Landmark victory on the horizon in CJD "nervous shock" litigation

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The victims of the one of the worst medical disasters in Australian history are at the brink of a landmark victory against the Commonwealth of Australia as a result of a recent Inquiry by the Senate Community Affairs References Committee. With the impending settlement of the litigation, the Courts will have lost a valuable opportunity to rule on a controversial aspect of "nervous shock" law.

Introduction

It would appear that the Commonwealth of Australia (the Commonwealth) may soon settle "nervous shock"[1] litigation and compensate recipients of human pituitary hormones, at risk of developing Creutzfeldt-Jakob Disease (CJD), and who have suffered a psychiatric injury.

Those recipients who can establish that they have suffered from a recognisable psychiatric injury prior to 1 January, 1998 as a result of learning that they have a greater risk of developing the fatal and undetectable Creutzfeldt-Jakob Disease, will be eligible for payments from a Trust Fund under a compensation package recently announced by the Commonwealth Government. The package follows an Inquiry by the Senate Community Affairs References Committee (SCARC) into the CJD litigation which has been on foot for a number of years in the Supreme Courts of New South Wales and Victoria.

Five Australian recipients of human pituitary hormones have died in recent years after receiving injections of hormones from batches contaminated with the infective agent of CJD. One recipient is currently dying from the disease and a possible seventh case is currently being investigated by the CJD Case Registry. An unknown number of Australian recipients will develop and die from CJD in the future. The hormone recipient population in this and other countries are left wondering how the disaster was allowed to occur and whether they too will have their lives cut dramatically short by the insidious disease.

Recipient plaintiffs therefore may not have to proceed with the litigation against the defendants whose resources appeared to be endless and whose commitment to defending the proceedings was unrelenting. However, if the lengthy, expensive fascinating and extremely complex litigation does not proceed, the Courts will have lost a valuable opportunity to rule on an interesting and novel area of the common law concerning "nervous shock".

Background to the AHPHP

Between 1967 and 1985, some 2100 Australian men, women and children received injections of human pituitary hormones[2]. The hormones were derived from human pituitary glands collected at autopsy. Despite very early warnings about the safety of using such hormones, the Australian Human Pituitary Hormone Program (AHPHP) continued uninterrupted for almost 20 years. The AHPHP was belatedly suspended in 1985, following reports of the deaths of recipients overseas from a rare and fatal degenerative neurological disorder, CJD.

Human growth hormone (hGH) and human pituitary gonadotrophin (hPG) were manufactured by the then Commonwealth Serum Laboratories Commission. HGH was administered to children of short stature and hPG was administered mainly to infertile women. Some men also received injections of hPG. The hormones were listed as pharmaceutical benefits by the then Minister of Health and were distributed at no cost to recipients.

An advisory Committee established by the then Minister of Health, the Human Pituitary Advisory Committee (HPAC), oversaw the AHPHP. Subcommittees of the HPAC approved applications for treatment, monitored treatment results and the fractionation and extraction of the hormones at CSL.

As an Inquiry in 1994 found[3], the Committees were run by the very medical practitioners who ought to have been regulated. The committee members were those obstetrician/gynaecologists and endocrinologists who were administering the hormones to unsuspecting patients. The Allars Report[4] also correctly pointed out that they had a vested interest in ensuring that adequate supplies of the hormone were maintained. The practitioners were "at the forefront of an exciting new era of hormone replacement therapy".[5]

While the committee members had expertise in the area of treating endocrine disorders, they lacked the expertise necessary to identify and address a variety of matters which threatened the safety of the products. They were not virologists, microbiologists or neuropathologists and as the Allars Inquiry found, they failed to appreciate the limitations of their expertise.

When discussing the AHPHP, it is important to note that the treatment was not successful for all patients. Some women did not conceive after receiving hPG injections. For those who did, not all delivered a live child. A number suffered from miscarriages and/or the potentially life-threatening Ovarian Hyperstimulation Syndrome (massive enlargement of the ovaries). Some children did not grow at all in response to hGH treatment and others did not grow significantly taller.

Some members of the medical profession have been quick to respond to the

emerging fatalities by arguing that "these women would have done anything to have a baby", "the parents of these children would have done anything to have their children grow taller" or "there was no other treatment available". Such comments ignore the fact that the treatment was not universally successful, that a number of potentially serious side effects were associated with the use of hPG, of which the majority of recipients were largely unaware, and that a safer alternative to hPG was available.

