Senate Community Affairs References Committee

Report on the CJD Settlement Offer

Commonwealth Government Response

March 1998

Recommendation 1. That the decision not to proceed with an epidemiological study be reconsidered. However, any future study should not be limited only to the Allars recommendation that it be undertaken in the context of monitoring past and possible cases of CJD in the recipient community.

Response
The Government accepts this recommendation. The National Pituitary Hormones Advisory Council (NPHAC) will be asked to review its earlier decision and seek independent expert advice on the possible benefits of conducting a longitudinal study of hormone recipients.

Context
An epidemiological study of the pituitary hormone recipients was not conducted as recommended by Professor Allars following advice from the National Pituitary Hormone Advisory Council that there was no value to be gained from such a study. The Senate Community Affairs References Committee is proposing a wider study following an NHMRC report on the long-term effects on women of assisted conception.

Recommendation 2. That the following areas of concern relating to the implementation of the Allars recommendations be addressed:

(a) Counselling - Ensure that the revised arrangements introduced in October 1996 to assist all recipients and their families who need counselling, are understood and are able to be accessed by all recipients. In particular, that these arrangements are quite distinct from, and alleviate the difficulties associated with those that have previously operated. In addition, that counsellors who may have been providing a service to the satisfaction of particular recipients are not precluded from assistance under the revised arrangements;

Response
The Government accepts this recommendation. The next edition of the *HPH newsletter* will outline the counselling services currently available; the changes that have occurred from the previous arrangements and the process by which recipients or members of their family can seek counselling.

Context
Counselling services are available to all hormone recipients and their families to assist them to manage the risk of CJD in their lives. Counsellors require accreditation by an independent expert panel and each counselled person can receive only 15 sessions after which a review is conducted of their needs. The counselling services have changed several times since the scheme's inception in 1990.

(b) Epidemiological study - That the decision not to conduct an epidemiological study be reconsidered, though any

future study should proceed with broader objectives. (This is the subject of a separate recommendation);

See Recommendation 1 above.

(c) Tracing recipients - That renewed efforts be made to identify and trace remaining approved and unapproved recipients, with due sensitivity in recognition of the time which has elapsed since the Program concluded (This is also the subject of separate recommendations);

Response
The Government accepts this recommendation and notes that the Department of Health and Family Services is currently pursuing avenues to identify unapproved hormone recipients and to trace the remaining recipients.

Context
Approximately 90.2% of approved recipients (i.e. 1784 of 1976) and 56% (i.e. 98 of 175) of the known unapproved recipients have been traced. The Department is investigating further strategies to identify and trace the remaining recipients.

(d) Access to information - That treatment records and other information requested by recipients be provided directly to them without adopting a restrictive interpretation of s.135A of the National Health Act;

Response
The Government notes this recommendation. A protocol will be prepared by the Department of Health and Family Services, in consultation with the NPHAC and the Privacy Commissioner which sets out the procedure for a recipient to access information about their treatment.

Context
When recipients make initial contact with the Department, they receive information about their treatment through a General Practitioner nominated by the recipient, to ensure that the recipient is correctly identified and that there is support immediately available to the recipient when they are informed of the increased risk of CJD and any related issues.

(e) Index to Allars Report - That an index to the Allars Report be prepared and made readily accessible for all recipients and other interested parties;

Response
The Government notes this recommendation and that an index to the Allars Report was prepared following the release of the Allars Report. The next edition of the *HPH newsletter* will include a statement that this index is available and indicate how copies can be obtained.

(f) NPHAC - Ensure that NPHAC's processes and procedures are sufficiently open and flexible to enable it to receive views and opinions from all members of the recipient

community on issues under consideration by the Council; and that all recipients are kept informed of decisions taken by NPHAC and their outcome.

Response
The Government accepts this recommendation. The next edition of the *HPH newsletter* will include a re-statement of the role of the NPHAC and of the mechanisms available to the hormone recipient community to have input in to the Council's activities.

