Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 118–139
Articles DOI: 10.53386/nilq.v76i1.1141

Developing product liability networks for AI systems in the medical context

James Devenney
University of Reading*
Geraint Howells
University of Galway†
Correspondence emails: j.devenney@reading.ac.uk; geraint.howells@universityofgalway.ie.

ABSTRACT

Product liability is again a matter of contemporary discussion due to the increased integration of technology into products. In particular, artificial intelligence (AI) has come to the fore, with machines, for example, using big data to make decisions faster and often with greater accuracy than humans. AI is being used at all stages of medicine. Such advances in technology have the potential to provide great benefits. However, there are potential risks. Many of these risks relate to data privacy but even in the field of safety uncertainty about the risks remain. This has led, in part, to reform of the European Union (EU) Products Liability Directive. The United Kingdom (UK) is, of course, no longer bound to follow, but it is likely it will also in time feel the need to do something in this space. In 2021 the Law Commission tentatively suggested 'product liability and emerging technology' for its programme of Law Reform, but concluded the time was not right. Subsequently, the Government has alluded to the need for modernising product liability law, but has only mentioned the possibility of extending the definition of product to include software and taking AI into account when assessing defectiveness. The context is a country hamstrung by Brexit, without a real vision for the future of UK consumer law nor for achieving the competitive advantages which Brexit promised to deliver. On the other hand, the EU has considered both a strict liability regime for high-risk AI products and a revised negligence regime for AI, as well as a revised strict product liability regime adapted to the AI context. This article will, first, consider how negligence might apply. Then, liability under the product liability regime, the EU's amended regime and the proposed strict liability regime for high-risk AI will be considered. The advantages and disadvantages of negligence and strict liability will be discussed with a preference being for strict liability for all products. Finally, a plea to consider network liability or an even more ambitious insurance-based solution will be made.

Keywords: product liability; AI; Brexit; medical arena.

* Professor of Transnational Commercial Law, University of Reading; Visiting Full Professor, UCD, Ireland; Professor, Neapolis University of Pafos, Cyprus; and Visiting Professor, Dalian Maritime University, China.

† Established Professor, University of Galway; and Visiting Professor, University of Manchester.

INTRODUCTION

It is an honour to contribute to this celebration of the work of Professor Christopher Newdick, one of the leading medical law thinkers of our generation. As private lawyers, the most obvious intersection of our interests with Chris's fields of expertise lies in product liability; an area to which Chris directed his customary incisive critique in relation to the emerging strict product liability regime in the 1980s.[1] Fortunately for us, product liability is again a matter of contemporary discussion due to the increased integration of technology into products.[2] Moreover, artificial intelligence (AI) has come to the fore in the medical arena, with machines, for example, using big data to make decisions faster and often with greater accuracy than humans (even medics!).[3] AI is being used at all stages of medicine: it can help triage patients to assist doctors with determining the order of priority for treatment; it can assist with clinical risk prediction; it can assist with diagnosis; it can help develop drugs and match drug regimes to patients; and it can assist in surgery, including through the use of robots.[4]

Such advances in technology have the potential to provide great benefits.[5] However, there are also potential risks. Many of these risks relate to data privacy,[6] but, even in the field of safety, uncertainty about

1 See, for example, C Newdick, 'The future of negligence in product liability' (1987) 103 LQR 288–310; C Newdick, 'The development risk defence of the Consumer Protection Act 1987' (1988) 47 Cambridge Law Journal 455–476; and C Newdick, 'Risk, uncertainty and "knowledge" in the development risk defence' (1991) 20 Anglo-American Law Review 309–326.

2 See, for example, Law Commission, *Automated Vehicles: Joint Report* (Law Comm No 404, 2022); European Law Institute, Guiding Principles for Updating the Product Liability Directive for the Digital Age (2021); and European Commission, *Expert Group on Liability and New Technologies – New Technologies Formation: Liability for Artificial Intelligence and Other Emerging Digital Technologies* (2019).

3 Cf M Prictor, 'Where does responsibility lie? Analysing legal and regulatory responses to flawed clinical decision support systems when patients suffer' (2023) 31 Medical Law Review 1–24.

4 A Oliva et al, 'Management of Medico-legal risks in digital health era: a scoping review' (2022) 8 Frontiers in Medicine 1; S Jassar et al, 'The future of artificial intelligence in medicine: medical-legal considerations for health leaders" (2022) 35 Healthcare Management Forum 185–189; M Morris et al, 'Ethical, legal and financial consideration of artificial intelligence surgery' (2023) 89 The American Surgeon 55–60.

5 See, for example, NHS England, Artificial Intelligence (AI) and Machine Learning (updated 13 March 2023).

6 See B Murdoch, 'Privacy and artificial intelligence: challenges for protecting health information in a new era' (2021) 22 BMC Medical Ethics 122. See, generally, Information Commissioner's Office, Guidance on AI and Data Protection (updated March 2023).

the risks remains.[7] The program may be developed using inadequate data. There may be flaws in the data. The data may fail to take account of all categories of patients based on gender or ethnicity. There may be design errors causing abnormal system behaviour. The AI system may not be used in the original design context. There may be impact from permanent or transient hardware defects, such as 'bit flip' linked to radiation particles.[8] Furthermore, there is a risk that doctors are deskilled if they rely automatically on AI results (which may be wrong) or at least overdevelop some skills (such as interpreting AI outputs) at the risk of not recognising, for example, normal images. Education is clearly needed.[9] Equally there may need to be a 'surgeon in the loop' principle to ensure the surgeon remains responsible for all decisions, and these are not outsourced to an AI.[10] The 'black-box' algorithm is also potentially problematic as it often provides an answer, but without any supporting rationale. Should the doctor just trust the machine? If things go wrong the injured party may not know on what basis the machine acted due to intellectual property law keeping the basis of the algorithm secret.