There is currently no way of determining the extent of CJD contamination of CSL's products. Some have argued that CSL's entire plant requires examination. There is currently no method available which can detect those recipients who have been exposed to contaminated batches. The Department of Health and Family Services have rightly advised recipients that no batch of the hormones can be presumed to be safe.

The Elusive Nature of the Infective Agent of CJD

The nature of the infective agent of CJD also remains elusive. CJD is one transmissible spongiform encephalopathy of human and animals. Scrapie in sheep has been known for hundreds of years. More recently Bovine Spongiform Encephalopathy (BSE or "mad cows disease") has received much attention in the media following the discovery in the United Kingdom of a new variant of CJD in individuals who have eaten British beef. Kuru, which is found in certain hill tribes in Papua New Guinea and which was first investigated and described in the 1950s, has all but been eradicated after cannibalism was prohibited.

The prion theory, advanced by Nobel Prize winner Stanley Prusiner in the early 1980s, postulates that the infective agent of CJD is an abnormal form of a protein found in most organs and cells of the body. The abnormal form of the protein, called prion protein (PrP) serves as a template which induces the normal form of the protein to structurally transform to the abnormal form. The prion theory has not received universal acceptance.

The prion theory was and is considered heresy by some in the scientific community because of the fundamental notion in biological science that nucleic acids are a necessary prerequisite for replication. Nucleic acids in the form of RNA and DNA are required by cells of a living organism for cell replication and the production of proteins.

Viruses contain small quantities of DNA or RNA. Prior to Prusiner's prion theory, it was widely believed that CJD was thought to be an unconventional slow virus, "slow" because the incubation period of the disease is measured in years and decades. However, no one has been successful in identifying nucleic acid unique to the infective agent of CJD. The viral and prion theory continue to have their own supporters and the debate about the nature of the infective agent of CJD remains hotly contested.

If statistics from overseas are any indication of how many Australian recipients will develop and die from CJD, it would seem that the legacy of the AHPHP will not be known for many years. In the United Kingdom a comparable number of recipients received hGH injections. Twenty recipients of hGH have died in that country. Litigation has been ongoing there for a number of years. Recently, recipients who had suffered a psychiatric injury as a result of learning of their greater risk of developing CJD obtained awards from the High Court of between 3,000 and 300,000 pounds.

It also remains to be seen whether CJD can be transmitted by blood. The transmissibility of CJD by blood has been achieved in a number of laboratory experiments but the experts still maintain that there is no evidence that the disease can be transmitted that way. The issue has serious implications for the safety of the blood supply in this country. In recent years, countries overseas such as the United States, Canada and New Zealand, have been forced to recall large volumes of blood products after discovering that blood donors had either suffered from CJD or had been exposed to the infective agent during treatment with hGH.

Recipients of hGH and hPG in Australia are not permitted to donate blood or organs and must present a Departmental document about their risk status on visits to their doctor or dentist. Infection Control guidelines have been developed by the National Medical and Research Council (NHMRC) but they have been criticised by some as being inadequate. Some dentists and doctors remain unaware of the necessary precautions.

Plaintiff lawyers can expect that there will be cases in the future where persons may develop CJD as a result of contaminated blood transfusions, organs or surgical instruments. Some patients have already died in Australia from CJD after receiving dura mater and corneal transplants.

The tragedy of the AHPHP is that the risk that CJD might be transmitted to recipients of human pituitary hormones could and should have been known by the authorities.

Viral Contamination of CSL's Hormone Products

It was well known at the time when human pituitary hormones were first being used in humans that it was impossible to guarantee that the preparations would be free of viral contamination. In 1965 the Commonwealth and CSL were warned that there was no way of limiting the collection of glands to safe cadavers and that virus particles, such as serum hepatitis, would precede the hormone through the columns used during fractionation thereby contaminating the equipment and the final product. The warning came from Dr. W. Whitten, an officer of the National Biological Standards Laboratory (NBSL). NBSL, the precursor to the Therapeutics Goods Administration (TGA), had been established by the Commonwealth in 1958 after the Thalidomide disaster to ensure the safety and efficacy of therapeutic goods.