Context
The NPHAC was established following the Allars Inquiry, to provide advice to the Minister on issues of national significance to the hormone recipient community. The procedures available for recipients to bring issues to the attention of the NPHAC were set out in two editions of the *HPH newsletter*. Recipients can raise issues with their CJD Support Group Co-ordinator, the National Co-ordinator of the CJD Support Group Network Inc., or to write directly to the NPHAC. Information about the discussions and decisions of the NPHAC is contained in the *HPH newsletter* following a meeting of the NPHAC.

(g) *Statement on Human Experimentation - That the review of the Statement on Human Experimentation which is not due to be finalised until late 1998 be expedited. To ensure that this review is not delayed, the Committee urges the Minister to finalise the appointment of members of the AHEC as soon as possible;*

Response
The Government notes this recommendation. The Chair of the NHMRC has advised the Department of Health and Family Services of progress with this Review.

Context
The Australian Health Ethics Committee (AHEC) is a principal committee of the NHMRC. The first round of consultation on the review of the *Statement on Human Experimentation* is complete and submissions will be considered at the next meeting of AHEC.

(h) *Amendment of s.135A of the National Health Act - That s.135A of the National Health Act be amended to ensure that personal information can be disclosed directly to the people about whom the information relates (such as in the case of people who received hormone treatment) and that the Attorney-General's Department broader review of existing secrecy provisions, which includes s135A, be expedited; and*

Response
The Government notes that the Attorney-General's Department is undertaking a broad review of existing secrecy provisions, which includes consideration of s.135A of the *National Health Act 1953*. The Government will consider the question of amendment of s.135A in light of the outcome of this review.

Context

Section 135A of the *National Health Act 1953* requires that personal information cannot be released to a third party without the consent of the individual, or where the delegate of the Minister deems it to be in the public interest. The Department must be satisfied as to the identity of the person seeking personal information. An ongoing review of such provisions is taking place within the Attorney-General's Department.

(i) Amendment of s.100 of the National Health Act - That the ALRC review which includes consideration of the Allars recommendation to repeal and replace s.100 by a provision which specifies clearly the circumstances where by reason of physical and similar factors associated with the distribution of a pharmaceutical benefit 'special arrangements' are appropriate, be expedited.

Response
The Government notes this recommendation. A review of previous applications of section 100 will be conducted to ensure such use has been consistent with the purpose of that provision. The Government will consider the need for amendment to section 100 in light of this review.

Context
Section 100 of the *National Health Act 1953* allows for special arrangements for providing pharmaceutical benefits to people living in isolated areas or who are receiving medical treatment such that pharmaceutical benefits cannot be conveniently or efficiently supplied in accordance with the general provisions of the pharmaceutical benefit scheme.

Recommendation 3. That should legal action proceed, the documentation requested from the Commonwealth through a discovery or further and better discovery process be complied with in a more expeditious manner than has been the case to date. In complying with such discovery processes the Commonwealth should refrain from adopting a restrictive interpretation of s135A of the National Health Act.

Response
The Government accepts that discovery in litigation should be undertaken by the Commonwealth expeditiously and without taking an unduly restrictive approach to secrecy provisions.

The Government notes that arrangements have been agreed between the solicitors acting for the parties as to how the further discovery would proceed. These agreed arrangements have been followed by the Commonwealth.

The Government notes the Committee's recommendation regarding the interpretation of s.135A of *the National Health Act 1953* but does not agree that the Commonwealth in ensuring that s.135A has been complied with, has adopted a restrictive interpretation of the section. The Commonwealth's interpretation and application of s.135A permitted hormone recipients to have access to their own medical information once the identity of the hormone recipient had been verified. The

Commonwealth did not rely on s.135A as a means of preventing disclosure of relevant material in discovery.

The Government also notes that the Attorney-GeneralÕs Department is currently undertaking a review of secrecy provisions, including s.135A.

Recommendation 4. That the process whereby a Department, being a defendant in a legal action taken against the Commonwealth, is placed in the situation of advising on the release (or refusal) of documents to a plaintiff - yet having full access to all documents themselves - is reviewed, so that procedures may be implemented to ensure that the process is transparent and that any conflict of interest, perceived or otherwise, is avoided.

