

A BRIEF HISTORY OF PHARMACEUTICAL GROUP ACTIONS IN ENGLAND AND WALES

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INTRODUCTION

In keeping with the title of my talk, I will endeavour to be brief. However, in outlining some of the key features in the evolution of pharmaceutical group actions in England and Wales over the past 30 years, I will inevitably skip over some of the detail and I apologise in advance for any disappointment that may cause.

THE PRODUCT LIABILITY DIRECTIVE

The 1985 Product Liability Directive harmonised product liability rules across EU Member States. It created a strict liability regime so that individuals who had sustained physical injury or other damage as a result of purchasing goods could obtain compensation from the producers of those products. Strict liability required the consumer of the product to prove that their injury or damage was caused by a defect in the product supplied. The Directive was incorporated into English law on 1 March 1988 - the UK was the first Member State to do so. France was a little later - 10 years later to be precise - with the Directive becoming part of French Law on 19 May 1998.

To set the evolution of the strict liability regime in context I will now give an overview of the landmark cases:-

1 Thalidomide

The tragedy of Thalidomide will be familiar to all. Although developed as a safe and effective treatment for morning sickness, the taking of this tablet led to the birth of 8,-10,000 children in Europe with severe defects.

The litigation centred on a question of negligence rather than one of strict liability. Therefore the injured children and their parents were required to prove that the UK Manufacturer Distillers Company (Biochemicals) Limited had been negligent in the research and development of the product.

A settlement was reached in 1968.

2 Opren

Opren was a non-steroid anti-inflammatory drug with the potential to arrest the progress of arthritis. The threat of a group action in England came about following the voluntary withdrawal of the drug by the manufacturer in August 1982. It is important to note that Opren had an unexceptional adverse event profile, with all necessary information appearing in the supporting product literature.

The Opren group action was the first case when the English Courts used the powers available to them to impose a wide range of orders to govern the running of the group action. These included:

- At an early stage a single Judge was assigned to manage the litigation;
- Master pleadings were produced, incorporating detailed elements of the claim and defence,
- Individual Statements of Claim were prepared for each Claimant.
- A full medical report had to be produced to support every claim.

The first wave of Opren cases were settled in 1987. However, further claims followed which were primarily concerned with limitation because they had been too late to join the original group. The majority of these claims failed with the remaining claims appealing to the English Court of Appeal leading to them being time barred from proceeding in 1992.

In a separate move, the Legal Aid Board (who funded the claims on behalf of the British taxpayer) withdrew all remaining funding for these claims.

From a procedural perspective, the Opren Litigation is the first example of detailed Case Management Directions being imposed by a Judge in pharmaceutical group litigation.

3 The HIV Haemophilia Litigation

This group action was notable for the speed at which it was run. This is because the parties recognised that there was a real urgency to achieving settlement of the claims in view of the serious risk of impending death to the thousand or so Claimants involved. Litigation was commenced by those Haemophiliacs who had contracted the HIV virus and wished to pursue compensation against the various Government Departments and National Health Service Hospitals. Rather than trying these cases on a preliminary issue, the objective was to seek the resolution of generic issues through lead cases.

A number of case management measures were implemented:-

- Instead of binding Court Orders the presiding Judge gave preliminary indications of his views on points which might become the subject of future orders.
- Steering Committees were formed quickly amongst both Claimant and Defendant groups of solicitors in order to ensure that both Claimant and Defence strategy was coordinated with minimal scope for duplication and wasted costs.

A confidential settlement fund was agreed to which the UK's Department of Health contributed an additional £42 million.

4 The Benzodiazepine Litigation

Benzodiazepine was discovered in 1953 and found to have a number of useful medicinal properties. This litigation involved thousands of Claimants and attracted a huge amount of publicity.

The key issue supporting the litigation was an allegation that the long term use of Benzodiazepine medication would cause psychological and physical dependence on the product. A group action commenced in 1988 which grew to a total of 17,000 claims. The vast majority of these claims had the benefit of legal support from the UK tax payer. Large numbers of the claims ended when the Defendants began to investigate them in detail.

