.

quality control - refers to the sampling and testing procedures done during manufacture, either by quality control staff or by production staff working to quality control personnel.

recombinant - manufactured using genetically modified cells or organisms.

serum - here it means blood serum, the fluid that separates from clotted blood and blood plasma on standing. Serum is essentially similar in composition to **plasma** but lacks **fibrinogen** and other substances that are used in the coagulation process; **sera** is the plural of **serum.**

TGA - Therapeutic Goods Administration, diagnostic inspectorate established under the Therapeutic Goods Act 1989; also contains drug evaluation functions. The TGA has many functions; inter alia it inspects blood banks for compliance with a code on blood and blood products, and CSL for compliance with the code of good manufacturing practice.

TQM - total quality management, in this context a therapeutic goods manufacturing program conducted within an organisation to increase efficiency and productivity, and ensure the quality of the goods produced.

vaccine - a preparation of killed or modified **antigens** that can stimulate the development of antibodies and in this way confer immunity.

whole blood - a unit of blood collected into anticoagulant and not further processed, used for transfusion.

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APPENDIX ONE

Endorsers of the Blood Project 1991- 1994

1. **Professor John Braithwaite,** leading international criminologist and author, Professorial Fellow in Law, Research School of Social Sciences, Australian National University, Canberra; Visiting Member, American Bar Association, Part-time Commissioner, Trade Practices Commission (Australia).

2. **Ms Esther Peterson,** Representative to the United Nations of the International Organisation of Consumers' Unions, former adviser on consumer affairs to US Presidents Kennedy, Johnson and Carter; Washington US.

3. **Dr John Deeble,** Health Services Fellow, National Centre for Epidemiology and Public Health, Australian National University, Canberra.

4. **Ms Elizabeth Reid,** Director of Women in Development, United Nations Development Program, New York; Author of Australian Government Whiter Paper on AIDS.

5. **Quaker Service Australia,** Hobart, Tasmania.

6. **Dr Ian Campbell,** Medical Adviser, International Headquarters, the Salvation Army, London.

7. **Senator the Hon. Bob McMullan,** Minister for Trade, Australian Government.

8. **Ms Philippa Smith,** Commonwealth Ombudsman; former Director of Public Policy and Public Affairs, Australian Consumers' Association.

9. **Mr. Ralph Nader,** consumer and public interest advocate and author, Washington; founder of Centre for the Study of Responsive Law, Critical Mass, the Health Research Group, Multinational Monitor, Essential Information Inc;

10. **Mr John Richard,** Director of the Centre for Study of Responsive Law, Washington.

11. **Dr. Richard Pembrey, AO.** Director, Australian Red Cross Society Blood Transfusion Service for the Australian Capital Territory, Canberra, practicing oncologist and haematologist.

12. **Ms Anita Roddick,** Founder and Chief Executive of The Body Shop International, UK.

13. **Professor Robert Beal, AO**. Director, Australian Red Cross Society Blood Transfusion Service of South Australia, former Head of the Blood Donor Programme of the International Federation of Red Cross and Red Crescent Societies

14. **Dr John Hirshman,** President, Australian Third World Health Group; Member, Community Services Committee of Australian Red Cross; former Director of Health Services of the World Health Organisation/WPRO.

15. **Dr Jukka Koistinen,** former Director, Global Blood Safety Initiative of the World Health Organisation, Geneva; Director of Quality Management, Finnish National Red Cross Transfusion Service.

16. **Dr Norman Swan,** Presenter, The Health Report; ABC radio.

17. **Mr John Wood,** Deputy Commonwealth Ombudsman, formerly head of the Commonwealth Government's policy advising on Consumer Affairs between from 1983 to 1993, Joint founder and current Chairperson, Rupert Public Interest Movement Inc.

18. **The Executive Committee of the Australian Council for Overseas Aid** (co-ordinating body for over one hundred nongovernment organisations working in overseas aid and development.)

19. **Mr John McMillan,** Senior lecturer in Law, Australian National University, Canberra, public interest advocate and author, authority on Freedom of Information legislation, constitutional reform and whistle blowing, former adviser to Senate Standing Committee on Constitutional and Legal Affairs' reference on Freedom of Information, co-founder Rupert Public Interest Movement Inc., co-author with Gareth Evans and Haddon Storey of Australia's Constitution:Time for Change?; council member Australian Consumer's Association.

20. **Mr. Allan Asher,** Commissioner, Trade Practices Commission, Canberra; Chair, OECD Committee on Consumer Policy.

21. **Mr Mike Smith,** Senior Consultant, International Public Relations; former Editor, The Melbourne Age

22. **Mr. Anwar Fazal,** former President of the International Organisation of Consumers' Unions, former Director, Regional Office for Asia and the Pacific of the International Organisation of Consumers' Unions, Penang; UNDP Consultant.

23. **Mr Quentin Dempster,** ABC journalist; former presenter, ABC 'The 7:30 Report'.

24. Dr Robert Hodge, Director of Rural Health Education, ANUTECH, Australian National University, former Professorial fellow, School of Health Sciences, University of Wollongong, New South Wales, former National Director of the National Heart Foundation of Australia, former Director of Drug Evaluation, Federal Government.

25. Mr Jack Waterford, Deputy Editor, The Canberra Times.

25. Mr Donald K Ross, Executive Director, Rockerfeller Family Fund, New York; former Director, the New York Public Interest Research Centre.

26. Professor Paul Wilson, criminologist and author, Dean of Arts and Professor of Social Sciences, Queensland University of Technology, former Director of Research, Australian Institute of Criminology, Canberra.

Advisers to the Blood Project

1. Mr John McMillan (refer to list of endorsers, no. 19)

2. Dr John Deeble (refer to list of endorsers, no. 3)

3. Professor John Braithwaite (refer to list of endorsers, no. 1)

4. Professor Robert Beal, (refer to list of endorsers, no. 13)

5. Dr Richard Pembrey, (refer to list of endorsers, no. 11)

APPENDIX TWO

Australian Drug Registration Guidelines Volume One, September 1992

Appendix Nineteen

Intending sponsors of products derived from human blood or plasma should note that Australia favours National self-sufficiency in products derived from human blood or plasma, believing that a policy of not being reliant on donors in other countries is not only in the national interest but an international responsibility.

Blood products sourced from foreign countries will be registered only if the foreign product has a demonstrably significant advantage over the local product. Intending sponsors or foreign-sourced blood products should

discuss their prospects of satisfying the criterion before lodging and applying for registration.