

This turns on the fact that doctors are required to record "abortion" as the reason for absence when completing certificates of temporary incapacity for work.

Societal attitudes

Naturally, it is possible to beat the system and, according to the article in *Working Woman*, a bribe of 30 roubles will do the trick as well as ensuring a degree of comfort and considerate treatment. Specifically in the case of women doctors, professional solidarity can guarantee that no record of the operation will exist.³ Generally, however, the health service takes no account of a woman's need for a protective cloak of anonymity. That is all the more necessary on account of the strongly negative attitudes that premarital and extramarital pregnancies continue to evoke in a society that frequently demonstrates a high degree of social conservatism.

Given the prevalence of social and parental disapproval, it is to say the least an unfortunate rule that a girl under the age of 18 who is seeking a legal abortion has to be accompanied by her mother. This requirement is referred to in a novel by the Moscow surgeon Yuli Krel'in and, although I can not corroborate it, I consider that its existence in reality is essential to the credibility of one episode.

Krel'in's quasibiographical hero, though after much persuasion, agrees to perform a criminal abortion on a schoolgirl of 17 who has protested that "they will simply kill me at home." He recounts to his friends how, in a country area some years before, a similar girl had threatened to hang herself rather than face her parents. He had said "go back to your parents and confess." Half an hour later they discovered her dead body.⁴

Consideration of both legal and illegal abortions in a wider perspective is bound to entail large questions about the failure of the Soviet state to ensure the provision of adequate sex education, family planning advice, and the supply of user acceptable and effective contraceptive methods. The deficiencies that lie within the remit of the health service must be accounted all the more

remarkable because a concern with prophylaxis ranks high among asserted principles of Soviet medical practice.

While Soviet specialists do not draw attention to a fundamental contradiction in this connection, it seems possible that they have hopes of influencing the policy makers in favour of measures to raise the level of public awareness about contraception. Certainly some have gone as far as to advocate the supply of contraceptives without charge or at a reduced cost.

Lives to be saved

The specialists would be aware of the findings that knowledge of the possibility and means of preventing unwanted pregnancies is positively correlated with a woman's age, level of education, duration of marriage, and the number of abortions that she has had. They would also know that the reported failure to use contraceptives rose to 80% among women who had illegal abortions.²

Given the existence of Mikhail Gorbachov's policy of *glasnost* (openness, open reporting), the ordinary citizen is also becoming better informed about the dimensions of a major social problem that has been largely obscured or concealed by deep rooted prudery. Whatever the validity of that conjecture, readers of *Working Woman* could hardly have missed the chilling statement that 30% of illegal abortions end in a woman's death.

I thank Ms Barbara Holland for the reference from *Rabotnitsa*.

References

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Medicolegal

The penalties of issuing misleading advertisements

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Roussel Laboratories is appealing against its conviction by a jury at the Old Bailey on 19 December on charges of issuing a misleading advertisement, and the appeal is likely to be heard in June or July. Also appealing is the company's medical director, Dr Christopher Good, found guilty of consenting and conniving at the issue of the advertisement. The advertisement was for the non-steroidal anti-inflammatory drug Surgam (tiaprofenic acid), which appeared five times in the *BMJ* between March and June 1983.

The prosecution, brought by the Department of Health and

Social Security under the Medicines Act 1968, is the first against a major drug company in the 14 years that the advertising provisions of the act have been in force. Only four previous prosecutions have been brought for breaches of the advertising provisions of the Medicines Act, all against individuals making false claims for products promoted on a small scale.

Roussel, a subsidiary of Hoechst, was accused of issuing an advertisement which was misleading because claims for "gastric protection and selective prostaglandin inhibition were not justified or substantiated by clinical or other appropriate studies." Part way through the trial the company and Dr Good were cleared of further charges that claims in the advertisement that Surgam was safer and had a smaller incidence of side effects than the most common non-steroidal anti-inflammatory drug, indomethacin, had been made "in the absence of available evidence." Having found that there was "a preponderance of available evidence, particularly clinical trials, that accurately reflects the claim that Surgam was safer, had fewer

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and less incidence of side effects than indomethacin," Judge Capstick directed the jury to return not guilty verdicts on these charges.

Evidence on gastric protection

Of the remaining 10 charges—one against the company and one against Dr Good for each of five publications of the advertisement between March and June 1983—the jury found Roussel and Dr Good not guilty on counts one and two, which related to the first publication of the advertisement on 26 March, but guilty as far as subsequent publications were concerned. (Company memos dated just before the first advertisement show that doubts were surfacing about the strength of the evidence on which the claims were based, but by then it would have been too late to halt publication of the first advertisement.)

Accepting that no harm had been done to the public—counsel for the DHSS emphasised that Surgam was considered a useful non-steroidal anti-inflammatory drug and that its safety was not in question—the judge nevertheless said he did not regard the offences as trivial and fined the company £20 000 and Dr Good £1000. Roussel has also been ordered to pay £93 000 against prosecution costs of £123 000. But because the company was acquitted on 12 of the 20 charges the judge awarded Roussel £70 000 of its £137 000 costs from public funds.

