

## LEGAL FOCUS

# Pharmaceutical sector suffers burden

By Angus Rodger and Todd Corey, Steptoe & Johnson



or consumer fraud claims being brought on behalf of users of the drug

- If the drug manufacturer has insurance against legal liability to third parties arising out of its products, it will consider the extent to which such claims are covered by its insurers

### Regulatory oversight

Drug regulators — including the US Food & Drug Administration, the UK's Medicines &

Healthcare Products Regulatory Agency, the European Medicines Agency, the Pharmaceutical & Medical Devices Agency of Japan and the Health Products & Food Branch of the Department of Health in Canada — have been increasing their scrutiny of several drugs that have been on the market for decades.

Regulators' actions include reviewing adverse event reports made by consumers and physicians, undertaking more

critical reviews of companies' new drug applications, and requiring changes to product information and labelling.

Regulators have ordered the withdrawal of some drugs from the market and have seized inventory before it reached the marketplace. Pharmaceutical companies in some instances pre-empt this enforcement or limit public relations damage by voluntarily withdrawing their product. In any event, regulatory scrutiny provides fuel to claimants' lawyers in both the US and Europe.

In the US the costs of defending pharmaceutical claims may run into millions of dollars per case. Claims against a drug's manufacturer may be supported by allegations that the manufacturer knew of the dangers associated with the drug in question, such as those that might be contained in clinical trial data or spontaneous reports.

The discovery process can be expected to be a costly and time-consuming exercise, involving the broad disclosure of large numbers of documents. Defendants will seek

to limit the scope of pre-trial disclosure, especially where claimants demand access to documents that relate to the defendant's products and business operations.

US cases are tried before juries, and compensatory and punitive damages can be very high, especially if a jury finds a drug manufacturer concealed the known risks of the drug. Awards may be higher where the injury causes the loss of a large income, or (in practice) where the facts of the case elicit strong sympathy from the jury.

### Insurance coverage

Pharmaceutical companies may look to their insurers for recompense for such losses.

The insured and insurers will need to consider which law governs the insurance contract, since this will affect how the policy responds. For example, some laws prevent insureds from transferring punitive damages to their insurers. The extent to which losses may be recoverable will also depend on whether the policy covers only the indemnity paid by the insured, or

whether it also covers defence costs. Given the extent of disclosure, and the fact-intensive nature of pharmaceutical claims, defence costs can exceed the indemnity paid to claimants many times over.

Insurers will want to know when the insured first became aware of the problem with the drug and will consider at what point this was disclosed to the insurers. If the insured was aware of the problem and continued to sell the product without informing its insurers, the insurers may have common-law remedies for non-disclosure or contractual protections may apply.

The waves of drug-related litigation show no sign of abating and are placing a large burden on pharmaceutical companies. How much these losses will in turn impact the insurance industry will depend on the terms of the individual policies and the facts of the particular claims.

• *Angus Rodger is a partner and Todd Corey an associate in the insurance group in the London office of international law firm Steptoe & Johnson*