Any harsh treatment of the pituitary glands during processing, such as heating, would denature the hormones thereby rendering the hormones inactive and useless for therapeutic purposes. It was also known at a very early stage that one could not test for the presence of live virus unless samples were injected into laboratory animals and the animals were observed for signs of illness. In the case of slow viruses such as CJD, it was not practical to monitor animals for many years even if the authorities had decided ▶

that such tests were necessary. An additional problem arose from the fact that it was impossible to test the products for the presence of all known viruses. The amount of hormone required for such tests would have resulted in little, if any, hormone being available for therapeutic use. Even if all such tests could be performed, one could not determine whether the virus that was detected was active or inactive.

Supply and Demand, Exclusion Criteria, the Ferguson Method and Early Warnings

The availability of pituitary glands for the preparation of the hormones was always limited by the number of autopsies performed. A number of glands were required for just one cycle of hormone treatment in a patient and many patients required many cycles of treatment before the treatment was successful. Throughout the entire AHPHP, the demand for the hormone (and hence for the raw material) always exceeded supply. Whether or not the supply and demand problem prompted the authorities to overlook safety matters is a matter of speculation.

During the AHPHP, the authorities relied on two methods to reduce the risks of viral contamination of the final product: the Ferguson method of processing pituitaries and extracting hGH and hPG and exclusion criteria. The risk of viral and slow viral contamination of the product could, however, never be completely eliminated.

Exclusion criteria were first drafted in the 1960s to ensure that glands from persons who suffered from particular conditions before death were not included in the collection process. Batches of 1350 glands were processed by CSL at any one time. Moreover, the authorities assumed throughout the entire AHPHP that the processing method used by CSL, the Ferguson method, would separate virus particles from the hormones according to their molecular weight. The Ferguson method included a step of gel filtration chromatography. It was believed that larger molecular weight material, such as virus particles, would be separated from the hormones which had a smaller molecular weight.

Both safety precautions were bound to fail. The exclusion criteria were never distributed to all mortuary attendants and pathologists collecting glands. Most remained unaware that exclusion criteria even existed.[6] Glands were not screened at CSL for disease prior to processing. In the late 1970s CSL surveyed a sample of glands to determine their quality and found that much of the material which was being processed was extraneous material such as bone and blood vessel. Only then were poor glands, such as those in an advanced state of decomposition, rejected prior to processing[7]. The inclusion of poor glands previously probably explained the contamination of the product with pyrogens. Many patients complained of severe pain at the site of injection consistent with such contamination.

At no stage during the AHPHP did the Commonwealth or CSL subject the Ferguson method to a detailed examination to determine the scientific soundness of the assumption that virus particles would be removed from the final product. Moreover, they knew that the method could not guarantee that virus would be removed from the final product.

After the 1965 warning a further and very significant warning was given three years later by a member of the HPAC. In 1971 the HPAC was alerted to the fact that glands taken from deceased persons with chronic neurological disorders might be suspect. Dr. McGovern was aware of slow viruses at the time and of their transmissibility. As a result of this warning, the HPAC sought expert advice from the Special Virology Committee of the Royal College of Pathologists of Australia who confirmed that glands from persons with neurological disease should not be collected and processed. The exclusion criteria were subsequently amended. Until a curious omission occurred in the exclusion criteria in 1977, the criteria from 1971 onwards required that that glands from persons with neurological diseases of the central nervous system due, or possibly due, to viral infection, were to be excluded from the collection process. Yet few mortuary attendants and pathologists were provided with copies of the criteria by the Department or CSL. In any event, the exclusion criteria were not foolproof. Slow viruses could incubate for decades and a number of more common viruses such as herpes could lie dormant without the patient suffering from any symptoms. Glands could therefore be unknowingly collected from people harboring virus.

Developments in Knowledge - A Failure to Act?

As protein chemists were attempting to isolate and purify the pituitary hormones necessary for growth (hGH) and reproduction (follicle stimulating hormone, or FSH, and luteinizing hormone, LH) virologists, veterinary pathologists and neuropathologists were attempting to unlock the secrets of some neurodegenerative diseases in man and animal.

