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Medical Products: Claims, Coverage, and Emerging Technologies

FOIL brought together a panel of legal, insurance, and medical professionals at the London offices of DWF to examine the rapidly developing landscape of product liability claims involving medical devices and health-related products. Against a backdrop of advancing technology, a shifting regulatory environment, and growing claimant awareness, the event explored the current state of claims practice and the future challenges posed by AI, robotics, and nanotechnology, with attendees enjoying presentations from four expert speakers, each delivering a different perspective from their specialist area.

Alex Antelme KC, Crown Office Chambers - The Product Liability Claims Landscape

Alex opened with a survey of the current product liability environment, drawing on four major class actions in which he has been personally involved over the past two decades.

He began with the 2006 Northwick Park drug trial, in which six healthy volunteers were critically harmed during a clinical study. The litigation that followed involved small legal teams on both sides and was resolved at a single roundtable meeting. By contrast, the 2018 Pinnacle metal-on-metal hip litigation was considerably more complex, involving hundreds of claimants, teams of five counsel per side, and costs running into the millions. DePuy ultimately prevailed, and the case became an important reference point for interpreting the Consumer Protection Act 1987 (CPA), particularly regarding the meaning of 'defect'.

The ongoing diesel emissions litigation represents a further step-change in scale, with approximately 1.6 million claimants, five lead defendants, and litigation costs projected to reach approximately £0.5 billion. The most recent matter, concerning allegations that Johnson & Johnson's baby talcum powder causes mesothelioma and ovarian cancer, currently involves over 67,000 active lawsuits in the US and UK, with numbers continuing to rise.

These cases illustrate a clear trajectory: group litigation in England and Wales is growing in scale, cost, and international reach. The total number of group litigation orders has risen from 50 in 2006 to 125 and continues to grow, with no slowdown in the pipeline. The escalating cost of litigation is driven, in part, by inflation but also by the exponential growth in documentary disclosure, demands on expert witnesses, and a 'no stone unturned' culture in high-value cases.

In parallel, the funding landscape has changed, shifting from Legal Aid through conditional fee arrangements to international third-party funding, including hedge fund investment of over £500 million in the diesel proceedings, which introduce commercial interests into litigation decision-making.

Regarding the legal framework, Alex described CPA jurisprudence as having had a rocky journey that has now reached a degree of stability. Following the influential but controversial *A v National Blood Authority [2001]* judgment, the subsequent cases of Wilkes, Gee, and *Hastings v Finsbury Orthopaedics* saw the courts return to a more objective assessment of consumer expectations, settling the position that complex medical devices are not automatically defective where known risks are outweighed by the device's net benefit to society.

In closing, Alex offered two reflections: first, that Pinnacle may be unfairly used as evidence of the CPA's inadequacy, since those hips were criticised but not necessarily defective; and second, that the Law Commission's ongoing review, particularly its treatment of software and AI-enabled products and of collective consumer action mechanisms, will be watched closely by all interested parties.

Tim Johnson, Partner and Head of Insurance, Browne Jacobson – Policy Wording and Coverage Issues

Tim explored the coverage issues arising from medical product claims, highlighting that many existing policy wordings were drafted before modern technology and AI existed as meaningful commercial realities, leading to increasing disputes as new exposures are forced into old frameworks.

He outlined product liability, medical malpractice, professional liability, and clinical trials liability as the principal classes of insurance relevant to medical product claims, noting that in practice these policies are not mutually exclusive and that multiple policies may be engaged simultaneously. The 'deepest pockets' dynamic, in which claimants target the most

comprehensively insured party rather than the party most directly responsible, often creates significant tension between parties and their insurers.

On policy mechanics, Tim highlighted the difficulties arising from temporal scope (the distinction between occurrence-based and claims-made coverage), aggregation clauses, and series provisions, all of which can dramatically affect the quantum of insurer liability and trigger complex coverage disputes.

Among the key exclusions frequently found in medical product claims are product recall costs, regulatory fines and MHRA enforcement proceedings, intentional acts and known defects (with emerging disputes around constructive knowledge and 'controlling mind' provisions), contractual liability, gradual injury and pollution clauses, and data exclusions. The latter is increasingly important as medical devices collect and process sensitive patient data.

Going forward, Tim identified AI, surgical robotics, and nanotechnology as the primary emerging areas of risk. AI-driven diagnostic tools and clinical decision support software are increasingly regulated as medical devices in their own right, which blurs the boundaries between product liability and professional indemnity in ways that existing policies do not clearly address.

