

Judge dismisses test case on third generation pill

Clare Dyer *legal correspondent, BMJ*

Third generation contraceptive pills, whose sales plummeted after the 1995 "pill scare," carry no higher risks of venous thromboembolism than second generation pills, a high court judge ruled this week.

Mr Justice Mackay made his ruling in a group action by 99 women against three manufacturers of third generation oral contraceptives—Schering Health Care, Organon Laboratories, and John Wyeth and Brother. The women, who had strokes, pulmonary embolisms, and deep vein thromboses, argued that the newer pills were defective products as defined by the Consumer Protection Act.

The judge described the 42 days of expert evidence as

"almost certainly the most exhaustive examination that this question has yet received." The judgment is unlikely to resolve the controversy, which has raged since the United Kingdom's Committee on Safety of Medicines issued its warning in October 1995. The warning letter followed three epidemiological studies showing that the newer pills were associated with a twofold increase in the risk of venous thromboembolism compared with the older products.

Mr Justice Mackay halted the trial at the end of May, with eight weeks still to go. Both sides had agreed that the case would fail unless the women could prove a more than twofold risk for the newer products compared with

the older ones, and the judge decided to resolve that issue first.

After reviewing all the studies, with the help of 10 expert witnesses, the judge decided that the "most compelling evidence" in the case was the Cox regression analysis carried out by Kenneth MacRae and Michael Lewis on the data from the study by the Transnational Research Group on Oral Contraceptives (*Human Reproduction* 1999;14:1493-9.)

The original transnational study, by Walter Spitzer and colleagues and published in the *BMJ* in 1996 (1996;312:83-8), found a relative risk of about 1.7. The 1999 paper in *Human Reproduction* included full lifetime oral contraceptive exposure for over 90% of the subjects and found no association between third generation pills and any increased risk of venous thromboembolism.

"Based on that evidence, I find that there is not as a matter

of probability any increased relative risk of VTE [venous thromboembolism] carried by any of the third generation oral contraceptives supplied to these claimants by the defendants as compared with second generation products containing levonorgestrel," said the judge. If he had had to decide the case without the Cox regression analysis, he said, he would still not be satisfied that the relative risk was more than 2. The most likely figure was around 1.7.

The claimants' solicitor, Martyn Day, said that he was "astonished" that the judge had come to the conclusion that there was no increased risk. The legal team would be considering an appeal, but "the court of appeal has shown itself to be very unenthusiastic about appeals in these sorts of actions following a lengthy trial." □

The judgment is accessible at www.courtservice.gov.uk

Fertility watchdog says that donor identity should be revealed

Clare Dyer *legal correspondent, BMJ*

Sperm and egg donors in the United Kingdom should lose their right to anonymity, the Human Fertilisation and Embryology Authority has recommended in its response to a Department of Health consultation paper canvassing views on a possible change in the law.

The fertility watchdog's call for a reversal of government policy will dismay many infertility specialists who fear it would cause the supply of donors to dry up.

It coincided with a landmark ruling last week from the High Court in London, which opened the way for people born as a result of donor insemination to seek more information about their donors. Mr Justice Scott Baker ruled that article 8 of the European convention on human rights, the right to respect for private and family life, covers those conceived by artificial insemination by donor (AID).

The case was brought by Joanna Rose, aged 30, a post-graduate student from Brisbane, Australia, who was conceived in a private clinic in London, and an

unnamed 6 year old girl from York, known as EM. Neither is asking for the identity of her donor to be revealed. EM, through her parents, wants more non-identifying information about her donor to provide her with a pen-portrait of him.

Ms Rose wants the Department of Health and the fertilisation authority to take steps to preserve information on donors before 1991, when the authority came into being. She is also seeking the establishment of a voluntary contact register to which donors willing to be traced can sign up.

The judge said that article 8 of the convention incorporated the concept of personal identity, which included a person's origins and the opportunity to understand them. It was entirely understandable that children conceived by artificial insemination by donor should wish to know about their origins. □

The Human Fertilisation and Embryology Authority's response on donor information can be found on its website (www.hfea.gov.uk).



New surgery opens for asylum seekers

The Sanctuary, a GP surgery that caters exclusively for refugees and asylum seekers, opened at the John Scott Health Centre in the London Borough of Hackney last week.

The practice is the first of its kind in London and was set up by Hackney Primary Care Trust to cater for the growing population of refugees and asylum seekers in the Finsbury Park area of Hackney.

Most of the practice's patients will come from the nearby Pembury Hotel, run by the United Kingdom's Refugee Council, where up to 250 refugees and asylum seekers live.

Dr Angela Burnett, lead GP at the practice (pictured above, right, with Muhammed and Waheeda Lal from Afghanistan), has worked for seven years with the Medical Foundation for the Care of Victims of Torture and also works for Amnesty International. She said: "One of the difficulties is that our patients are not able to settle in one place when they arrive, and it is hard for primary care centres to look after them."

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