Response

In the GovernmentÕs view, the requirements of litigation, which apply to all litigants, render it impossible to avoid the situation to which this recommendation relates. However, the Government accepts that in special circumstances, and where practicable, it may be appropriate to take steps to reduce concerns regarding transparency or objectivity.

Context

Discovery is a process whereby parties to court proceedings identify and disclose to each other all their own documents which are relevant to the issues in the proceedings. This of its very nature requires a party to have full access to that party's own documents to determine whether a document is discoverable.

Once documents have been identified as relevant, a party may resist disclosure of the contents of a document on several grounds. These grounds include a statutory secrecy provision, public interest immunity (privilege) or legal professional privilege. Once again, it is necessary for a party to have full access to documents in order to determine whether a ground to resist production exists. Even where the party is legally represented, the party needs to have a knowledge of the material relating to the case, in order to be able to provide proper instructions to the legal representative.

Even if disclosure of relevant documentation is resisted, the existence of such documentation must be disclosed on discovery. Therefore, the discovery process prevents concealment of the existence of relevant documentation by a party in reliance on a secrecy provision. Overall, in relation to discovery, the Commonwealth is in no better position than a non-Commonwealth party to proceedings.

The Government acknowledges that adoption of normal practice may result in perceptions of unfairness in special circumstances, such as where relevant documents held by a department include the results of a public inquiry involving both parties to the litigation. In order to avoid that perception, for the purposes of the CJD litigation, within the Australian Government Solicitor (AGS) the discovery of the

documents of the Allars Inquiry was handled separately from the defence of the action. The discovery work was performed by a separate legal team (Ôthe AGS Discovery teamÕ). In deciding whether or not to recommend that documents be discovered in the Victorian proceedings, the AGS Discovery Team did not consult with AGS staff handling the defence of the litigation (Ôthe AGS Litigation TeamÕ). The AGS Discovery Team engaged separate counsel to advise on discovery issues relating to the documents of the Inquiry. The AGS Discovery Team did not at any stage work on the preparation of the defence of the litigation. Whenever Allars Inquiry documents were released to Rennick Briggs, the solicitors acting for the plaintiffs in the Victorian proceedings, copies were provided to the AGS litigation team, but not before. In the NSW proceedings Macedone Christie Willis, the solicitors acting for the plaintiffs, have agreed that the AGS Litigation and Discovery teams may confer about the relevance of documents for the purpose of discovery.

In summary, the discovery process of its very nature requires a party to have full access to all that party's documents. Generally, a Commonwealth Department which is required to also comply with a secrecy provision such as s.135A should be placed in no different position to a non-Commonwealth litigant reviewing its documents to determine whether documents are relevant to the proceedings and, if so, whether disclosure should be resisted.

Recommendation 5. That the settlement offer should not preclude a plaintiff making any future claim in relation to:

(a) other physical illnesses contracted by recipients which may be related to long term side effects of HPH treatment; and

(b) liability should the transmission of CJD, or other illnesses relating to HPH treatment, to immediate family be proven.

Response

The Government notes this recommendation and also that the settlement offer does not preclude a plaintiff making any future claim in relation to physical illnesses contracted by recipients which may be related to long term side effects of pituitary hormone treatment. The settlement offer does not preclude a plaintiff making a future claim that they have contracted CJD, or other illnesses relating to pituitary hormone treatment, as a result of being an immediate family member of a hormone recipient.

Recommendation 6. That, without conceding the likelihood or otherwise of a legal action on psychiatric stress succeeding, in addition to the current settlement offer, the Commonwealth:

(a) make an allocation of funds to the existing Trust Account and that its purpose be widened. The amount of additional funding should, as a minimum, be equivalent to the cost of the potential litigation;

(b) widen the purpose of the Trust Account to permit one-off payments to be made to recipients who provide evidence that they have suffered psychiatric injury as a result of

treatment under the AHPHP. This payment be made on a sliding scale relating to the level of psychiatric injury suffered by the recipient. This payment would be regarded as a form of ex-gratia payment and would not constitute any precedent for similar action;

(c) consider extending this offer of payment to include recipients who have suffered psychological stress or significant life disturbance; and

(d) appoint an independent governing Board to authorise payments from the Trust to replace authorisation by the delegate of the Minister. The Board would be responsible for receiving and assessing applications for recompense.

