Growth hormone deaths blamed on MRC and DoH

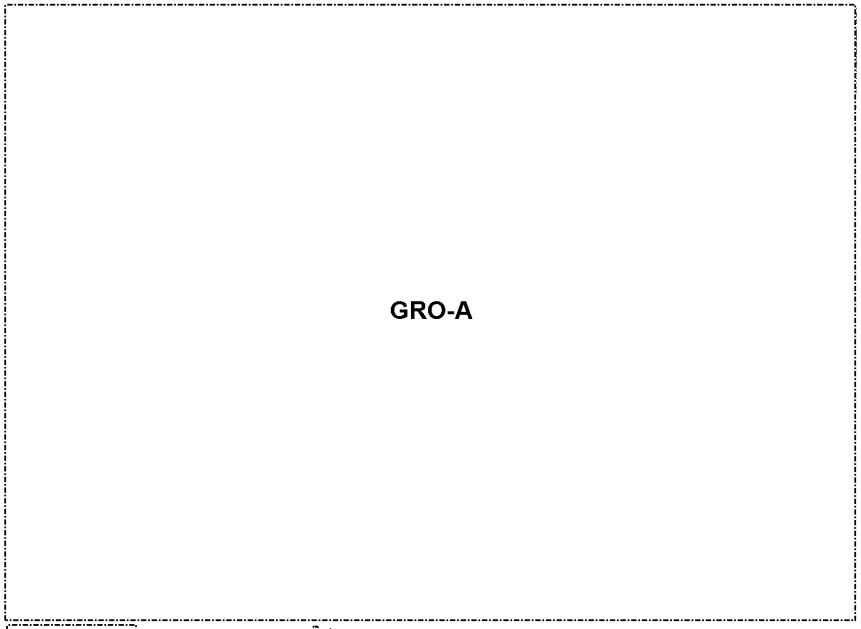
A High Court judge last week held the Department of Health and the Medical Research Council to blame for the deaths of young adults from Creutzfeldt-Jakob disease (CJD) who had been treated with human growth hormone.

In the first compensation claim over a pharmaceutical product to succeed in the British courts, Mr Justice Morland ruled that the two bodies were negligent in not passing on concerns raised by scientists that would probably have led to the treatment's suspension from July 1977. The decision means that only the families of patients who started the treatment after 1 July 1977 will be entitled to compensation.

The judge held, in effect, that had the Department of Health and the MRC fulfilled their duty of care, patients such as GRO-A GRO-A, who was treated between October 1977 and 1980, would never have undergone the treatment and contracted CJD. He died in 1992 aged 30, leaving two daughters now aged 9 and 10, who are in line for substantial compensation, which has still to be assessed. The test case was brought by eight of the 16 families of recipients of human growth hormone who have died from CJD since 1985, and by three others who are dying from the disease. In addition, 87 claimants in whom CJD has not been diagnosed but who are claiming compensation for psychological trauma, hope to have their case heard next year.

The MRC ran the growth hormone programme as a clinical trial from 1959 until 1 July 1977, when the programme was taken over by the Department of Health. Nearly 2000 children were treated with the hormone—extracted from the pituitaries of cadavers—between 1959 and 1985, until reports of the first deaths from CJD in the United States, after which synthetic hormone was used. The MRC retained responsibility for collecting and processing pituitaries until 1980.

In October 1976 a veterinary scientist, Dr Alan Dickinson of the Agricultural Research Council, who was working on scrapie, telephoned the MRC to alert officials to the risk of transmission of CJD through human growth hormone. In a letter in February 1977 he made four suggestions to improve the safety of the hormone. Two were never acted on, a third was only partly implemented, and the fourth—excluding the use of pituitaries from cases with dementia—was not put into force until 1980. Two virologists, Professor Cedric Mims of Guy's Hospital and Professor Peter Wildy of Cambridge University, were consulted by the MRC, but not until December 1977. Professor Wildy replied: "Any clinician who uses growth hormone must be made aware of the gruesome possibilities and their imponderable probabilities." But while the scientific steering committee overseeing the manufacture of the hormone were told, the clinicians' committee was "deliberately kept in the dark," the judge said. Charles Brook, professor of paediatric endocrinology at University College London Hospitals and Great Ormond Street Children's Hospital and a member of the clinicians' committee, gave evidence that he had never seen the letters from Dr Dickinson and the two virologists before the trial and he was "appalled" by them.—CLARE DYER, *legal correspondent, BMJ*



EMPICS/GRAHAM CHADWICK

GRO-A *in late 1992. His family is in line for compensation following his death from CJD*

Court action over smoking report

The Tobacco Institute of Australia and two cigarette companies are taking the country's main health advisory body to court over its draft report on the effects of passive smoking.