In 1958 Gemzell, a Swedish scientist, successfully treated an infertile woman with hPG (a crude mixture of FSH and LH). A report was also published in the same year of the successful treatment by Raben of a pituitary dwarf with hGH extracted from pituitary glands. Workers worldwide thereafter attempted to emulate the results of Gemzell and Raben. Their experiments in humans were dependent upon a supply of hPG and hGH, which in turn was dependent upon an adequate supply of human pituitary glands. Australia was the only country in the world to organise a government sponsored program to ensure the collection and processing of pituitary glands and the extraction and distribution of hGH and hPG.

Unfortunately, those at the forefront of endocrinology failed to consider the significant work of the researchers investigating slow viruses and degenerative diseases of the central nervous system in human and animal. Their failure to do so would be fatal for some of their patients.

The transmissibility of scrapie had been known for many years. The Australian authorities were well aware of the dangers and transmissibility of scrapie, especially after an outbreak in Victoria in the 1950s. The importation of sheep from countries other than New Zealand thereafter promptly ceased. In the 1950s and 1960s, many Australian medical practitioners, scientists and others with an interest in the obscure, were fascinated with the discovery and investi-

gations of kuru in Papua New Guinea.

Many diseases of the human brain were poorly understood at the time. In 1959 Hadlow reported the similarities between scrapie and kuru. Klatzo, Gajdusek and Zigas in that year had also reported neuropathological similarities between kuru and CJD. Thus, by the late 1950s, it was known that scrapie was transmissible and that there were similarities between CJD, scrapie and kuru. It was generally thought that the three were all slow viruses and that their infective agents were one and the same, if not similar.

In 1964 a symposium on slow, latent and temperate virus infections was held at the National Institutes of Health (NIH) in Bethesda. Medical virologists turned to the work of veterinary virologists in an effort to gain further understanding of neurodegenerative conditions in humans. A series of experiments were conducted at the NIH by Nobel Prize winner D.C. Gajdusek and his colleague Joe Gibbs. The experiments were conducted to determine whether there was an infectious etiology for Multiple Sclerosis and other human chronic degenerative disorders of the central nervous system, including kuru and CJD. Microbiology had failed to elucidate an etiology. The experiments were prompted by Hadlow's report in 1959.

A breakthrough came in 1965 when kuru was successfully transmitted. The transmission experiment of Gajudsek and Gibbs was published in *Nature* in 1966. Intracerebral inoculations of brain suspension from patients with kuru successfully transmitted the disease to chimpanzees.

The most significant report came in 1968 in *Science* - CJD had been successfully transmitted to a chimpanzee. Suspensions of brain tissue from a patient with CJD were inoculated into a chimpanzee who later developed the disease. At this stage it was known that scrapie, kuru and CJD, all slow viruses, were transmissible. It was also known that the infective agent of scrapie was very small and very resistant to a number of deactivants. Significantly, it was also known that the pituitary gland of scrapie affected sheep contained the infective agent. From the late 1930s, it was also known that a vaccine for louping ill made from the brains, spleens and spinal cords of scrapie affected sheep had transmitted scrapie to a large number of healthy sheep who were vaccinated. Processing had not deactivated the infective agent.

Once CJD had been successfully transmitted in 1968, research into the disease continued in an effort to determine the nature of the infective agent. In 1974 the first report of a possible human to human iatrogenic case of CJD was published in the *New England Journal of Medicine* after a patient received a corneal transplant from a patient who had died of CJD. The authors made explicit warnings about the wider implications of the case for all transplantation programs worldwide. Unfortunately, the warnings appeared to go unnoticed by the Department and CSL. It was to be argued at trial that the AHPHP should not have continued after these results were published unless recipients were warned of the possibility of transmission of CJD. ▶

Research in the mid 1970's continued to demonstrate the unusual resistance of the infective agent of slow viruses including the infective agent of CJD, to standard forms of deactivation such as formalin and heat.

Further warnings were published in 1974 and 1975 in widely read journals. All organs and tissues from patients suffering form presenile demenita (CJD) were to be regarded as infectious given the unusual resistance of the CJD agent. Those individuals conducting biopsies and autopsies on CJD patients were warned to take precautions to avoid the theoretical risk of occupational transmission of the disease.

