Scientists beg EU to repeal new rules for clinical trials

Thousands of academics and scientists across Europe are appealing to the European Union to repeal new legislation that they fear could seriously damage the prospects of non-commercial, academically led, patient focused clinical research.

Opponents of the new rules, which are due to come into effect on 1 May, are mounting a last ditch campaign. In the space of just two weeks they have collected signatures from over 2000 medical researchers, including some 150 professors of medicine and science, across Europe and further afield.

Their criticism is directed at the description of "sponsor" in the European Union's good clinical practice legislation. In future, any individual or organisation in this position would have to take full legal and financial responsibility for the clinical trial. The scientists point out that, although the pharmaceutical industry can provide this level of funding, charities and academic institutions cannot.

Rory Watson *Brussels*

See www.saveeuropeanresearch.org for details of the petition.

Doctor accused of misrepresenting evidence in child abuse cases

A Scottish chemical pathologist is facing charges before the General Medical Council of misrepresenting medical evidence as an expert defence witness in child abuse cases. Dr Colin Paterson frequently testified that seemingly non-accidental injuries were actually caused by temporary brittle bone disease—a condition that he himself first described and whose existence is disputed by many experts. Sixty to 70 children have been returned to their parents in cases where he testified.

Dr Betty Spivack, an American expert in the biomechanics of abusive child injury, giving evidence to the GMC via a video link, said that temporary brittle bone disease was not "a recognised disease" or "generally accepted condition." "I wish he would come up with the evidence to convince people like me who think that it is a lot of rubbish," she said. "He does not have the experience and training in this field."

On three occasions, British judges criticised Dr Paterson's evidence. On the last of these occasions, in the High Court care case in March 2001 of a young girl referred to only as X, Mr Justice Singer accused him of "tunnel vision," saying his evidence was "woeful."

The case began in November (*BMJ* 2003;327:1124) but was adjourned. It is expected to finish next week.

Owen Dyer *London*

Suspended consultant is reinstated

A consultant gynaecologist whose in vitro fertilisation unit was closed and who was suspended from her job after an embryo mix-up is to go back to work next week.

Geeta Nargund has been reinstated as a consultant in reproductive medicine at St George's Healthcare NHS Trust in south London.

Mrs Nargund was medical director of the Diana Princess of Wales Centre for Reproductive Medicine at St George's until October 2002, when she was suspended on full pay and the unit was closed. The closure followed a three way mix-up in April 2002, when the embryos of one woman were implanted in another, and hers in turn were implanted in a third woman (*BMJ* 2003;326:12).

The error, made by a doctor and an embryologist, happened when Mrs Nargund was away from the unit. It was discovered within 24 hours, and the embryos were flushed out.

Mrs Nargund launched an employment tribunal claim against the trust. The claim, which was due to be heard next month, was withdrawn as part of the settlement.

Clare Dyer *legal correspondent, BMJ*

Whistleblower vows to fight on

Clare Dyer *legal correspondent, BMJ*

A Canadian haematologist at the centre of a cause célèbre over academic freedom and research funded by a drug company vowed this week to continue her crusade after failing in her attempt to challenge the European marketing authorisation granted for the thalassaemia drug deferiprone.

Nancy Olivieri, professor of paediatrics and medicine at the University of Toronto, asked the European court of justice in Luxembourg to suspend the authorisation granted by the committee for proprietary and medicinal products (CPMP), the drug licensing body for the European Union.

Dr Olivieri, a specialist in thalassaemia, had been conducting trials on the drug in young patients when she broke a confidentiality agreement with Apotex, the Toronto based pharmaceutical company that owns the commercial rights to the drug. She went public with her belief that it was insufficiently effective and could cause liver damage in some patients.

In 1999 she launched proceedings to try to get the European marketing halted, but last month the court ruled she had no standing to challenge it and rejected her claim as inadmissible.

"The court did not proceed to an adjudication of any merits of the case but noted only that it finds that I lack sufficient 'interest'—legally speaking—to challenge the completeness of the company's submission, or the correctness of any scientific assessment submitted by the CPMP," said Dr Olivieri.

"This ruling guarantees that only a drug company attempting to sell a drug will control the content of the scientific data submitted or not submitted to the European CPMP," she said. "It no longer matters whether drug companies tell the truth, the whole truth and nothing but the truth, because it's unchallengeable now."

Apotex removed her from the trials, and she was sacked from her job at the Hospital for Sick Children in Toronto, an appointment she held jointly with her academic post at the university. She was eventually reinstated at the hospital, but with a five year leave of absence.

TIBOR KOLLEY/THE GLOBE AND MAIL

Nancy Olivieri may appeal

Neither the hospital nor the university backed her in the dispute, but in 2001 a report into the affair, commissioned by the Canadian Association of University Teachers, concluded that her academic freedom was violated when the company stopped the trials and threatened legal action if she made her concerns public (*BMJ* 2001;323:1085; *BMJ* 1999; 318:77, *BMJ* 1999;318:351).

Dr Olivieri said she was considering an appeal against the European court ruling. She has also launched a campaign against proposed changes to Canadian drug regulation laws, which she says will weaken the protections that Canadians now enjoy.

She is asking colleagues to sign an open letter urging the new Canadian prime minister, Paul Martin, to shelve plans for sweeping changes to regulatory laws. She argues that the changes would shift the existing burden of proof from the drug industry having to prove that products are safe to a presumption that they are safe unless harm has been proved.

Deferiprone is on the market in 29 countries, but not so far in the United States or Canada. It is marketed in the United Kingdom as Ferriprox. Fernando Tricta, medical director of Apotex, said: "The [European] court's decision is a major victory for the treatment of thalassaemia patients." □

More information about the open letter to Paul Martin is accessible at www.hemoglobal.org