Though all non-steroidal anti-inflammatory drugs are prone to cause gastrointestinal disturbances, the Surgam advertisement promised in prominent letters "tolerance in the stomach." The small print mentioned active peptic ulceration as a contraindication, cautioned care in patients with a history of peptic ulceration, and included gastrointestinal upset as an occasional side effect. Nevertheless, the body of the advertisement stated in much larger letters: "Surgam compared with indomethacin has a selective effect on prostaglandin biosynthesis. Surgam is highly potent in inhibiting prostaglandins (PGE_2 and $\text{PGF}_2\alpha$) involved in causing pain and inflammation, but has far less effect on prostacyclin (PGI_2), the prostaglandin that protects the gastric mucosa." This selective prostaglandin inhibition was a hypothesis that the company developed based on experimental results from two studies on animal tissues.

In summarising the evidence the judge instructed the jury that the first issue was whether there was a claim (which the company disputed) that Surgam provided gastric protection. There was no dispute that the advertisement made a claim for selective prostaglandin inhibition, but the defence argued that this was not caught by section 93 (7) of the Medicines Act, which says: "For the purposes of this section an advertisement shall be taken to be false or misleading if, but only if . . . it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses of effects. . . ." The jury had to decide whether selective prostaglandin inhibition was a quality, use, or effect of Surgam and, if satisfied, go on to consider whether the claim was substantiated by clinical or other appropriate trials.

Alternative sanctions

Why has the DHSS, which until now has been content to allow the industry to police itself through the code of practice committee of the Association of the British Pharmaceutical Industry (ABPI), decided to prosecute in this case? Perhaps the department has taken to heart the lessons learned from the saga of benoxaprofen (Opren), another non-steroidal anti-inflammatory drug, now withdrawn from the market and the subject of mass litigation over alleged side effects.

Claims made in the advertisements for Opren implied, without any real evidence for doing so, that data from animal studies could be extrapolated to man. Advertisements for the drug, launched in Britain in 1980, used data from rat studies with wording which suggested that the drug could not just relieve the symptoms of arthritis but could modify the disease process. The DHSS took no action. The ABPI, acting on complaints received, found Dista

guilty of a breach of the code of practice, and extracted a promise not to repeat the claims. At that time, however, the findings of the code of practice committee were not published, so doctors were not alerted to the fact that advertisements had been found to be misleading. (Since 1984 findings have been sent to the *BMJ* and to the *Pharmaceutical Journal*.) The procedure took a year, by which time the advertising campaign had got its message across. The failure of the DHSS to act was criticised on a BBC TV *Panorama Special* and in parliamentary debates in January 1983.

Criminal proceedings are, of course, a much lengthier, more expensive, and more cumbersome means of controlling misleading advertising, but the deterrent effect is much more powerful. It must also be questionable how far a jury of ordinary citizens is competent to weigh up complex pharmacological evidence and to decide whether an advertisement aimed at doctors is misleading. In the US several prosecutions were brought over misleading advertisements in the late 1960s, but since then there has been a shift away from using the courts in these cases and a move towards sanctions which act quickly to correct misinformation before the advertising campaign has run its course and the company reaped the benefits. (Food and Drug Administration powers to seize products for which unsubstantiated claims have been made have also fallen into disuse, since the seizure of drugs wrongly raised public fears about their safety.)

The commonest sanctions in the United States, "Dear Doctor" letters and remedial advertisements, are just as public and painful as prosecutions. The company is made to write to every doctor pointing out the particulars in which promotional claims were misleading or to insert in a later issue of a journal in which a misleading advertisement appeared another of the same size and eye appeal correcting the previous claims. The content of the letters and advertisements are negotiated between the Food and Drug Administration and the company, with the backstop of prosecution if the company refuses to comply.

In Britain the Medicines Act contains powers to make regulations prohibiting the advertising of particular products altogether or advertisements containing a specific word or phrase that is likely to mislead, but these have never been used to ban a particular advertisement. Regulations implementing the European Community's Misleading Advertising Directive, which will apply to advertisements generally and not just pharmaceutical advertisements, are expected to be laid by 1 May. These will give the Director General of Fair Trading backstop powers to apply to the High Court for an injunction to stop further appearances of a misleading advertisement.

**For many years the *BMJ* scrutinised all pharmaceutical advertisements and developed its own code of practice, the most important element of which was our insistence that statements of fact should be supported by trustworthy published evidence. When the Medicines Commission took on its own statutory duties we amended the code so that we allowed in advertisements any statements which appeared in the data sheet approved by the commission. For practical reasons our scrutiny has always been selective, but we nevertheless continue to challenge and on occasions refuse advertisements which do not conform to our standards.—ED, *BMJ*.

Is aspirin a safe prophylactic against migraine headaches?

The short answer is No. Aspirin is not an effective drug for migraine prophylaxis. A few years ago when the possibility of prostaglandins being involved in the aetiology of migraine was being discussed I "collected" three patients who suffered from rheumatoid arthritis and had classic and common migraine despite taking aspirin 300 mg four times a day over long periods. When you add the definite risk of gastric upsets in prolonged use of aspirin its application in the management of migraine is contraindicated.—K J ZILKHA, consultant neurologist, London.