In 1976, a scientist in Scotland awoke in the middle of the night and was startled by thought of the possibility that slow viruses, such as CJD, could be transmitted to recipients of hGH in the United Kingdom. He would later test one of the processing methods used in the United Kingdom to determine whether it removed the infective agent of scrapie. No such test would ever be performed on the method used by CSL.

In 1978 another NBSL officer, who was evaluating a commercial hGH product for import, was concerned by the possible viral contamination of the product and advised the Department that it was impracticable to test the product for all known viruses. It was acknowledged that no tests were available to determine whether the product was contaminated with slow viruses. The officer also thought it was conceivable that the pituitary gland could contain viruses derived from the brain or from the blood stream. The officer was not prepared to permit the importation of the product until such time as NBSL received evidence that, *inter alia*, positive efforts were made to exclude donors suffering from active viral infections and the product contained a warning that the product could not be guaranteed to be free from human viruses. Curiously, CSL's products were never subjected to such evaluation, a requirement for pharmaceutical benefits listing in 1967, nor did CSL's products contain such a warning.

With the emergence of the 1980s the published medical and scientific literature was awash with warnings about the dangers of CJD transmission.

The issue of slow viral contamination of CSL's products was considered by the HPAC and one of it subcommittees in 1980. The risks were essentially dismissed and patients remained unaware of the dangers. The AHPHP continued at a time when it was known that the prevalence of CJD in Australia and other first world countries was one per million population. As the Allars Inquiry found, it was "highly likely" that glands infected with the CJD agent would be collected and processed by CSL[8]. In 1982, 500 glands were destroyed by HPAC after an autopsy report indicated CJD in a patient. HPAC were clearly concerned that the inclusion of the glands might threaten the safety of the hormone products yet, remarkably, recipients remained unaware that CJD could theoretically be transmitted by the hormones and that the product could not be guaranteed to be free of virus.

Even more remarkable is the fact that the Department's *Communicable Diseases Bulletin* in 1983 contained an article on CJD stating that workers exposed to infective tissues should be aware of possible transmission following tissue penetration. The article also noted that organs and tissues from patients with CJD could not be used for transplantation purposes.

The End of an Era

After its suspension in 1985, most recipients of hGH and hPG in Australia remained unaware that there had been deaths from human pituitary hormone treatment overseas and that the use of the products had ceased in Australia. In 1988 an Australian hPG recipient died from CJD. In 1990 a second hPG recipient died and a further hPG recipient died in 1991. The fatal implications of the AHPHP only began to receive media attention in 1992 when the families of the deceased pressed the Department for an explanation. In 1993, the Department announced the fourth death of a hPG recipient in 1989. A case of CJD in a hGH recipient would be later identified.

Most Australian recipients appear to have been traced and advised of the risk only in 1992 and 1993. Some recipients had first learned of their risk after watching ABC TV's *7.30 Report* or as a result of reading newspapers and magazines. For some 7 to 8 years, many recipients had been unknowingly donating possibly contaminated blood and organs.

In 1993 an Inquiry was announced by the then Minister of Health, Senator Graham Richardson and in 1994 the Allars report was tabled in the House of Representatives. The report was damning indictment of the Department, CSL and the medical practitioners' role in the AHPHP. The Allars Inquiry had found that the authorities had been slow to respond to the knowledge concerning the transmissibility of CJD. It was also found that aspects of the AHPHP were unethical and unlawful, that the written informed consent of patients was often not obtained and that glands were often removed from cadavers illegally. It was also found that CSL's hormones were not subjected to the regulatory regime which had been established in this country after the Thalidomide debacle.

The tragedy of the AHPHP is that had CSL's hormone products been subjected to this regulatory regime, it is quite likely that the products would never have been distributed. Had the then Minister of Health and Director-General had the products tested by NBSL prior to their listing as pharmaceutical benefits (as was required), the AHPHP may never have commenced. Pharmaceutical benefits listing was dependent upon satisfactory results being obtained by NBSL after evaluation. CSL's hGH and hPG were listed without NBSL ever having evaluated the hormones. It is clear that CSL's products were plagued with myriad problems which would have prevented their listing quite apart from the issue of viral and slow viral contamination; batches were not sterile; some batches were contaminated with pyrogens; all batches were contaminated with an unknown quantity of other pituitary hormones; assays performed on the products to determine their potency were unreliable; packaging and labeling defects had occurred.

