ABSTRACT. This UK paper on multiparty litigation looks at the Opren case. This concerned an anti-arthritis drug licensed in the UK between 1980 and 1982. While a number of drug users died, the most common adverse reaction was photosensitivity. The main legal action involved almost 1,500 plaintiffs and seven defendants. In the early summer of 1987 a court ruling on the funding of the action meant that 500 of the plaintiffs might have to withdraw. With the help of a multimillionaire and a media campaign, the parties reached a controversial settlement at the end of 1987. This paper focuses on the plaintiffs’ case, the way the litigation proceeded through the courts and the nature of the settlement. It goes on to assess the problems the case highlighted in court procedures, legal aid and liability for defective drugs.

This paper looks at the Opren case and goes on to try to draw lessons about the way that group actions can be handled in the English courts, how they should be financed and their application to drug disasters. The issues in group claims are not simply a blown-up version of the access to justice issue for they throw up peculiar dilemmas of their own as this paper shows. However group claims inevitably force the interested observer back to basic principles — what is the role of the courts, what is the role of the state as against that of the individual, what is the object of the tort system.

The paper gives a simplistic overview of the Opren case and discusses some of the developments it has pointed to. Any reader interested in the implications of class actions and in the questions they raise about basic principles should read Agent Orange on Trial (Schuck, 1987) which details the six year US class action against the manufacturers of the defoliant used in the Vietnam war. In spite of the lessons that such a detailed study can bring home, no such study is likely to emerge from any UK group case. This is partly because the UK is not as open a society as the US is. There is no freedom of information law in the UK. It is partly because the rules of discovery and on interrogatories in US litigation have fewer restrictions on what information litigants can obtain from one another than the rules in the UK and Europe. And it is partly because the terms of any settlement in a UK group claim are likely to be confidential, as they were in the Opren case.
Opren (or Benoxaprofen) was produced by Eli Lilly, a multi-national drug company. It was an anti-arthritic drug, and as such was intended for a largely elderly market. The drug was licensed in the UK by the Medicines Act Licensing Authority in March 1980, six weeks after a licence had been refused in the USA. It was marketed as “a major significant breakthrough,” a unique new drug which had “mild and transient side effects.” Aggressive promotion included a three day Rhine cruise for leading UK rheumatologists so they could learn the benefits of the drug. Eli Lilly also used “patient pull” — encouraging patients to request the drug — as well as traditional marketing methods to doctors. It has been estimated that Eli Lilly spent several million pounds on promoting the drug, with the initial result that 1.47 million prescriptions were made at a cost to the National Health Service of £13.5 million during its two or so years on the market. It is quite possible that Eli Lilly spent more on marketing the drug than on researching and developing it (Hancher, 1987).

The same data which had helped secure a licence in the UK had failed to persuade the US Food and Drug Administration (FDA). The US authorities were not satisfied about the drug's safety and efficacy, and drew specific attention to photosensitivity as a potential adverse reaction. Two years after the drug had been licensed for the UK market the FDA was still concerned about an animal trial — “the two year rat study does not support the safety of this drug for its chronic use in humans.” In contrast to marketing claims that Opren was a unique new drug, the FDA classified it a C drug — one that offers little or no therapeutic gain over products already on the market.

The UK clinical trials were to be criticised as seriously flawed. Doubts were expressed about the size of the groups (11 of the 14 trials involved less than 40 patients), the duration of the trials (only one lasted more than 3 weeks), and the dosage used (almost half of those in the trials were given dosages less than that which was to be recommended to patients). The Opren victims believed that the tragedy could have been avoided had the drug been tested on elderly people for realistic periods before it was marketed, as opposed to on healthy young volunteers for relatively short periods. Inevitably these facts highlighted the role of the UK’s Medicines Act Licensing Authority and its relationship to the industry.