The concept of 'silent AI', related to policies that are simply silent on AI-related liabilities, resembles the 'silent cyber' challenge addressed by the LMA and FCA in 2018. Nanotechnology represents a distinct long-tail challenge, with harm potentially appearing gradually over many years after initial exposure, creating uncertainty around when an 'occurrence' takes place under traditional policy structures.

Tim concluded that insurance products must evolve to meet these demands, specifically, through express AI coverage provisions, a potential market shift towards claims-made cover in long-tail product classes, combined policy products designed to eliminate gaps at the malpractice and product liability boundary, and growing interest in captive insurance arrangements for larger organisations managing different exposures.

David Roberts, The Law Commission - Review of the Consumer Protection Act 1987

David provided an update on the Law Commission's review of Part 1 of the CPA, which has been commissioned by the Department for Business and Trade to assess whether the civil product liability regime remains fit for purpose after almost four decades in operation. Work began in October 2025, and a consultation paper is planned for publication towards the end of 2026, which will be followed by a 12-week consultation period and final recommendations expected by the end of 2027.

The Commission has identified three broad themes. The first evaluates whether the CPA has worked well, with stakeholder opinion divided between those who regard it as effective and those who consider it places an unfair burden on claimants. Areas of particular concern include the definition of 'defect', evidential and causation challenges, the ten-year longstop

limitation period, and access to justice barriers, including litigation costs and disclosure obligations.

The second theme concerns the growing prominence of software, digital products, and AI in a regime originally designed for physical products. Key questions under review include whether the definition of 'product' should be expanded to include standalone software, AI systems, and social media platforms, as well as how liability should be allocated for products modified after market entry, and how interconnected systems should be treated.

The third theme considers whether England and Wales should align with the new EU Product Liability Directive, which relates to products placed on the market after 9 December 2026 and proposes, among other changes, an extension of the longstop period from 10 to 25 years in latent damage cases, a change particularly relevant to medical devices.

David closed by encouraging FOIL members and practitioners to engage with the forthcoming consultation, emphasising that practical experience of how the current regime operates is important in stress-testing the Commission's proposals.

Dr Hugh Harvey, Managing Director, Hardian Health – Emerging Health Technologies

Hugh is a former consultant radiologist, member of the National AI Commission, and recognised expert in medical device regulation. In delivering a wide-ranging assessment of AI deployment in healthcare, Hugh highlighted that highly complex AI systems are being deployed at speed across the NHS under regulatory frameworks never designed for them, and that harm and resulting litigation are likely to follow.

Hugh outlined the difficulty of determining which AI products constitute regulated medical devices. The concept of 'intended use', as defined by a manufacturer's labelling, instructions, and promotional materials, sits at the heart of medical device regulation. However, increasingly sophisticated AI systems, particularly LLMs and foundation models able to perform a wide range of functions, are making it difficult to define a single, clearly identifiable intended use, and therefore exposing notable limitations in the current framework.

He categorised existing clinical AI across five areas: diagnostics (including radiology tools now deployed across approximately 90% of NHS Trusts); therapeutics (digital treatment tools for mental health, women's health, and wound healing); prevention and prediction (including sepsis and dementia risk tools); monitoring (including wearable devices such as the Apple Watch, now cleared for atrial fibrillation detection); and clinical agents (ambient AI scribes, automated coding, and AI-assisted prescribing).

The emerging generation of multimodal foundation models, which can analyse imaging data alongside clinical records and genomics, presents the most substantial regulatory challenge, as their outputs are broad, unpredictable, and difficult to categorise within existing frameworks.

The most significant regulatory gap identified was the Class I loophole. The MHRA's recent regulatory update has retained the pre-Brexit framework without introducing specific provision for AI, meaning that complex, black-box AI clinical decision support tools can self-certify compliance as Class I devices, the lowest risk category, without independent third-party review. This means some of the most consequential tools now deployed across the NHS are subject to almost no meaningful regulatory scrutiny.

For insurers and lawyers, the implications are that liability attribution in AI-assisted clinical care will become increasingly contested and regulatory non-compliance among AI manufacturers may become a significant factor in future product liability claims. In addition, drafting cover for broad, multi-purpose AI systems with unpredictable outputs will be a growing challenge, as the pace of AI deployment within the NHS continues to outstrip governance frameworks.

Whilst welcoming the potential benefits AI can bring to healthcare, Hugh warned the audience that claims are coming, and those who understand the regulatory landscape and its current gaps will be best placed to respond.