This has led, in part, to reform of the EU Products Liability Directive.[11] The United Kingdom (UK) is, of course, no longer bound to follow such initiatives, but it is likely the UK will also in time feel the need to do something in this space. Indeed, in 2021 the Law Commission tentatively suggested 'product liability and emerging

---

7 Compare H Smith and K Fotheringham, 'Exploring remedies for defective artificial intelligence aids in clinical decision-making in post-Brexit England and Wales' (2022) 22 Medical Law International 33–51. See also Medicines and Healthcare Products Regulatory Agency, Software and Artificial Intelligence (AI) as a Medical Device (updated 3 February 2025).

8 Oliva et al (n 4 above).

9 Ibid.

10 Ibid. See also C Jones, J Thornton and J C Wyatt, 'Artificial intelligence and clinical decision support: clinicians' perspectives on trust, trustworthiness, and liability' (2023) 31 Medical Law Review 501–520.

11 Directive (EU) 2024/2853 of the European Parliament and of the Council on liability for defective products and repealing Council Directive 85/379/EEC. Consumers will rarely directly buy complex medical devices, so we leave out of this account the reform of the law for contractual liability for digital content and services found in the UK Consumer Rights Act 2015 and Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services. See G Howells and C Twigg-Flesner, 'Interconnectivity and liability' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022); and A De Franceschi and R Schulze (eds), *Digital Revolution: New Challenges for Law* (Beck International 2020).

technology' for its programme of Law Reform.[12] Yet, in February 2023 the Law Commission concluded that the time was not right to establish a new programme of reform, noting that it had 'taken this decision in view of the Government's focus on priorities for the remainder of this Parliament'.[13] Subsequently, in a report mainly concerned with product safety reform, the Government has alluded briefly to the need for modernising product liability law, but concretely has only mentioned the possibility of extending the definition of product to include software and taking AI into account when assessing defectiveness.[14] The context, we would suggest, is a country hamstrung by Brexit, without a real vision for the future of UK consumer law nor for achieving the competitive advantages which Brexit promised to deliver.[15]

On the other hand, the EU has proposed both a strict liability regime for high-risk AI products (which would encompass medical devices) and a revised negligence regime for AI (though recently withdrawn) as well as a revised strict product liability regime adapted to the AI context. This article will, first, consider how negligence might apply, including under the revised EU regime. Then, liability under the product liability regime, the EU's amended regime and the proposed strict liability regime for high-risk AI will be considered. The advantages and disadvantages of negligence and strict liability will be discussed with a preference being for strict liability for all products. Finally, a plea to consider network liability or an even more ambitious insurance-based solution will be made.

NEGLIGENCE

Introduction

In many cases, medical use of AI systems will be under the supervision of trained medics. For example, there may be computerised systems for determining the best mix of medicines to be administered, robots may

12 See Law Commission, 'Generating ideas for the Law Commission's 14th programme of law reform'.

13 See Law Commission, 'An update on the 14th programme of law reform' (15 February 2023).

14 Department for Business, *Energy and Industrial Strategy, Smarter Regulation: UK Product Safety Review* (August 2023) 42.

15 Compare general policy statements such as wanting 'a more active pro-competition strategy to deliver more targeted and effective pro-competitive interventions' (Department for Business, Energy and Industrial Strategy, *Reforming Competition and Consumer Policy: Driving Growth and Delivering Competitive Markets that Work for Consumers* (2021) para 0.15). See also the UK Government policy paper *Establishing a Pro-innovation Approach to Regulating AI* (CP 728, 2022).

be used in surgery and AI systems may guide anaesthetists, but the final call will normally be with the trained medic.[16] Medical liability is likely to remain negligence based outside those few systems that adopt no-fault liability;[17] and so the starting point is that AI liability in medicine will continue to be judged on a negligence basis, taking into account the availability and performance of AI devices. However, in the context of negligence and AI systems, some interesting questions are posed, particularly around the complicated interaction between the person using the AI system and the performance of the product. For example, a well-known phenomenon is automation bias under which people sometimes trust machines more than personal judgement.[18] Whether this is due to a belief that the machine is really likely to be accurate, or simply due to pressure of workload, there is a risk that doctors will rely too much on machines and not use their independent judgement to question it.[19]

Conversely, there is also the risk of being found negligent for not using, or following, an available AI system. What, for example, if a doctor reflects on the advice of the AI device and decides not to follow its instructions, but it turns out the patient would have benefited from the doctor following them? Or an AI system is found to perform better than humans, for example in reading X-rays, but it is decided not to use it? Or a surgeon prefers to deactivate an automated tool when the outcome can be shown to have been more likely to be successful if automation had continued? It may in fact be hard to allocate blame and prove negligence.[20] That is why some authors have favoured strict liability over negligence when AI is involved.[21] Also, the difficulty for the injured party in assigning liability to a particular actor where AI devices are involved, relying on data feeds and used by professionals, has also been a factor in calls for network liability. We will return to

16 F Pasquale, 'Liability standards for medical robotics and AI' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022).

17 Compare S Holm, C Stanton and B Bartlett, 'A new argument for no-fault compensation in health care: the introduction of artificial intelligence systems' (2021) 29 Health Care Analysis 171–188.

18 See, for example, M Grissinger, 'Understanding human over-reliance on technology' (2019) Pharmacy and Therapeutics 320–321.

