

To: Mr McKeon PS/SofS

From: Mr R M Gutowski MCA

Date: 4 June 1990

GRO-C

c.c. Mr Alder MCA
Mr Bewley MCA
Mr Love MCA
Mr Bendal SOLC5
Mr Canavan EHFI
Mr Rees MCA

OPREN LITIGATION

1. As requested by your office this note provides the latest position on Opren following a phone-call from No.10 about a recent newspaper article - we have been unable to trace the article in question.

Background

2. Opren, a non-steroidal anti-inflammatory drug used in the treatment of arthritis was licensed in 1980. In 1982 the Licensing Authority (LA), on the advice of the Committee on Safety of Medicines (CSM) suspended the product licence because of reports of serious adverse reactions. Subsequently, Opren was withdrawn from the world market. A number of people either personally or on behalf of relatives claimed damages in the High Court from the manufacturers Eli Lilly. The LA at CSM were joined as co-defendants.

Settlement

3 Eli Lilly and most of the original plaintiffs (1,400) have negotiated a private settlement which does not involve the Government defendants. Jack Ashley and others lobbied unsuccessfully at the time for Government intervention, to improve the terms of the settlement. However, there are still approximately 400 plaintiffs left pursuing the matter through the courts. Many of these are newly on the scene.

Latest Development

4. The LA and CSM have recently been served with a summons issued by the Solicitors for Eli Lilly which seeks to exclude some of the new plaintiffs under the terms of the Limitation Act 1980. On grounds that their claims are outside the statutory time limits. The summons, although issued by solicitors for Lilly, also includes the LA and CSM because in our original defence pleading in 1985 the right to plead limitation was reserved. To date, this position has not been abandoned.

5. There will be a hearing on the 13 July 1990 for Order of Directions then a further hearing on the 9 October which will consider limitations. This means that instructions will need to be given as to whether to pursue the limitations point or drop it. This needs to be viewed in connection with the limitations argument currently being considered in the HIV litigation where it is proposed not to run the point - Mr Canavan's submission of 30 May to Mr Davey refers.

6. Counsel has been asked to advise as a matter of urgency. On receipt, officials will make a further detailed submission to Ministers.

GRO-C: R. M. Gutowski