Notable Case Management features were as follows:-

- A preliminary commentary was ordered to be served in place of a defence.
- Each Claimant had to plead their individual claim - a common or master form of pleading was not deemed to be acceptable.
- Claimants seeking public funding were given a cut-off date by which they had to apply for Legal Aid.
- The Legal Aid Board was to be represented at administrative hearings in order that evidence concerning funding issues could be heard.
- In relation to the striking out of individual cases the Judge first considered whether a cause of action was disclosed in the pleadings. He then went on to take into account the risk of benefit balance inherent in the litigation and the potential difficulties to be faced by Claimants were they to continue with their claims.

The group litigation culminated in 1993 with the withdrawal of Legal Aid against the lead Defendants, being Roche Products Limited and John Wyeth & Brother.

Following the collapse of the litigation it was revealed that £35 million of Legal Aid Funding had been squandered in pursuing the claims. Not surprisingly the collapse of the Benzodiazepine Litigation led to an overhaul of the Legal Aid system.

5 Norplant

The claims in this group action involved a contraceptive implant device inserted under the skin. It first became available in 1993 and it was subsequently alleged that the manufacturers did not adequately warn users of its side effects. The Norplant case is particularly interesting from a costs perspective. In the Opren Litigation the Managing Judge had confirmed that the costs of the generic case i.e. costs of pursuing the issues common to all members of the group - as distinct from the individual personal injury claims - should be borne by each member on a pro-rata basis.

The Judge in the Norplant case further refined the standard order in relation to costs so that if a Claimant left the group action she would be unable to recover her share of costs of the action relating to general liability and causation issues, even if the remaining Claimants were to succeed on the generic issues at trial.

The Norplant Litigation was discontinued by the Claimant group shortly before the trial fixed for February 1999, following the withdrawal of Legal Aid.

6 MMR Vaccine Litigation

In February 1998, Dr Andrew Wakefield, a gastroenterologist at London's Royal Free Hospital, published an article in the Lancet Medical Journal linking the measles, mumps and rubella vaccines to a bowel disorder and the onset of what he described as a severe, regressive form of autism.

This was a controversial piece of group litigation which led to vaccination rates tumbling in the UK and led to an upsurge in measles cases with several fatalities.

From a Case Management perspective MMR had a number of notable features. The judicial approach to managing these cases was in line with that of group litigation orders as created in 1999 under the Reforms of the Civil Litigation Procedure led by a Senior Judge, Lord Woolf.

At the first Case Management Conference in September 1999 the Judge ordered the creation of a Register of Claimants which included details of each Claimant and the particular Defendants they were pursuing for compensation. This was updated monthly, to reflect Claimants joining and leaving the group.

At an early stage the Judge also made a costs sharing order which was later subject to appeal by the Claimants. This was appealed on the basis that it was unfair to penalise Claimants who left the group action by not allowing them to recover of the generic costs if the remaining claims were ultimately successful at trial. The Court of Appeal was sympathetic to this view, ruling that the recoverability of generic costs should be decided following the main trial.

Of course, all this became largely irrelevant following the withdrawal of Legal Aid in 2003, when a slow trickle of discontinuing claims gradually turned into a deluge of discontinuances. The Defendant firms never recovered a penny of their costs incurred in defending the claims and the British tax payer was left £15 million poorer.

In January 2010, the UK's General Medical Council (after a hearing running for over two years), ruled that Dr Wakefield had acted "dishonestly and irresponsibly" in carrying out his research.

Conclusion

This is of course far from being the whole story of UK pharmaceutical group actions. There are currently a number of EU and UK-based initiatives although the UK Government prefers to see change introduced based on the needs of particular business sectors, such as the financial services industry, rather than introducing a generic group actions procedure. A major report on civil costs published by a senior Judge, Lord Justice Jackson, recommends the introduction of US style contingency fees for group actions, whilst also being cautiously approving of third party funding. These are topics for us to discuss together on a further occasion.

For now I hope that I have given you a some idea as to how UK-based pharmaceutical group actions have developed into their current form.

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