19 See D Lyell and E Coiera, 'Automation bias and verification complexity: a systematic review' (2017) 24 Journal of the American Medical Informatics Association 423–431.

20 See, generally, C Witting, *Street on Torts* 16th edn (Oxford University Press 2021) 410–411.

21 On policy considerations generally, see H Zech, 'Liability for AI: public policy considerations' (2021) 22 ERA Forum 147–158.

these broader policy questions after surveying the current law and reform initiatives.[22]

If AI systems develop in such ways that once deployed they operate autonomously without the ability for a medic to intervene, then the decision to use such an autonomous device will itself be subject to judgment for reasonableness.[23]

EU proposal on adapting non-contractual civil liability rules to artificial intelligence

The EU proposed to adapt the rules of Member States in respect of non-contractual fault-based liability and AI.[24] The proposal, now withdrawn, sought to make it easier to recover for fault-based liability by introducing rules relating to the disclosure of evidence with a rebuttable presumption of non-compliance with duty of care if not complied with and a rebuttable presumption of a causal link in the case of fault.[25] The proposal differentiated high-risk AI (as defined in the then proposed AI Act).[26] Indeed, the rules on disclosure of evidence would have only applied to high-risk AI.[27] The operation of AI systems can be very opaque so that claimants are unable readily to assess whether there has been, for example, any negligence. The phrase 'black-box' is often used to describe the secrecy surrounding the algorithms used in AI systems.[28] These proposals were intended to make it easier to bring claims by making the AI more transparent. On presenting facts and evidence to support the plausibility of a claim, national courts would have been empowered to require the disclosure of relevant risks.[29] Steps could have been taken to preserve the confidentiality of any alleged trade secret, such as the algorithms underpinning the AI operation.[30] The requirements of the AI Act would have ensured such

22 See below at 135ff.

23 See J Herring, *Medical Law and Ethics* 9th edn (Oxford University Press 2022) paras 3.2.2ff.

24 Proposal for a Directive of the European Parliament and of the Council on Adapting Non-contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive), COM/2022/496 final. On withdrawal, see Legislative Train Schedule: AI Liability Directive.

25 See O Dheu and J De Bruyne, 'Artificial intelligence and tort law: a "multi-faceted" reality' (2023) 31 European Review of Private Law 261–298.

26 See art 2, cross-referring to art 3 of the now Regulation (EU) 2024/1689 of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act).

27 Art 3(1).

28 See Y Bathaee, 'The artificial intelligence black box and the failure of intent and causation' (2018) 31(2) Harvard Journal of Law and Technology 899–938.

29 Art 3.

30 Art 3(4).

information was readily accessible to the defendant.[31] The claimant would first have needed to take all proportionate efforts to gather the information from the defendant. Failure to disclose such information would have led to the presumption of fault.[32] This was significant as it also led to a rebuttal presumption of a causal link.[33]

A rebuttable presumption had also been proposed as regards the causal link between the fault of the defendant and the output of the AI system or the failure of the AI to produce an output.[34] For this presumption to arise, three conditions need to be met. First, the claimant had to have demonstrated fault, or this must have been presumed by breach of a duty to disclose.[35] In the case of high-risk AI systems, there must have been a failure to comply with certain rules in the then proposed AI Act aimed at risk management, design and development or there must have been a failure to take required corrective measures.[36] Second, it needed to be likely that the fault influenced the output produced by the AI system or its failure to produce an output.[37] Failure to comply with record-keeping requirements are unlikely, for example, to have influenced the functioning of the AI system. Third, it had to be demonstrated to be reasonably likely that the output produced by the AI system or the failure of the AI system to produce an output gave rise to damage.[38] These rules did not apply to high-risk AI systems where there was sufficient evidence and expertise was reasonably accessible.[39] This might be possible based on the documentation and logging requirements of the AI Act. This presumption of causality would only have applied for non-high-risk systems when courts considered it would be excessively difficult for the claimant to prove the causal link. It was not clear how serious a barrier this would have been given that the recitals note that the claimant should not be required to explain the characteristic of the AI system or how these characteristics make it harder to establish the causal link.[40] It was noted that the claimant had the difficult task of pointing to the human act or omission that constituted fault leading to the output or failure of output from the AI system causing damage. Also, whilst it was called a rebuttable presumption, there was built-in a requirement

31 See art 13.
32 Art 3(5).
33 Art 4(1)(a).
34 Art 4.
35 Art 4(1)(a).
36 Art 4(2).
37 Art 4(1)(b).
38 Art 4(1)(c).
39 Art 4(4).
40 Recital (28).

to show likelihood of a causal link, so it was uncertain how reduced the burden would have been. This is discussed further below in relation to similar rules in the Product Liability Directive. AI that has been found suitable for use by non-professionals would not normally have been subject to the presumption of causality.[41] This would have been unfair on non-professional end users. The presumption would only have arisen where they materially interfered with the operation of the AI system or failed when required to determine the conditions of operation of the AI system.

Even if medical liability remains fault based, there remains the question of the distinct liability under other liability systems. If this is a product it may already be subject to the distinct strict product liability regime. Indeed, the proposal on adapting non-contractual liability to AI was specifically stated not to affect any rights the injured person may have under the Product Liability Directive 85/374/EEC.[42] Now the proposal on AI liability has been withdrawn, product liability will become even more central to many. It is to that Directive and its reform that we now turn.

PRODUCT LIABILITY DIRECTIVE

Introduction

The previous Product Liability Directive (85/374/EEC) was transposed in the UK by part 1 of the Consumer Protection Act 1987.[43] That Act included an explicit reference to the purpose of part 1 being to comply with that Product Liability Directive, a reference which has survived Brexit albeit with a change from the present to past tense.[44] Thus, it is still legitimate in the UK to refer to the previous Product Liability Directive.

