Legal action against the manufacturers of third-generation pills fails in the UK

An action against the manufacturers of combined oral contraceptives (COCs) containing third-generation progestogens began in 1997 and was heard in court between March and July 2002. The lawyers representing the former users of these contraceptive pills had to show beyond reasonable doubt that the third-generation pills were defective (i.e. not as safe as the women were entitled to expect) and that they caused the injuries sustained by the women. On 29 July 2002, the judge gave his judgement that he accepted the defence case that the evidence did not establish reliably that there was an excess risk from the third-generation pills compared to second-generation pills. The judge also concluded that none of the claimants were able to demonstrate that their venous thromboembolism (VTE) was more likely than not to have been caused by the third-generation contraceptive pill. The claimants had to show that the third-generation pills were twice as likely to have caused the VTE than a second-generation pill containing levonorgestrel and this they had failed to do.

Although the judge expressed the view that this trial was ‘the most exhaustive examination this question has ever received’, this can only be said to be true in the legal sense.

Most readers of this journal will remember the intense and sometimes acrimonious public and private discussions following the publication of the four epidemiological studies in 1995 and 1996 showing a difference in the incidence of venous thrombosis between second- and third-generation pills. Notwithstanding, the number of events was small compared to the number of users. However, the conclusion from these studies that third-generation pills carried twice the risk of the second-generation pills led to the Committee for Safety of Medicines (CSM) in the UK issuing a warning to prescribers. The advice was to only use third-generation pills if the user was intolerant of second-generation pills. Following reanalysis of the original data obtained in the epidemiological studies, the estimated risk of VTE was revised downwards, while controversy continued about bias and statistical manipulation.

By 2001, the regulatory authorities in the UK and in Europe had concluded that degree of difference in risk between second- and third-generation pills was of the order of 1.5 to 2. The information that is given to patients quantifies the risk of VTE as:

- about five cases per 100 000 women per year when not taking any hormonal contraception
- about 15 cases per 100 000 women per year when taking second-generation COCs
- about 25 cases per 100 000 women per year taking third-generation COCs.

The legal decision does not affect this advice which should be put into proportion by considering the risk of VTE in pregnancy (about 60 per 100 000 women per year).

While welcoming the news that the class action against the manufacturers of the third-generation COCs has failed, the legal decision does little to help practising clinicians in their everyday work with patients. Scientific evidence, argued over by many experts in journals, seems a better guide than a decision based on a single legal judgement. For the majority of patients with no added personal risk factors, the differences between the small risks of VTE associated with the use of a second- or third-generation progestogen will matter less than the acceptability of their chosen pill. Discussion of the risks and benefits with patients, in language that they can understand, will be the best protection against further legal actions.

Source: Report and comment by Dr Gill Wailke, Writer and Lecturer, General Practitioner Non-MRCOG, Consultant in Community Gynaecology, Family Planning Services, Edinburgh, UK