

Whipping up panic about the Pill

The British Committee on the Safety of Medicines seems to have acted with needless haste by warning women against forms of contraceptive pills whose risks may not be all that great.

LAST week was a week of high drama on the contraceptive front in Britain. Last Wednesday (18 October), the Department of Health sent a letter to all physicians in general practice, telling them that specified brands of contraceptive pills carry a risk of thrombosis that is twice as high as that caused by earlier contraceptive pills. Some doctors received this letter, and one of them, married to a journalist, told her husband, who promptly made a story of it. Other physicians had to wait longer for word of what the scare was about. Pill-using women, on the other hand, did not wait to besiege their physicians by telephone and otherwise. Then the general confusion was made worse by the arrival in person of Professor Walter Spitzer, of McGill University and the Potsdam Institute in Berlin, which appears to be in the business of designing and conducting large epidemiological studies. Spitzer, whose study of 6,000 women over five years had been cited by the British government, denounced both the Department of Health and its advisory body, the Committee on the Safety of Medicines (CSM) for hasty and premature action, causing an "epidemic of anxiety". All this came out at a press conference hastily arranged at London Airport.

The circumstances are more than a little odd. The forms of contraceptive pills now under a cloud contain synthetic analogues of female hormones that are more effective (gram for gram) than the constituents of earlier contraceptive pills. That was chiefly the reason why they were supposed to be less likely to cause thrombosis in those taking them over long periods. But since 1989 there have been reports from Germany that even the low-dose pill entailed the risk of thrombosis among those who used it. That, no doubt, is part of the reason why Schering commissioned Spitzer's five-year study.

To be fair, the CSM had other reasons to be concerned. In July, the World Health Organization produced preliminary results of an inquiry in 17 countries suggesting a link between the new pills and venous thrombosis. There is also an international study of doctors' records based on Boston University, while the CSM also says it had access to a "final" version of Spitzer's data. (Spitzer says that, nevertheless, it should have waited at least until the data had been submitted for publication and, in the process, peer reviewed.) All three studies, the CSM says, pointed in the same direction, that the risk of venous thrombosis with the new pill is roughly twice that with the now-safer ver-

sions of the old, and is roughly six times greater than the risk in women who take no pills at all. So, the CSM says, it had a moral duty to recommend quick action.

Really? The absolute numbers are as important as the relative risks. In Britain, roughly 25 per cent of women between the ages of 16 and 49 use contraceptive pills, perhaps half of them the newer versions, implying for a population of 58 million that there would be 1.5 million women at risk. If, as quoted, the risk of thrombosis with the new pills is less than one in 200,000 per year, the incidence of thrombosis would be of the order of one every 50 days among women taking the new pills. Granted that the CSM must be alert to the dangers in the use of the medicines licensed on its recommendations, the numbers hardly justify the haste with which the CSM appears to have made its recommendations on this occasion. Even pregnancy is not risk-free, after all.

The lessons to be learned from this curious tale are complicated, but are likely to be more than ever needed in the years ahead. Sudden announcements that widely used medicines have unexpected side-effects are almost always likely to cause panic, as on this occasion. The urgency with which bad news is made public must be commensurate with the absolute, not the relative, risk, uncertain though both may be. In this case, it would have been acceptable to let Spitzer's paper embark on the process of peer review. It might even have been found that the increased risk of thrombosis is offset by a decreased risk of other conditions — the 'old' pill is, for example, now known to protect against ovarian cancer. Who (except Spitzer) can know at this stage whether the new pills offer protection of a similar kind?

What this implies is that the CSM should have waited with its recommendation. A few weeks either way would have made no significant difference. That way, it would even have been able to devise some means of making the health department's blunt announcement intelligible to those affected. It is an assault on the supposed rationality of the communication between the regulators of social practices and their practitioners that the regulators should issue warnings without what is called, in the trade, counselling. And, whatever may be thought of the motives of the pharmaceutical companies, it is crass to take them by surprise when they are best equipped to put out health warnings to their ultimate customers and those people's physicians. □