At first glance, that Product Liability Directive's stated aim of achieving a 'fair apportionment of the risk in modern technological production'[45] seems well suited to resolving the problem of AI liability. Unfortunately, there was no clarity about what the precise underlying

41 Art 4(6).

42 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

43 Part 1 of the Consumer Protection Act 1987 applies to England, Wales and Scotland. For Northern Ireland, see part 2 of the Consumer Protection (Northern Ireland) Order 1987.

44 The amendment was made by the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019/696, sch 3.

45 Recital 2.

policy was seeking to achieve. One model was to see product liability as sharing the risks so that if new developments go wrong those affected are compensated.[46] Without unduly pre-empting later discussion, it could be seen as a form of insurance. However, in practice there is a danger that it can become a matter of avoiding liability by simply warning the user of potential risks. Burton J's concern in *A v National Blood Authority*[47] that warnings should not slip into being exclusion clauses[48] (which are not allowed)[49] is at risk of not being heeded.

Whatever the underlying policy, there are doubts that this Product Liability Directive, and the Consumer Protection Act 1987 regime enacting it into law in England, Scotland and Wales, had the scope and definitions to deal appropriately with AI systems. In particular, is an AI system a 'product'? A product is defined in the Consumer Protection Act 1987, section 1(2), and is primarily defined as goods, the definition for which is found in section 45 as including:

> substances, growing crops and things comprised in land by virtue of being attached to it and any ship, aircraft or vehicle ... .

Two challenges thus arise for bringing AI systems under the ambit of the Consumer Protection Act 1987. First, the purpose of some AI systems might be to provide information. In *VI v KRONE – Verlag Gesellschaft mbH & Co KG*,[50] incorrect paramedical advice was printed in a newspaper and subsequently followed by a reader, causing injury to the reader. The Court of Justice of the European Union (CJEU), noting that the then Product Liability Directive did not apply to services, held that the situation did not come within the scope of that Product Liability Directive. However, the CJEU did note:

> In the present case, it must be observed that the service in question, namely the provision of inaccurate advice, is unrelated to the printed newspaper, which constitutes its medium. More specifically, that service does not concern either the presentation or the use of the latter. Therefore, that service is not part of the inherent characteristics of the printed newspaper which alone permit an assessment as to whether the product is defective.[51]

Thus, an AI diagnostic system is, perhaps, more likely to come within the Consumer Protection Act 1987 than an AI system merely conveying information.

---

46 See, generally, S Deakin and Z Adams, *Markesinis and Deakin's Tort Law* 8th edn (Oxford University Press 2019) 584ff.

47 *A v National Blood Authority* [2001] 3 All ER 289.

48 Ibid [70].

49 Consumer Protection Act 1987, s 7.

50 Case (C-65/20) ECLI:EU:C:2021:471.

51 Ibid at [36].

Secondly, does software come within the definition of 'goods' under the Consumer Protection Act 1987? A similar debate, of course, has been simmering under the Sale of Goods Act 1979,[52] where the fairly widely accepted view has been that software is not *per se* 'goods' but defective software installed on hardware may render the hardware of unsatisfactory quality.[53] By contrast the CJEU held, in the context of the Commercial Agents Directive,[54] that goods 'can cover the supply, in return for payment of a fee, of computer software to a customer by electronic means where that supply is accompanied by the grant of a perpetual licence to use that software'.[55]

The EU reform of the Product Liability Directive includes software allowing an AI system producer to be liable for the system or as a component of the final products.

Defects

Assuming a particular AI system is subject to the (UK) strict liability regime, the next issue is to determine whether the product is defective. The definition of defect – 'there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect'[56] – has been subject to many criticisms. In particular, it has been criticised for circularity as the answer to what is a defect depends upon answering the question of what safety a person is entitled to expect.[57] Indeed, Herbert Zech describes this strict product liability regime as a 'de facto negligence' regime.[58] He suggests this is the case on the ground that the defect requirement entails negligence and the injured party has the burden of proving defectiveness. Although many[59] have hinted at the regime risking collapsing back into a negligence regime, especially if the development risks defence is allowed, few have gone this far.

52 See, generally, S Green and D Saidov, 'Software as goods' (2007) Journal of Business Law 161–181.

53 *St Albans City and DC v International Computers Ltd* [1997] FSR 251.

54 Council Directive 86/653/EEC of 18 December 1986 on the coordination of the laws of the Member States relating to self-employed commercial agents.

55 *Software Incubator Ltd v Computer Associates (UK) Ltd* (C-410/19) [2022] 2 CMLR 3 at [52].

56 S 3.

57 J Stapleton, *Product Liability* (Butterworths 1994) ch 10.

58 Zech (n 21 above).

59 Including C Newdick, 'The future of negligence in product liability' (n 1 above); Newdick, 'The development risk defence' (n 1 above); and Newdick, 'Risk, uncertainty and "knowledge" (n 1 above).

The key question is what safety a person is *entitled* to expect, rather than what they actually expect.[60] Only a few clues are given to the factors to be taken into account on how those expectations should be assessed. Nevertheless, it may involve the courts (and indeed potentially reformers) in questions of policy around, for example, risk-benefit analysis.[61]

The very open-textured nature of the standard[62] means that it could be applied to AI systems, even if the Consumer Protection Act 1987 is not reformed to expressly make reference to factors specifically relevant to AI. The age-old problem remains of determining what standard a person is entitled to expect. Would we, for example, always be entitled to expect AI systems to have better outcomes than human interventions, so that if it does not reach that standard it does not offer the safety we are entitled to expect? Can we always be entitled to expect AI to take account of social factors such as race and ethnicity and so a failure to do so would render it less safe than we are entitled to expect?[63] To the extent that AI is self-learning, do we have to accept that comes with risks that it may learn in ways that create additional risks?