The institute, Philip Morris, and Rothmans allege that the National Health and Medical Research Council was in breach of its statutory duties by ignoring evidence that passive smoking was not harmful.

Mr Brendan Brady, the chief executive officer of the institute, said that the council's working party had failed to consider all the relevant material as its terms of reference and the law requires. "It is my view that in this report the council has selectively chosen certain studies to support a politically correct antismoking agenda," he said. A spokesperson for the council confirmed that the legal action was going ahead but said that the report in question was still only at a draft stage.

The report, which was released last November for public comment, suggested restricting smoking in public places such as prisons and child care facilities.

At the time of the report's release the chairman of the working party, Professor Alistair Woodward, said there was persuasive evidence that passive smoking caused health problems, especially to children. "In our estimates of health risks, the working party has taken a great deal of care to include only that evidence which has been through a process of peer review in the scientific literature," he said.

The Tobacco Institute claims, however, that the council did not consider all the relevant scientific studies, including some that said that the link between passive smoking and adverse health effects was weak and inconclusive. Mr Brady said that the institute had only begun legal action after the council refused repeated requests to redraft its report to take all the material into consideration. The legal action is not expected to reach court for some weeks and is seen as a delaying tactic by the tobacco lobby.—CHRISTOPHER ZINN, *Australian correspondent, Guardian*

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Fast track scheme for medical negligence starts

A fast track scheme for handling medical negligence claims under £10 000 ($15 000) quickly, efficiently, and cheaply is to be piloted at Birmingham county court from 1 October.

The scheme, the first of its kind in Britain, is backed by local NHS trusts and health authorities and could provide a blueprint for dealing with such cases nationwide.

A local initiative by solicitors, judges, and an NHS risk manager, it has the support of the Lord Chancellor's department and will be monitored by a researcher at Nottingham Law School. The results of the pilot scheme will be compared with data from another court where cases are dealt with in the traditional way. One law firm, the Lewington Partnership, which acts for more than 90 trusts and health authorities, estimates that the scheme will cover more than 50% of its caseload.

Moves to speed up and simplify medical litigation are expected to follow the publication next week of Lord Woolf's final proposals for reforming the civil justice system. Fast tracking of claims under £10 000 is one of the key planks of his recommendations for reducing costs, delays, and uncertainty in the litigation process.

Like Lord Woolf's proposals, the Birmingham scheme obliges lawyers to adhere to a strict timetable for each stage of litigation. Instead of costs at an hourly rate, the losing side will have to pay only a fixed amount towards the other side's costs, depending on the stage at which the case is resolved.

This will enable NHS trusts to know exactly what it will cost them to settle a case at a particular stage or fight it through to a trial. If a trust settles at the earliest stage after examining the evidence provided by the patient's lawyers, costs will be £2000, plus £350 for each expert's report after the first.

Fixed costs will also mean more certainty for patients and more chance of pursuing a claim on a "no win, no fee" basis with insurance against the risk of loss. Under the rules, the trust's lawyers will provide the patient's medical notes in answer to a completed request form from the patient's solicitors. Before issuing proceedings, the patient will supply the trust with a "mini-trial" bundle, a package of documents including a chronology of events and the core evidence relied on—information provided usually only much later in the proceedings. Within two months the trust will notify the patient's lawyers whether it is willing to admit any part of the claim.

Cases that are not settled will go to trial around 12 months after proceedings are started, compared with a typical 24 months under the standard procedure. Costs recoverable from the losing side if the case goes to trial will be limited to a maximum of £3250 plus value added tax.—CLARE DYER, *legal correspondent, BMJ*

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