Curiously, Professor Allars had hoped that the litigation commenced by recipients would settle following the Inquiry's Report[9]. Unfortunately the Commonwealth did not settle. In all of the proceedings, it was alleged that the recipient plaintiffs had suffered from a

recognisable psychiatric injury as a result of learning of their greater risk of developing CJD and that the injury was a result of the negligence of the Commonwealth and CSL.

A Test Case Collapses - APQ v Commonwealth of Australia Anors

APQ v Commonwealth of Australia Anors was to be the test case in the Supreme Court of Victoria. It was anticipated that the result obtained in APQ would determine the fate of the proceedings commenced by recipients in New South Wales.

In the April 1997 issue of *Plaintiff*, APLA members were advised of the plight of APQ by Rennick Briggs, the Victorian solicitors who acted for APQ. As a result of the Commonwealth's refusal to provide legal aid to APQ, Rennicks were unable to run the test case and APQ was advised to accept a settlement offer made by the defendants on the eve of the trial. Acceptance of the offer ensured that APQ's legal costs were paid and that common law damages were available in the event that APQ later developed CJD. The offer was subsequently extended to litigants in the NSW proceedings and to all other "official" recipients. Compensation was not dependent upon the recipient proving liability and the offer was extended to all "official" recipients regardless of when they were treated. No provision was made in the offer of settlement for compensation to recipients for any psychiatric injury they suffered. Some recipients were of the opinion that nothing had been gained - the families of the deceased recipients had already settled claims for compensation with the Commonwealth and CSL out of court and monies for medical treatment and care were available from a Trust Fund established by the Commonwealth after the Allars Inquiry reported.

Interesting Questions of Law- Fear for the Future and Secrecy Provisions

One interesting question of law posed by the CJD litigation was whether the Commonwealth could rely on a secrecy provision in the National Health Act 1953[10] to prevent the discovery of certain documents to the plaintiffs in the litigation or to avoid producing certain documents to the Court in response to a subpoena. Macedone Christie Willis (MCW) for the plaintiffs had sought the discovery of relevant documents generated by or provided to the Allars Inquiry. The Commonwealth refused to disclose information contained in the Allars document which related to the affairs of a third person, arguing that the disclosure of such information would be in breach of the secrecy provision. MCW argued that such a provision had no application to the discovery process or where the information was sought via subpoena. A number of cases supported MCW's proposition. The Commonwealth continued to maintain that the secrecy provision applied. The result during discovery in the CJD litigation was that documents were discovered with information expurgated. The use of the secrecy provision in the litigation was examined by the SCARC in its Inquiry (see below).

The CJD litigation commenced by ▶

recipients in Australia also raised an interesting question of law relating to compensation for "nervous shock". The Commonwealth had maintained from the outset of the litigation that there was no cause of action known in law which provided compensation for "nervous shock" caused by being advised of a distressing fact, an apprehension that a plaintiff may suffer a disease at some indeterminate time in the future. It was argued by the Commonwealth that what was required was a single phenomenon (such as an accident) with accompanying proximity.[11] The defendants insisted that that there must be a *sudden* impact to the senses in line with *Jaensch v Coffey*[12] and other "nervous shock" cases. They also argued that the floodgates would be opened if recipients were compensated for their psychiatric injury.

MCW, Rennicks and other firms and their counsel who were involved in the litigation did not agree with the Commonwealth's interpretation of the common law and were confident that the common law could accommodate the claims. Commentators also supported their opinion that there could be liability for pure psychiatric injury as a result of fear or worry for future consequences, a claim that was distinct from those claims where psychiatric injury was consequent upon fear of one's own immediate physical injury or death by impact anticipated through one's own unaided senses.[13]

The Commonwealth's assertion was rejected by a single judge in the Supreme Court of Victoria in interlocutory proceedings in *APQ*.[14] The Commonwealth maintained that the question would be taken to the High Court if necessary. The then President of the Court of Appeal in NSW, Mr. Justice Kirby, discussed at length the undesirability of an unduly narrow interpretation of "nervous shock" law in *Coates v GIO*.[15] Finally, In December of last year a Court in the United Kingdom found the defendants liable for the psychiatric injury suffered by hGH recipients in that country, as a result of learning of their greater risk of CJD. Unfortunately, with the impending settlement of the CJD litigation in this country, the Courts have lost a valuable an opportunity to rule on the issue.