At this point we will limit ourselves to highlighting three further issues. First, at what point in time are safety expectations judged? The traditional view would be at the time the product is supplied,[64] but how does this apply in the context of any ongoing software updates or, indeed, development of the AI system through self-learning?

Secondly, at least in the context of high-risk AI used in the medical setting, the EU's AI Act proposes a raft of regulatory requirements.[65]

---

60 See, for example, *Richardson v LRC Products Ltd* [2000] Lloyd's Rep Med 280 (consumers not entitled to expect that condoms will never fail).

61 See Witting (n 20 above) 416, citing C Newdick, 'Strict liability for defective drugs in the pharmaceutical industry' (1985) 101 Law Quarterly Review 405–430.

62 Consumer Protection Act 1987, s 3(2) states: '(2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including—(a) the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product; (b) what might reasonably be expected to be done with or in relation to the product; and (c) the time when the product was supplied by its producer to another; and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question.'

63 See, for example, P Noseworthy et al, 'Assessing and mitigating bias in medical artificial intelligence: the effects of race and ethnicity on a deep learning model for ECG analysis' (2020) 13(3) Circ Arrhythm Electrophysiol e007988.

64 Compare Consumer Protection Act 1987, s 3(2)(c).

65 AI Act (n 26 above).

Would compliance with such requirements provide a defence to an allegation that the product was defective? This is not based on reliance on the very narrow compliance with mandatory requirement defence,[66] but would rely on the argument that if the AI system is designed and built according to the best contemporary standards then it must offer the standard of safety people are entitled to expect. This argument has been run and accepted in principle in case law in England and Wales, but even in generally pro-defendant judgments there was a reluctance to make it an automatic defence.[67] The weight given to compliance would depend upon the context and might take into account whether the standards had addressed the particular issue and how recently the standards had been updated. In a fast-changing area like AI, one might expect the courts to be slow to accept that mere compliance with regulatory requirements would provide an effective shield against liability. At a more general level, the function of regulation and the *ex post* assessment by a court are very different tasks that should not be unduly confused.

Thirdly, warnings are clearly relevant to the presentation of the product and should, therefore, be taken into account in determining appropriate safety expectations. However, the precise effect the warning will have on the assessment of safety expectations remains unclear. For example, simply warning a consumer that AI is being used and therefore the producer might not be able to control the way the product acts presumably should not be an excuse. French case law has been sceptical of the role of warnings in avoiding liability. The new Product Liability Directive also sounds a similarly cautionary note about warnings, stating in recital that:

> warnings or other information provided with a product cannot by considered sufficient to make an otherwise defective product safe, since defectiveness should be determined by reference to the safety that the public at large is entitled to expect. Therefore, liability under this Directive cannot be avoided simply by listing all conceivable side effects of a product.[68]

Of course, medical AI systems are often used under the guidance of medical professionals. Warnings or instructions may be given to such professionals. In *A v National Blood Authority*,[69] Burton J had held that this information was not relevant when assessing the expectations of the general public. Other cases have taken a different view,[70] which is probably the correct approach with the blood decision being assessed

66 See Consumer Protection Act 1987, s 4.
67 See *Gee v DePuy* [2018] EWHC 1208.
68 Recital 31.
69 [2001] 3 All ER 289.
70 See, for example, *Worsley v Tambrands Ltd* [2000].

in the unique context of the facts of that case. Thus, the public would expect its medic to be informed of the risks and look to them to assess the product and ensure informed consent to the use of the AI system.

Development risks

A controversial[71] feature of the previous Product Liability Directive was the presence of the development risks defence. This was intended to protect industries against risks which could not be discovered given the state of scientific and technological knowledge when the product is put into circulation. At first glance, this might seem to be applicable to autonomous AI as it is not known how the AI will develop. However, we would suggest that this misses the point. When one uses autonomous AI, it is known that the system will develop in ways it determines itself based on its learning from the data and possibly in ways which are hard to predict. In a sense this involves risks which are unknown. However, the inherent risk of the AI taking a decision which creates a safety risk is known. If one follows the logic of *Commission v United Kingdom*,[72] once a risk is known about the trader should be responsible and decide whether to investigate further to reduce risk or take out insurance against the risk.

Revised Directive on liability for defective products

The preamble to the 2024 Product Liability Directive[73] notes 'life-sustaining medical devices, entail an especially high risk of causing damage to people and therefore give rise to particularly high safety expectations'.[74] It adds certain factors which would need to be considered when assessing defectiveness and which seem to be relevant to the safety assessment of AI systems. For example, the effect on the product of any ability to continue to learn after deployment is a factor clearly aimed at AI products that have the ability to act autonomously based on their learning.[75] Here, the distinction between AI systems that simply follow coded instructions and those that have the ability to learn from data and make autonomous decisions is crucial. The recitals provide guidance on how this should be interpreted, noting the 'expectation that a product's software and underlying algorithms are

71 See, for example, S R Ghasemzadeh, 'The economic and legal bases of the development risk defence in European product liability: a critical approach to proponents' bases of the defence' (2019) 27 European Review of Private Law 1023–1050.

72 (C-300/95) [1997] ECR I-2649.

