Opinion

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AUSTRALIAN SENATE INQUIRY INTO TREATMENT OF HORMONE RECIPIENTS HEARS NEGLIGENCE ALLEGATIONS

By Melinda Tankard Reist

"It was a shocking product, I can't believe this had ever been marketed" - Dr Wes Whitten, reproductive physiologist, former assistant director, National Biological Standards Laboratory (now known as the Therapeutic Goods Administration Authority).

"..it is my opinion that not one batch of fertility hormone met all the regulatory standards and many did not even meet CSL's own rudimentary standards." - Dr Frank Peters - former assistant and acting director, NBSL.

"It is the consumers who will pay the heaviest price...when the duty of care plays second fiddle to other imperatives...- Dr David Howes, former chief virologist and head of biologicals branch, NBSL

An Australian Senate Committee has heard evidence of breaches of proper procedure in the processing of pituitary hormones used in infertility and growth treatments and linked with the rare fatal brain disorder Creutzfeldt-Jacob Disease (CJD). It is alleged Australian Government bodies failed in their responsibility to ensure the highest standards in the regulation and manufacture of biological products.

The Senate Community Affairs References Committee was appointed to examine the Australian Federal Government's treatment of recipients of human pituitary hormones, whether the Government's response to the 1994 Allars inquiry into the pituitary hormone program was fair and adequate, whether documents related to the inquiry were withheld and why legal aid was denied to "APQ", a claimant in a land-mark test case for compensation.

The inquiry is also examining whether the Commonwealth Serum Laboratory (CSL) or CSL Ltd, the National Health and Medical Research Council, the Department of Health and Family Services or any other Commonwealth department, agency or employee failed to adequately protect public safety in relation to the Human Pituitary Hormone Program.

A Commonwealth Ombudsman investigation is also underway into the handling of the CJD matter by the Department of Health and the Australian Government Solicitor.
The test case seeking compensation for nervous shock involving 132 recipients of hormones manufactured by CSL, and distributed at the direction of the Department of Health from1967-1985, was settled in April on the eve of what was to be a 15-week jury trial. The case was hampered by denial of legal aid by the Commonwealth and

problems securing necessary documents. An out-of -court settlement involved no immediate money and no admission of liability on the part of the Commonwealth.

Australia was the only country providing a government sponsored program using human pituitary hormone (hPG). It was banned in the US. CSL collected, manufactured, and distributed the glands which were derived from dead bodies. A total of 171,091 pituitary glands were collected with removal carried out mainly by mortuary staff who were paid fifty cents for each gland collected. Relatives had not given their consent. Dr P Schiff of CSL's representative on the Human Pituitary Hormone Advisory Committee (HPAC), and responsible to the Minister for Health in overseeing the program, advised gland collectors that "unless the body is badly decomposed it is never too late to take the gland." In other words, decomposing body parts could be removed and processed for use in living humans.

There was enough information in 1966 to indicate that the program should not have been allowed to proceed. However it continued until May 1985 when two US recipients died of CJD, a form of bovine spongiform encephalopathy (BSE) or mad cow disease which causes spongy formations in the brain. It has so far killed four Australian women and one man - another woman is being assessed for CJD and believed to be dying.

The Senate Committee heard damning evidence against CSL.

CSL did not follow world's best practice in the pooling and homogenising of glands, had failed to comply with the Code of Good Manufacturing Practice and told pathologists to ignore the exclusion criteria about possible Hepatitis infected glands. CSL had also failed to utilise a simple technique to destroy the infectivity of enveloped viruses such as Hepatitis B in pituitary hormones. The Department had not taken steps to monitor the health of recipients during and after treatment to determine whether the virus had been transmitted, nor sought to find out if recipients suffered hepatitis or liver problems.

Less harmful techniques for ovarian stimulation such as the use of gonadotrophin from menopausal urine, a standardised product with lesser side effects including fewer multiple births and the preferred treatment in almost all other countries, were not used (even though CSL described hPG as a treatment of "last resort").

The Committee also heard that in addition to the 2000 hormone recipients on the official program, possibly another 500-600 unofficial recipients were treated with "leftover" product and in other experimental programs.

Disturbing evidence was given by reproductive physiologist, Dr Wes Whitten, that batches of pituitary hormones were 99.9 percent impure, i.e only one tenth of one percent pure.

The lack of informed consent is a constant issue in the thousands of pages of submissions and transcripts.

Hormone recipients believed the hormones were safe and "natural". They did not know they were guinea pigs in an unlawful, experimental program using hormones processed from the glands of cadavers. They did not know that hPG had not been evaluated for clinical use before the program started. They were not informed of a risk per treatment cycle of ovarian hyperstimulation of 30 percent. The first guidelines for selecting women for the program was that they should not be ovulating. However ovulating women were given hPG.

It has only come to light recently that some hormone batches were contaminated with Hepatitis B, others were unsterile, and there is the possibility of mother to child transmission of CJD.

Conflicts of interest were also alleged. Convenor of the CJD support group and a recipient, Sue Byrne told the hearing: "Four people who were intimately involved with the program are actually controlling the program. The regulation of product is being conducted by somebody who works for the organisation who is controlling the products and who invented the process. There were no checks and balances. There was no independent review. There was no scope of expertise. It was a very narrow, a very self-interested group, who were running the ... Program"

All overseas cases involving hormone recipients have settled in favour of the recipients. France has gaoled two doctors for manslaughter and a pathologist in charge of the program for poisoning. But in Australia, no-one has been prosecuted and no one has admitted fault. Ted Allender whose former wife Jane and mother of his two children died of CJD has written to prosecutors asking them to consider laying criminal charges against HPAC members. Hormone recipient Samantha Ogilvie told the committee: "It is not the money that matters. It is the fact that people should be accountable for what they did to us."

Geraldine Brodrick gave birth to nontuplets in 1971. The six babies born alive died within two days. She told the committee "All who conspired to force this terrible legacy on hPG and hGH [human growth hormone] recipients are now being protected by a government and its officers who would rather see innocent recipients denied justice than admit to the ineptitude and negligence of those involved in producing these treatments and administering this program."

Public confidence in experimental programs is at an all time low in the wake of recent revelations about questionable experiments on orphanage babies, the elderly, "tall girls" and other vulnerable groups. It is hoped the CJD inquiry will lead to a serious tightening of the rules governing human experimentation in Australia.

The Committee's report will be released in October.