

Life sciences: clinical trials and product liability

CLINICAL TRIALS

Clinical trials claims are similar in many respects to medical malpractice claims, but do have their own quirks, particularly surrounding the no-fault schemes that many of the trials are undertaken under and the respective insurance cover. There are specific industry guidelines for clinical trial compensation and we regularly advise upon their applicability in an individual clinical trial matter.

We have gained significant experience assisting those carrying out clinical trials, including universities, pharmaceutical companies and their insurers.

Examples of claims that we have assisted on include:

- A participant who died some time subsequent to a trial of combination chemotherapy
- A participant who suffered permanent tinnitus following a trial within an MRI machine
- A participant who suffered permanent headaches following a trial which included a lumbar puncture
- A participant who suffered drug induced cholestatic hepatitis in a Phase I part-randomised, double-blind study to assess oral doses of a potential new drug.

PRODUCT LIABILITY

The healthcare industry is, as most industries are, becoming more automated, and as it does so, there are likely to be more product liability issues, including as to where the liability lies. Capsticks have developed a practice in assisting Insurers, clinics, clinicians and manufacturers in product liability claims.

We have been involved in:

- PIP breast implant litigation, acting for a number of private surgeons
- Metal-on-metal hip prosthesis litigation, acting for a number of private surgeons
- Vaginal mesh claims, acting for private hospitals
- IV Amoxicillin causing extravasation injuries in children, acting for the pharmaceutical manufacturer and their insurer
- Bottle cap safety for liquid paracetamol.

HOW CAPSTICKS CAN HELP

In both clinical trials and product liability claims, we can:

- Review policy coverage issues and provide detailed policy coverage advice
- Undertake the necessary investigations including instructing independent experts were required
- Advise upon any industry specific guidelines that may be in place, such as the Association of British Pharmaceutical Compensation Guidelines, and their applicability in any particular claim
- Act in a group litigation
- Offer advice and assistance to your insureds on risk management and, for example, assist with re-wording of consent to treatment forms to minimise the risk of future claims, or their impact.

Essentially, we are able to manage any complaints or claims from their early stages through all steps in the litigation process and offer advice on wider issues to reduce the risk of future claims being made against insureds.

TAILORED TO MEET YOUR NEEDS

A central tenet of our service is that we will tailor the service to meet your requirements and have a small but dedicated and specialist team able to help. This means you will always know those lawyers assisting on any particular matter.

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