73 Directive (EU) 2024/2853 (n 11 above).

74 Recital 30.

75 Art 7(2)(c).

designed in such a way as to prevent hazardous product behaviour.'[76] It does not seem that a producer can blame rogue post-product conduct on the AI device, but rather should take responsibility for it.[77]

Equally, the effect on the product of other products that can reasonably be expected to be used together with the product should be considered.[78] This is clearly intended to cover the internet of things, where products interact with one another. However, as a product will cover software under the proposal,[79] it will cover the interaction between software and hardware which is common in AI products. This protective approach is further underlined by the safety assessment not only being when the product is placed on the market but for as long as the manufacturer retains control over the product after that moment.[80] So if a manufacturer continues to provide updates, or feed data to the AI product, they will be responsible for any resulting defects. This reform also maintains the development risks defence but would extend the time for assessing knowledge for as long as the manufacturer controls the product.[81]

Some of the new innovations are intended to make redress more practicable. As the explanatory memorandum to the proposal explained, 77 per cent of respondents considered that technically complex products created difficulties in respect of the injured person's burden of proof. This went up to 95 per cent among consumer organisations, non-government organisations and members of the public, with even 38 per cent of business and industry organisations sharing this concern. Industry stakeholders were more open to information disclosure obligations and easing the burden of proof in complex cases than to reversing the burden of proof.[82] This perhaps explains why the EU Commission was keen to stress that a presumption of defect or causation is not the same thing as a reversal of the burden of proof.[83] Whilst formally the burden may remain on the claimant, in practice the presumption will have a very similar effect to reversing the burden of proof.

The courts will be given powers to order disclosure of evidence where there is evidence of a plausible claim. The disclosure would have to be necessary and proportionate and would take into account

76 Recital 32.
77 Ibid.
78 Art (7)(2)(d).
79 Art 4(1).
80 Art 7(2)(e).
81 Art 11(1)(e).
82 Com/2022/495 Explanatory Memorandum, p 8.
83 Recitals 42 and 46.

confidentiality and trade secrets.[84] From a common law perspective familiar with discovery rules, this seems unremarkable.

Presumptions of defectiveness are introduced where there has been a failure to comply with the disclosure obligations, or non-compliance with mandatory safety requirements, or an obvious malfunction. There is clearly here an intention to incentivise compliance with disclosure orders and to follow safety requirements.[85] Recital 46 explains the inclusion of obvious malfunction on the ground that it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed. With respect, if it was so obvious there would be no need for the provision but it may stop defendants entering technical defences. There is a presumption of causality where it is established the product is defective and the damage is consistent with that type of defect.[86] There is a presumption of defectiveness or causality where the claimant faces excessive difficulty and is able to establish it is likely the product was defective/caused damage. The recital gives the following examples of factors giving rise to excessive difficulty as including:

> the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analysed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition, or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.[87]

What is quite perplexing though is that the claimant will still have to show the defect or causation was likely, and the question is how much more claimant friendly is that than proving the case on the balance of probabilities?

STRICTER LIABILITY FOR HIGH-RISK AI SYSTEMS?

Introduction

The AI Act[88] does not directly address the liability of AI systems. Direct rules on liability are limited to the requirement of notified bodies to have compulsory insurance[89] and the continued liability under national

84 Art 9.
85 Art 10(2).
86 Art 10(3).
87 Recital 48.
88 AI Act (n 26 above).
89 Art 31(9).

law of AI involved in regulatory sandboxes.[90] It notes the problems that different approaches to liability can pose for the development of the single market and favours harmonising measures, but leaves this for other legislative initiatives.[91] Fenwick and Wrbka[92] also note that, indirectly, the AI Act may make it easier to identify potential defendants due to the *ex ante* conformity assessment obligations and registration requirements for high-risk AI systems.

European Parliament Resolution of 20 October 2020 with Recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence

The EU Parliament has also proposed a form of strict liability for high-risk AI, backed up by compulsory insurance.[93] This would be additional to any other liability such as under the Product Liability Directive and would impose liability on operators of AI systems. This covers both frontend operators (who benefit from an AI operation and exercise a degree of control over a risk connected with the operation) and backend operators (who exercise control over a risk on a continuous basis, define the features of the technology and provide data and essential backend support services).[94] Strict liability would apply to all AI systems listed in an annex to the regulation. However, this certainty for operators is to some extent undermined by the exception mentioned in the Resolution whereby AI systems, which have not yet

90 Art 57(12).

91 See Explanatory Memorandum, para 2.1.

92 M Fenwick and S Wrbka, 'AI and legal personhood' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022).

93 European Parliament Resolution of 20 October 2020 with recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence (2020/2014 (INL) OJ C 404, 6.10.2021, p 107) (the Resolution). This was informed by, and largely based on, Committee on Legal Affairs, *Draft Report of 27 April 2020 with Recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence* 2020/2014(INL) (JURI AI draft report).There had been a background study: see E Karner et al, *Comparative Law Study on Civil Liability for Artificial Intelligence* (European Commission 2021). See also A Bertolini, 'Artificial intelligence and civil law: liability rules for drones – study for the JURI Committee' (2018); M van Lieshout et al, 'Study on safety of non-embedded software; service, data access, and legal issues of advanced robots, autonomous, connected, and AI-based vehicles and systems – study for the Commission/DG CONNECT' (2019); BEUC, 'Product liability 2.0: how to make EU rules fit for consumers in the digital age' (2020); A Bertolini, 'Artificial intelligence and civil liability – study for the JURI Committee' (2020). These are excellently discussed in Fenwick and Wrbka (n 92 above).