Response

An amount of up to a further three million dollars will be allocated to the Pituitary Hormones Trust Account to allow for payments to be made to recipients who can demonstrate that, prior to 1 January 1998, they have, or have suffered, a recognised psychiatric injury due to the recipient having been informed that they are at a greater risk of contracting Creutzfeldt-Jakob Disease.

These funds will be made available in two separate instalments. The first instalment of $1.5 million will be provided in 1998-99, with a second instalment of up to $1.5 million in 1999-2000 after consideration has been given to the position of the Pituitary Hormones Trust Account and any new litigation costs, particularly the costs to the Commonwealth of having to defend such litigation, as a result of hormone recipients having chosen to litigate rather than pursue payments from the Pituitary Hormones Trust Account.

In making payments, priority will be given to those hormone recipients who have the most serious psychiatric injury. The *Pituitary Hormones Trust Account Management and Administration Guidelines* will be amended to provide a framework within which such payments can be made.

The Government has also considered extending payments from the Pituitary Hormone Trust Account to recipients who have suffered psychological stress or significant life disturbance, and has decided not to extend payments in this way.

The Government will appoint an independent Board to authorise payments from the Pituitary Hormones Trust Account. Payments will only be made to those hormone recipients who can demonstrate they have a recognised psychiatric injury due to the recipient having been informed that they are at a greater risk of contracting Creutzfeldt-Jakob Disease.

Recommendation 7. That recipients who have already accepted the settlement offer would also be eligible for the additional offer as outlined in Recommendation 6, providing they have evidence of psychiatric injury, psychological stress or significant life disturbance.

See Recommendation 6.

Recommendation 8. That unapproved recipients, who are formally identified and accepted through the process outlined in Recommendations 2 & 14, be eligible for the additional settlement arrangements already offered to recipients as well as those outlined in Recommendations 6 & 15.

Response
The Government agrees to adopt this recommendation.

Recommendation 9. The Commonwealth formally acknowledge:

(a) the deficiencies in the operation and oversight of the AHPHP;

(b) the experimental nature of aspects of the treatment under the Program; and

(c) the anxiety and stress that has been caused to hormone recipients.

Response

(a) The previous Government received a report from Professor Allars in June 1994. In the *Report of the Inquiry into the use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease,* Associate Professor Allars reported a number of concerns about the operation of the AHPHP and the decisions taken by various advisory committees and departmental officers at the time.

The Commonwealth formally acknowledges that there were some deficiencies in the operation and oversight of the Australian Human Pituitary Hormone Program.

In order to ensure the highest standard in future programs the Commonwealth has adopted most of the recommendations made by Professor Allars.

The Commonwealth acknowledges that it is a great tragedy that some of the people who were treated under the AHPHP have now died as a result of CJD and that a group of Australians now live with the uncertainty of being at risk of contracting CJD. It is deeply regrettable that this tragedy has occurred.

(b) The Government does not acknowledge that treatment administered under the AHPHP was experimental. When hormone products were first issued in 1967 for the treatment of patients approved under the AHPHP, hormone treatment had been in operation overseas since 1958 and in Australia since 1963.

It is acknowledged that a small number of recipients received hormone in a small number of research studies which were undertaken under the AHPHP, some of which were referred to by the Senate Community Affairs References Committee.

(c) The Government acknowledges that a number of recipients have suffered distress and anxiety and it expresses its sympathy to those recipients who have been affected.

Context
In her *Report of the Inquiry into the use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease,* Associate Professor Allars reported a number of concerns about the operation of the AHPHP and the decisions taken by various advisory committees and departmental officers at the time.

Recommendation 10. That the current eligibility guidelines for the provision of legal aid be revised to ensure that cases, particularly test cases, involving issues of public interest such as those raised in APQ's case be eligible to receive legal aid assistance in the future.

Response
The Government does not accept this recommendation.