Nevertheless, the impending settlement of the litigation has demonstrated that the Senate can be a powerful tool for plaintiffs and their lawyers who are involved in public interest litigation.

The Inquiry by the Senate Community Affairs References Committee

An inquiry into the CJD Settlement Offer by the SCARC was announced in June, 1997. The terms of reference of the Committee's Inquiry were broad and extended to an examination of *inter alia*, whether the CSL and the Commonwealth had failed to adequately protect public safety in relation to the AHPHP.

The Committee heard evidence during three days of public hearings. The NBSL officer who had warned the Commonwealth of the risks of viral contamination in 1967 told the Inquiry that CSL's best hPG was 99.6% impure. Of CSL's hPG, he said "It was a shocking product. I cannot believe that this could have been marketed".

A further scientist criticised the Commonwealth's failure to submit the gel chromatography step in the Ferguson method to a detailed analysis and argued that this failure was "a major contributor to the disaster".

Some recipients could not understand why there was a need for an Inquiry when a departmental officer had basically admitted that the Commonwealth had been negligent. The SCARC was shown a video recording of a current affairs television program from 1994 when the Department's Chief Medical Officer (CMO) confirmed that recipients were "guinea pigs". The CMO also confirmed that recipients were not provided with an opportunity to give informed consent and that the doctors involved in the AHPHP were "over enthusiastic". He confirmed that guidelines were either "ignored or fudged" and that the patients' "welfare was sacrificed" concluding that the situation "should have been corrected earlier than it was". In conclusion, the CMO stated that the Government and the Committees were "derelict in their duty in not stopping the AHPHP sooner".

When the Committee's unanimous Report was tabled in the Senate in October of last year, the damning findings of the Allars Inquiry were confirmed. The SCARC went further and recommended that some of the information provided to the Inquiry, which may not have been considered by the Allars Inquiry, should be provided to Professor Allars for review. This information mainly concerned a debate which had arose about whether the Department and CSL had knowingly distributed batches of hPG and hGH contaminated with the hepatitis or pyrogens. A number of individuals had argued that some of CSL's hGH and hPG which were administered to patients were contaminated with hepatitis. The Department and CSL strongly denied the allegations even though they were presented with copies of their own documents which suggested they were wrong.

The SCARC's report also contained scathing criticism of the Department's approach in the litigation with MCW and Rennicks. It found that a range of possibly relevant Departmental and CSL files held in Archives had been destroyed. It also found that relevant documents had been provided to legal firms during discovery which contained material that was unnecessarily expunged or withheld totally. The SCARC further found that the Department had relied on an "overly restrictive interpretation" of the secrecy provision contained in the National Health Act 1953 and that "Departmental actions in this regard may have been deliberately obstructionist". The SCARC noted that a sixth month delay in providing some discovered documents to MCW "could be regarded as deliberately obstructionist".

The report of the SCARC contained a number of recommendations. The most significant recommendation related to the payment of compensation to those recipients who could establish that they had suffered a recognisable psychiatric injury as a result of learning of their greater risk of developing CJD.

When the report was tabled in the Senate in October, 1997, Senator Brian Harradine, who was instrumental in establishing the Inquiry, summarised the findings as follows:

"Our examination of the whole CJD episode provided a window into lax process and cover-ups by those responsible for regulating human experimentation and by those

whose grave duty it is to ensure the highest standards in the regulation and manufacture of biological products...Women seeking help for infertility, and men and women of short stature were essentially guinea pigs in an unlawful experiment...CSL did not meet the requirements of the Australian regulatory authorities...There was enough information in 1966 to indicate that the program should not have been allowed to proceed"

The Commonwealth's Response - The End of a Lengthy Battle on the Horizon

On 31 March 1998, the Commonwealth's response to the SCARC's report and recommendations was tabled in the Senate. The Commonwealth agreed with the majority of the SCARC's recommendations. It also agreed to compensate those recipients who could establish that had suffered from a psychiatric injury prior to 1 January, 1998 as a result of learning of their greater risk of CJD. The Commonwealth also acknowledge the deficiencies in the operation and oversight of the AHPHP but it continued to deny that the use of hGH and hPG during the AHPHP was experimental, a response most curious given the findings of the Allars Inquiry and the admissions made by the Department's CMO in 1994.