94 Para 12.

been assessed for high risk, could be made subject to strict liability if they caused repeated incidents resulting in serious harm or damage.[95]

The liability would be strict and arise for any harm or damage *caused* by a physical or virtual activity, device or process driven by that AI system.[96] It would be no defence to have acted with due diligence or that the harm was caused by an autonomous activity, device or process driven by their AI system. *Force majeure* would be a defence.[97] This sort of strict liability regime based on causation has been mooted before, notably by the Australian Law Reform Commission for product liability.[98] Whilst it seems in principle both stricter and simpler, the risk is that litigation will then get drawn into abstract causation debates that can be as complicated as determining defectiveness. That is not to say the idea should not be considered and the UK's Automated and Electric Vehicles Act 2018[99] might serve as a model. Under that law the insurer is required to pay the victim of an accident caused by an autonomous car with the driver and car manufacturer and their insurers left to fight over where the actual liability lies. The proposal does not go quite that far. It does require operators to have insurance,[100] but that would only kick in to compensate once liability is established.

There are maximum limits for strict liability of €2 million for personal injury and €1 million for property damage with a threshold of €500. One suspects this lower threshold mirrors the then Product Liability Directive and will be removed in line with its removal from the Product Liability Directive.

For non-high-risk AI, the proposal would maintain a fault-based regime. This would not have any limits on the amount of compensation. The rules provide two ways in which the operator would be able to prove the harm or damage was caused without being their fault.[101] There would be no liability where the AI system was activated without their knowledge and all reasonable and necessary measures to avoid such activation outside the operator's control had been taken. Liability can also be avoided by showing due diligence was observed by selecting a suitable AI system for the right task and skills, putting the AI system duly into operation, monitoring the activities and maintaining the operational reliability by regularly installing all available updates. However, the operator will not be able to escape liability simply by

95 Para 21.
96 Art 4(1) of the proposed Regulation contained in the Annex to the Resolution.
97 Art 4(3) of the proposed Regulation contained in the Annex to the Resolution.
98 Australian Law Reform Commission, *Product Liability* (ALRC Report 51 1989).
99 See also L Clinch, 'A long road ahead for automated vehicles' (2022) 172 New Law Journal 13–14.
100 Art 4(4).
101 Art 8(2).

arguing that the harm or damage was caused by an autonomous activity, device or process.

The EU is unlikely to take this strict liability initiative forward after the reform to the Product Liability Directive and the withdrawal of rules on AI non-contractual liability. It seems at least that the question of adopting no-fault liability for AI not covered by the Product Liability Directive will be kicked down the line.[102]

REFLECTIONS

Negligence or strict liability?

Strict product liability has been a terrain for fierce policy debate with competing (moral and economic) arguments for and against strict liability.[103] Some consider it unfair to impose liability on a party that has done everything they could reasonably have been expected to do.[104] Equally, some suggest it makes no economic sense to require more than foreseeable steps to prevent harm.[105] Negligence for them provides a fair and rational liability standard. By contrast, those who favour strict liability suggest it should be seen as the entry price for

102 Note original proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM/2022/496 final, Recital 31: 'It is necessary to provide for a review of this Directive [five years] after the end of the transposition period. In particular, that review should examine whether there is a need to create no-fault liability rules for claims against the operator, as long as not already covered by other Union liability rules in particular Directive 85/374/EEC, combined with a mandatory insurance for the operation of certain AI systems, as suggested by the European Parliament. In accordance with the principle of proportionality, it is appropriate to assess such a need in the light of relevant technological and regulatory developments in the coming years, taking into account the effect and impact on the roll-out and uptake of AI systems, especially for SMEs. Such a review should consider, among others, risks involving damage to important legal values like life, health and property of unwitting third parties through the operation of AI-enabled products or services. That review should also analyse the effectiveness of the measures provided for in this Directive in dealing with such risks, as well as the development of appropriate solutions by the insurance market. To ensure the availability of the information necessary to conduct such a review, it is necessary to collect data and other necessary evidence covering the relevant matters.'

103 See, generally, G Howells, *Product Liability* 2nd edn (Butterworths 2007).

104 D Owen, 'Product liability: principles of justice for the 21st century' (1990) 11 Pace Law Review 63–86 and 'The Moral Foundations of Products Liability Law: Towards First Principles' (1993) 68 Notre Dame Law Review 427–506.

105 See, generally, R Posner, *Economic Analysis of Law* 9th edn (Aspen 2014).

being allowed to enter the market for profit.[106] Internalisation of costs for the harm flowing from the use of the products is seen as a way for ensuring only the optimum amount of the product is used.[107]

Similar divides emerge in relation to liability for AI systems. Though there are also some pragmatic issues affecting possible policy choices, some echo the preference for negligence by arguing that, if AI systems generally have better outcomes than humans, then negligence is the standard that will encourage their deployment for the greater good.[108] On the other hand, Pasquale notes that in the medical context the position is complicated by the likely greater ongoing guidance of healthcare providers in managing the deployment of AI.[109] Moreover, there are practical problems with assessing negligence in the context of an AI system. Although all humans are different, we feel confident in determining an objective standard against which to judge them. By contrast, it has been argued that AI is heterogeneous by nature with the variety of different techniques for creating AI only likely to increase.[110] There are other practical difficulties with enforcing negligence laws given the problems of attributing liability between healthcare professionals, hospitals, AI vendors and others, such as those who stream or process data.[111] In truth, this is more about potentially needing to adopt some form of network liability, and similar problems might arise under strict liability systems depending on how it is framed. Strict liability might also assist in providing compensation when there is automation bias, that is, over-reliance by professionals who place too much faith in the judgements of machines.[112] It can also be a means of ensuring that those groups who tend to be underrepresented in the data sets used to create algorithms (women and ethnic minorities) at least obtain compensation if the AI system does not take their needs sufficiently into account.[113] However, perhaps the strongest arguments for strict

106 T Honoré, 'Responsibility and luck: the moral basis of strict liability' (1988) 104 Law Quarterly Review 530–553.

107 G Calabresi, 'Some thoughts on risk distribution and the law of torts' (1961) 70 Yale Law Journal 499–553.

108 R Abbott, 'The reasonable computer: disrupting the paradigm of tort liability (2017) 86(1) George Washington Law Review 1–45.