Context
The principle which underpins the legal aid system in Australia is one of matching priorities to available funds. Legal aid in Australia is not an entitlement based system. Accordingly, each case must be considered not only from the perspective of its merits but also in relation to whether funds are available.

Recommendation 11. That, in future, the determination of legal aid applications should be made in accordance with the guidelines operating at the time the application was submitted. Thus, any variations to eligibility criteria would only apply to applications submitted after such variations had been introduced.

Response
The Government does not accept this recommendation.

Context
Assistance under the guidelines for legal aid must be considered in light of available funds at any particular point in time.

Recommendation 12. That the Department review all possible tracing methods in an attempt to identify the remaining 190 or so untraced approved recipients.

Response
See response to recommendation 2(c) above.

Recommendation 13. That the coding system being developed for lists of recipients distributed to Blood Banks and organ and tissue agencies be completed as a matter of priority.

Response
The Government notes this recommendation and that the list of names of recipients has now been encoded and provided to the National Centre in HIV Epidemiology and Clinical Research, for a preliminary trial to evaluate the effectiveness of the coded system. This matter is being progressed as a matter of priority.

Context

A list of the names of hormone recipients has been provided to blood, organ and tissue donation agencies to ensure that people at an increased risk of CJD (through hormone treatment) are not included in donation programs. Concerns were raised by some recipients that this was an invasion of their privacy. The NPHAC agreed with the need for this list to be made available and that any copies of the list distributed in the future should be in a 'coded' form to protect the privacy of recipients as far as possible.

Recommendation 14. That the Department allocate resources to tracing unapproved recipients of human-derived pituitary hormones.

Response
The Government notes this recommendation and that the Department of Health and Family Services is currently investigating strategies to identify unapproved recipients of the hormone and to trace the remaining recipients.

Context
Information about unapproved recipients is only available in the records of doctors who were providing treatment under the AHPHP. The Department will be required to contact each surviving treating doctor requesting their further assistance in identifying unapproved recipients.

Recommendation 15. That once it is established that a person did receive hPG or hGH from the AHPHP, the recipient's status should be of no difference to that of approved recipients. In the event of a dispute between the Department and a person who claims to have received human pituitary derived hormone, the matter should be referred to an independent arbiter for resolution.

Response
The Government accepts this recommendation. No distinction is made between those recipients who were approved and those who were not approved for treatment by HPAC. An independent arbiter for any cases of dispute will be appointed to determine whether or not a recipient has received human pituitary derived hormones.

Context
See recommendation 8.

Recommendation 16. That the Department put in place protocols to ensure sympathetic early intervention so that information and assistance is provided to a recipient suspected to have contracted CJD as soon as the recipient's condition becomes known, rather than await official confirmation.

Response
The Government accepts this recommendation and notes that a procedure for responding to possible further cases of CJD in hormone recipients is in place and was implemented in relation to the recent possible case of CJD.

Context
When the possible fifth case of CJD in a hormone recipient was recognised in 1995, a protocol was prepared setting out the procedure for responding to future possible cases of CJD in a hormone recipient. This procedure was subsequently refined with the establishment of the Pituitary Hormones Trust Account and the availability of funds for medical and other care costs.

Recommendation 17. That the Department inform the recipient community of the steps to be taken to make an application to the Department for assistance, including the persons to be contacted and the information required, in the event that it is suspected of that a person has contracted CJD.

Response
The Government accepts this recommendation. This information will be included in the next edition of the *HPH newsletter*.

Context
See Recommendation 16.

18. *That, in view of the availability of further information (much of which is conflicting in its nature) which may not have been considered by the Allars Inquiry, Professor Margaret Allars be invited to review, with the necessary independent scientific advice, this further information on scientific matters concerning the AHPHP which has become available since the Allars Inquiry reported. If Professor Allars in unavailable, another suitable qualified person be invited to undertake the review.*

Response
Associate Professor Allars has been asked to review the 'further information on scientific matters concerning the AHPHP' that was submitted *in camera* to the Senate Community Affairs References Committee Inquiry and determine whether this information was available at the time that she conducted the *Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease*.