Recipients and their lawyers are now waiting for the Commonwealth to establish the Independent Board which will assess claims for compensation. Three million dollars is to be deposited into the Trust Fund to fund the compensate package. However, serious questions have arisen, especially in light of the recent awards in the United Kingdom, as to whether such an amount will be sufficient.

Regardless of whether compensation is forthcoming or not, many recipients will never be able to put their AHPHP experiences behind them. For some recipients and their families, the fear that they will develop and die from CJD will tragically materialise. It can only be hoped that the AHPHP has provided the authorities with a salutary lesson in the regulation of therapeutic products. ■

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Notes:

1. The term 'nervous shock' is used reluctantly by the author.
2. In addition to these 'official' recipients, an unknown number of people were treated 'unofficially', some of whom remain untraced and unaware of their risk today.
3. The Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt- Jakob Disease, chaired by Professor Margaret Allars (the Allars Inquiry).
4. *Report of the Inquiry Into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease,* AGPS, June 1994 (Allars Report).
5. Allars Report, pp. 505-510.
6. Ibid., p.65.
7. Allars Report, p.95.
8. Allars Report, p.360.
9. Submission of Professor M. Allars to the Senate Community Affairs References Committee,
10. Section 135A. Section 135A is in similar terms to other secrecy provisions contained in Commonwealth legislation.
11. Submission of the Australian Government Solicitor to the Senate Committee Affairs References Committee, Inquiry into the CJD Settlement Offer, p.2.
12. (1984) 155 CLR 549
13. See for example Mullany NJ *Fear for the Future: Liability For Infliction of Psychiatric Disorder,* in Mullany NJ (Ed), Torts in the Nineties, Law Book Co, 1997, pp.101-173.
14. *APQ v Commonwealth Serum Laboratories Ltd, Unreported, Supreme Court of Victoria, No 8546 of 1993, 2 February 1995.*
15. Unreported, Supreme Court of New South Wales, 30 November, 1994, pp. 8-9.

After 150 planes a day, woman sues

By STEPHEN GIBBS

A Sydenham woman has won the right to sue the body which controls Sydney air traffic for hearing loss she claims was caused by up to 150 planes flying over her home each day.

An application by Airservices Australia was dismissed by the Court of Appeal yesterday, allowing Mrs Carmen Zarb to sue the authority in the District Court.

Mrs Zarb's solicitor said last night her case was "the tip of the iceberg" of a possible class action.

Mrs Zarb launched a damages action against Airservices in May 1996, claiming loss of hearing because of increased flights over her home since the opening of the third runway.

Her statement of claim alleged it owed a duty of care, which it had breached by co-ordinating flight paths which exposed her to damaging noise levels, failing to warn her that flight plans adopted upon the opening of the third runway would damage her hearing and failing to protect her from hearing loss.

The authority appealed to the District Court to have the matter struck out on the ground Mrs Zarb had failed to disclose a cause of action. That application was dismissed, appealed on the basis that Airservices was immune from suit, and dismissed again yesterday.

Her solicitor, Mr Michael Twemlow, hailed the decision as the first legal step forward for other Sydney residents seeking compensation for aircraft noise damage.

"This proves that a simple housewife who has lived in the same small, semi-detached house for 35 years has had the courage to step forward and have her rights examined," Mr Twemlow said.

But yesterday's victory was only the first step, "because all the judge said today is this lady has a right to have her day in court".

The appeal was heard by Justice Priestley, Justice Powell and Justice Rolfe. Justice Powell dissented.

Mrs Zarb, who says up to 150 aircraft fly directly over her roof each day, will now wait for her action to be listed before the District Court.

At the earlier District Court hearing, an affidavit by Sydney Air Traffic Services terminal control unit manager Mr William Sims stated on behalf of Airservices Australia that Mrs Zarb's house was "almost exactly on the centre line" of runway 16R.

"Operational restrictions mean that certain suburbs, particularly those close to the airport, will always be exposed to a high level of aircraft noise, regardless of what noise abatement policies are put in place," Mr Sims's affidavit read.

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