109 Pasquale (n 16 above) 209.

110 J Turner, *Robot Rules: Regulating Artificial Intelligence* (Palgrave Macmillan 2019).

111 Pasquale (n 16 above) 208.

112 E Parasidis, 'Clinical decision support: elements of a sensible legal framework' (2018) 20 Journal of Health Care Law and Policy 183.

113 A Adamson and A Smith, 'Machine learning and health care disparities in dermatology' (2018) 11 JAMA Dermatology 1247–1248; and C Perez, *Invisible Women: Data Bias in a World Designed for Men* (Abrams Press 2019).

liability of AI systems remain that the costs associated with their use should be internalised and borne by those who seek to make profit. This is strengthened by the knowledge that rules can be built into AI systems to prevent them from causing deliberate harm.[114]

The EU seems to favour keeping the strictest form of liability for high-risk AI. However, the Product Liability Directive now clearly brings software and AI systems into its fold. It is true that it is arguable that the Directive does not provide a very strict form of liability. One might foresee negligence and strict product liability under the Directive applying across the board with the strictest form of liability retained for high-risk AI systems. Arguably, such a system amounts to no-fault liability that is more demanding than the strict liability found in the Product Liability Directive that can be justified to promote the use of such high-risk AI systems. However, in the current climate such a move is not imminent.

Network liability?

Traditional liability rules required there to be either a contractual nexus or negligence. Although the previous Product Liability Directive broke the mould, it did not specifically address the problem of allocating liability when several actors may potentially have caused the harm.[115] AI systems may involve various actors: a system might, for example, have hardware (developed by A) powered by background software (developed by B) which runs different programs based on algorithms (developed by C and D) and relying on data inputs (by E) and interaction with other devices as part of the internet of things. If something goes wrong and harm occurs, this might be due to one of several products, the programs they run, the algorithms or the quality of the data received. Indeed, the harm may lie in how they interreact or perhaps fail to interreact. Disentangling this network of relationships to allocate responsibility may be complex and often impossible, especially for the injured party. If one party controls the whole network then liability may be easier to establish, but this is often not the case. That is why it has been argued that there should be a form of network liability under which the injured party could sue an entire network or just one party within the network, leaving members of the network to fight over the allocation of liability.[116]

---

114 Pasquale (n 16 above) 211 quoting Asimov's Laws of Robotics.

115 Art 5 of the Directive merely provided: 'Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.'

116 Howells and Twigg-Flesner (n 11 above).

A medical sector solution?

The medical sector is well known for pioneering no-fault solutions.[117] In relation to AI in the medical sector there is a justification for such a no-fault solution to promote the development of AI which may have great societal benefits.[118] In order to encourage acceptance of AI medical systems and to mitigate the impact on public confidence of the, hopefully, rare instances when things go wrong, no-fault liability could play a role. Borrowing from the UK approach to automated vehicles, one party could be selected and their insurer required to pay for harm caused by AI. Although the parties might want to argue over allocation of liability, in practice this will most likely be sorted out on a practical basis. The injured party need not be involved. However, the problem, alluded to above, of linking causation to the AI system remains. This can be handled more pragmatically under no-fault insurance-backed regimes than under traditional tort law causation rules. However, as the experience under the Vaccine Damage Payments Act 1979 demonstrates, this can still be problematic.[119] Future research is needed into how causation can be fairly applied so that compensation goes to parties whose harm can reasonably be attributed to AI-systems. Scandinavia may provide some useful evidence of good practice.

CONCLUSION

As AI becomes more pervasive, there is a need to tackle important liability questions. Is it enough to adapt existing negligence and strict liability rules by procedural tools such as disclosure requirements and presumptions of negligence, defect or causation? Or does the interconnection between actors require new approaches to liability, such as network liability or the even more radical solutions we have already seen for autonomous cars. Indeed, does the medical context raise its own set of issues surrounding the interaction between medical practitioner and devices that may demand novel no compensation solutions? A lesson from the autonomous car context is that strong liability regimes can serve to bolster confidence in AI innovation. However, the history of attempts to introduce no-fault regimes in the health sector does not provide grounds of optimism

117 Compare also Holm et al (n 17 above).

118 On justifications for no-fault schemes, see G Howells, 'Justifications for preferential adoption of no-fault accident compensation schemes' (2019) Otago Law Review 127–155.

119 D Fairgrieve et al, 'Comparing no-fault compensation systems for vaccine injury' (2023) 31(1) Tulane Journal of International and Comparative Law 75–118.

as saving money seems to be the bottom line.[120] The EU is starting to grapple with how existing liability regimes can be adapted to AI. The UK is lagging behind. The consequence of Brexit so far seems to be that our legal regimes remain moribund, whilst the EU laws are reformed in response to innovation. Brexit does, it is often stated, give the UK the freedom to forge ahead and fashion its own novel solution, whether for AI generally or for the medical context in particular. To date, however, there are few signs of the groundwork for proposing any imaginative reforms.

120 See, for example, the proposal for a rapid resolution and redress scheme for birth injuries: J Cumberlege, *The National Maternity Review: Better Births* (NHS England 2016) Annex D.