properties in rheumatoid arthritis. It is possible that these agents really were lethal, but we find it difficult to believe that they were more dangerous than the agents we presently use. The adverse effects from gold salts and penicillamine are maintained at an acceptable level only by careful monitoring of patients during treatment. If these drugs were used in uncontrolled circumstances, as was benoxaprofen, the Committee on Safety of Medicines would genuinely have urgent need to withdraw the products because of adverse effects.

By taking the safest course the Committee on Safety of Medicines may minimise public criticism but it is denying us safer agents than those we possess at present. Rather than producing a public scare with the ensuing hue and cry it should be advising the profession at an early stage on the monitoring necessary for new agents so as to minimise the side effects. It would thus provide safer benefits from therapeutic research rather than blocking progress altogether as it appears to do now.

The Committee on Safety of Medicines has become a watchdog which attacks friend and foe alike, preventing all callers from reaching the house. Our only recourse is to have it humanely destroyed and replace it with a dog which barks before it bites.

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Benoxaprofen

SIR,—I read your leading article (14 August, p 14) on benoxaprofen with much more than usual interest since this has not been a run-of-the-mill drug scandal. The lay press and one or two MPs have been even more vitriolic than usual, whereas members of the medical profession, including contributors to your columns, have been striving not to pillory the manufacturer, for the first time in my experience.

The yellow card system has served us well over the years but it is extremely sensitive to so many random influences. The "side effects" reported after three papers had appeared in the same issue of the *BMJ* might as well be discounted, including the 3500 side effects and the now infamous 61 deaths. They have as much validity as a public opinion poll relying on self-selected respondents answering leading questions. Benoxaprofen probably did contribute to some of those deaths—but how many? If it was only three, as it might have been, would we have worried at all?

More importantly, Sir, I take issue with you when you recommend "a cautious approach to the drug," whatever that means. Consider a singlehanded GP with 20 patients with joint disease needing anti-inflammatory drugs. How does he manage the cautious approach? Pick one or two at random, choose the worst, or the youngest, or, indeed, the most moribund? If, like you, he had become convinced that the drug had a useful and interesting profile of activity, a convenient regimen, and a lower incidence of the usual gastrointestinal side effects he would surely be tempted to try it in all his patients who were not doing well on their current drug.

Leaving aside for a moment the use of radio, television, and the lay press in the introduction of new prescription drugs (which I do not condone), would your cautious approach have helped? "Explosive" marketing brings a very large number of disparate patients into the net for the first time, including those with clinical "warts." Phase III trials always, and phase IV usually, exclude the under 16s, the over 65s, those taking other drugs, those with any other important illness, plus a host of specific exclusions—a patient has to be pretty fit to take part in a trial. Dr Inman's post-marketing surveillance foundered, if it did, on the age-old problem of poor record-keeping by family doctors, especially in those patients too housebound to get to the surgery whom they generously saw on a regular basis at home.

I submit that the way the hazards of benoxaprofen came to light is peculiarly British and probably as good a way as any: it depended on clinical acumen. That "explosive" marketing, far from contributing to the potential hazard, may actually have sensitised more doctors to the drug and thus shortened the time to indictment of an unusual risk, which, in turn, has led to a reduction in the time any individual patient on the drug has been exposed unknowingly to that risk.

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SIR,—In your leading article (14 August, p 459) you state: "As a general principle clinicians should be slow to use new drugs when others are available with a longer cumulative weight of clinical experience to back them." The question then occurs: once a drug is released having passed the currently approved tests, how is the medical profession to obtain cumulative experience of the new drug other than by its being prescribed fairly widely and frequently? This is a modern doctor's dilemma. If a new drug is really effective it will be widely and frequently used. If this drug also has latent side effects they will frequently come to light.

GEOFFREY HORTON

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SIR,—The letter from the Committee on Safety of Medicines notifying GPs of the suspension of the drug licence for benoxaprofen (14 August, p 519) was dated 3 August but not received until 11 August. (Rival drug companies got their circulars to us before this.) The Chairman particularly regretted "that you will probably have heard of the Licencing Authorities' decision before this letter reaches you, because of the need to take urgent action on the grounds of safety." For seven days patients were worrying and hastily seeking our advice when we had little more to go on than what we ourselves had gleaned from the lay press. The media were scaremongering as usual and giving inaccurate, misleading information.

Was it really necessary to axe benoxaprofen in this manner? What difference would a few more days have made? Perhaps a statistician would write and tell us the incidence of adverse reactions and deaths during those few extra days compared with the risk of injuries (and even death) from road traffic accidents in the same group of patients hurrying to the doctor's surgery for advice to allay their worries.

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SIR,—In common with many members of the medical profession I heard on television news on the evening of Wednesday 4 August of the Department of Health's decision to suspend the product licence of benoxaprofen. Within 48 hours I had had a mailing from another pharmaceutical company extolling the virtues of their product and suggesting that any patients that were taking benoxaprofen should be taking theirs. This was followed in the next two or three days by two more mailings from various drug houses along the same lines. Eight days after the original announcement was made I finally received a letter from the Committee on Safety of Medicines.

While in no way do I wish to criticise the decision to withdraw benoxaprofen, which presumably was taken on good advice, I feel that the Committee on Safety of Medicines could have been somewhat more speedy in telling us officially of their decision. If the pharmaceutical companies can manage to produce a mailing so quickly after the withdrawal of a drug, presumably with no previous warning, I would have thought that the Committee on Safety of Medicines should not have been so tardy in producing its notification. It reminds me very much of the difficulties that we in practice suffered when high-oestrogen oral contraceptives were withdrawn some 13 years or so ago. I hoped then that such difficulties would not arise again. Obviously I was mistaken.

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SIR,—The sudden banning of benoxaprofen is as disquieting as its dramatic introduction to the drug scene two years ago. The publicity in the lay press at the time impressed our department to obtain its introductory data sheet and there to read with surprise that in its pre-release trials benoxaprofen had already been shown to produce "light sensitivity rashes" in 10% of patients.[1] Our interest was therefore aroused and our report of Stevens-Johnson syndrome[2] was, I believe, the first skin side effect to be reported in Britain.

The Committee on Safety of Medicine's statistics are only as good as the reports it receives and it is probable that the initial publicity given to this drug, which most doctors disliked, created the side effect of making them more than usually keen to report adverse reactions to the Committee on Safety of Medicines. Apart from the unique skin side effects most of benoxaprofen's serious adverse reactions are the same as those of other non-steroidal anti-inflammatory agents. It is therefore likely that the Committee on Safety of Medicines does not have an accurate estimate of these latter for comparison. Gastric haemorrhage and deaths from aspirin scarcely generate enough interest to reach the local paper.

I am not competent to say what place, if any, benoxaprofen has in rheumatology, but its unique skin reactions surely give us a molecule as a research tool to study photo-