

# The Dalkon Shield saga

Twenty-five years ago, in 1977, the Family Planning Research Unit of the University of Exeter issued its sixth and final report on the ill-fated Dalkon Shield.<sup>1</sup> Should it have been the last word on this topic? Maybe, but it certainly was not!

On 24 February 1984, the Chief Justice for Minnesota arraigned the officers of AH Robins, manufacturers of the Shield: 'You have planted in the bodies of these women instruments of death, of mutilation, of disease ... a deadly depth charge in their wombs, ready to explode at any time'.<sup>2</sup> In 1986, the solicitor to the West Midlands Regional Health Authority, claiming that 1200 women in his Region had been injured by the Shield, quoted the Minnesota judge and thus strongly implied that doctors in the West Midlands had also been planting 'depth charges'! He followed this up by demanding that every family planning doctor in the Region should explain why they had been fitting Shields.<sup>3</sup> The mountain of litigation, mostly in the USA, destroyed AH Robins.

The Shield had made a good start. In 1970 the inventor Hugh Davis, reporting 640 insertions, subtitled his paper 'A superior modern contraceptive'.<sup>4</sup> A much fuller account was given in his 1971 book.<sup>5</sup> However, in June 1974, AH Robins suspended sales because there had been cases of septic mid-trimester abortion in the USA in wearers of the Shield, some of which had been fatal.<sup>6</sup> A few months later, in October 1974, a subcommittee of the Obstetrics and Gynaecology Advisory Committee of the Food and Drugs Administration (FDA) in the USA concluded that the safety and efficacy of the Shield was 'not significantly different from other IUDs' and recommended the ban be lifted. It was not lifted. Suggestions had been made that the multifilament tail of the Shield facilitated ascending infection. Initially AH Robins intended to introduce a modified version but never did so. In 1980, AH Robins and the International Planned Parenthood Federation (IPPF) recommended that women still wearing Shields should have them removed. A case-controlled study in the USA in 1983<sup>7</sup> concluded that Dalkon Shield users were five times as likely to get a pelvic inflammatory disease (PID) as compared to users of other devices.

So what about the UK experience as documented by the Family Planning Research Unit? The Unit was keeping records of every intrauterine device (IUD) fitting in 20 centres. Their first report<sup>8</sup> in 1972 recorded 1031 Shield fittings with no mention of infection. The fifth report, in 1974,<sup>9</sup> reported 368 pregnancies occurring in IUD wearers. Among 4191 Dalkon Shield users there were 173 pregnancies with two septic abortions. One was in a woman sleeping rough who had gonorrhoea prior to the abortion. The other occurred at 19 weeks; the woman's physician stated that 'some inducement appears likely'. Both women recovered. In neither case was the Shield thought to be responsible for the sepsis. The sixth report in November

1977<sup>1</sup> stated that the Research Unit had collected the records of 40 000 IUD fittings which included 7282 Dalkon Shields of which 2412 had been in Dublin. When pregnancy occurred the spontaneous abortion rate, at 39%, was highest in Shield users. Septic abortion was rare, there being only two cases in 100 spontaneous abortions. The PID rates were as follows: the Shield 1:128, the Gravigard 1:116, the Lippes Loop D 1:297 and the Saf-T-Coil 1:253. With regard to perforations the Shield had the lowest frequency. The report implied that the problems occurring in the USA might have been partly due to illegal abortion procedures. In 1984<sup>10</sup> a detailed analysis of 13 349 IUD users in the UK and Ireland of four different devices concluded: 'reports that the Dalkon Shield was uniquely related to high levels of infection when compared to other intrauterine devices were not substantiated'.

Thus, it is clear that the UK and Dublin experience failed to confirm the USA experience. The problems in the USA resulted, on that side of the Atlantic, in an aversion to the IUD method on the part of doctors and the public, an aversion which is only now beginning to dissipate.<sup>11</sup>

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